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Washington, DC 20002

RESERVATIONS: (202) 741–6008

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0170; Airspace Docket No. 08–AEA–16]

Modification of Class E Airspace; Staunton, VA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule, request for comments.

SUMMARY: This action modifies the effective time of the Class E Airspace at Staunton, VA. The Shenandoah Valley Regional Airport Commission is requesting to change their current Class E2 Airspace from part time (currently 1200 to 0400 Zulu) to full time. This action enhances the safety and management of Instrument Flight Rule (IFR) operations in the area by providing the required controlled airspace to support terminal operations continuously at Staunton, VA.

DATES: Effective 0901 UTC, June 5, 2008. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments. Comments for inclusion in the Rules Docket must be received on or before May 15, 2008.

ADDRESSES: Send comments on this rule to: U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001; Telephone: 1–800–647–5527; Fax: 202–493–2251. You must identify the Docket Number FAA–2008–0170; Airspace Docket No. 08–AEA–16, at the beginning of your comments. You may also submit and review received comments through the Internet at *http://www.regulations.gov.*

You may review the public docket containing the rule, any comments received, and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 am. and 5 p.m., Monday through Friday, except Federal Holidays. An informal docket may also be examined during normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Avenue, College Park, Georgia 30337.

FOR FURTHER INFORMATION CONTACT: Melinda Giddens, System Support Group, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; Telephone (404) 305–5610, Fax 404–305–5572.

SUPPLEMENTARY INFORMATION:

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comments, and, therefore, issues it as a direct final rule. The FAA has determined that this rule only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. 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 effective date. If the FAA receives, 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

Although this action is in the form of a direct final rule, and was not preceded by a notice of proposed rulemaking, interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. The direct final rule is used in this case to facilitate the timing of the charting schedule and enhance the operation at the airport, while still allowing and requesting public comment on this rulemaking action. An electronic copy of this document may be downloaded from and comments submitted through *http://www.regulations.gov.* Communications should identify both docket numbers and be submitted in triplicate to the address specified under the caption **ADDRESSES** above or through the Web site. All communications received on or before the closing date for comments will be considered, and this rule may be amended or withdrawn in light of the comments received. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://wwwfaa.gov* or the Federal Register's Web page at *http://www.gpoaccess.gov/fr/index.html.*

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of this action and determining whether additional rulemaking action would be needed. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. Those wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2008–0170; Airspace Docket No. 08–AEA–16.'' The postcard will be date stamped and returned to the commenter.

The Rule

This amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 modifies Class E2 airspace at Staunton, VA, establishing a 24 hour environment to support Instrument Flight Rule (IFR) operations around the Shenandoah Valley Regional Airport. Controlled airspace extending upward from the surface of the Earth is designated to provide for terminal operations where a control tower is not operational. Due to the expanded hours and numbers of operation by Air Carrier and larger

business and corporate aircraft, the Shenandoah Valley Regional Airport Commission is requesting their Class E2 airspace become continuous. The FAA is amending Title 14, Code of Federal Regulations (14 CFR) part 71 to modify Class E2 airspace at Staunton by removing language in its legal description to accommodate for this change thereby making the Class E Surface Airspace in effect 24 hours a day.

Designations for Class E Airspace Designated as Surface Areas are published in FAA Order 7400.9R, signed August 15, 2007 effective September 15, 2007, which is incorporated by reference in 14 CFR part 71.1. The Class E designations listed in this document will be published subsequently in the Order.

Agency Findings

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among 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 only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore, (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies controlled airspace at Staunton, VA.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE 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 7400.9R, Airspace Designations and Reporting Points, signed August 15, 2007, effective September 15, 2007, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

AEA VA E2 Staunton, VA [REVISED]

Shenandoah Valley Regional Airport, Staunton/Waynesboro/Harrisonburg, VA
(Lat. 38°15′50″ N., long 78°53′47″ W.)
STAUT NDB (LOM)
(Lat. 38°12′06″ N., long 78°57′26″ W.)

Within a 4.1-mile radius of Shenandoah Valley Regional Airport and within 2.5 miles each side of the Shenandoah Valley Regional Airport southwest localizer course extending from the 4.1-mile radius to 7 miles southwest of the STAUT NDB (LOM).

* * * * *

Issued in College Park, Georgia, on March 7, 2008.

Lynda G. Otting,

Acting Manager, System Support Group, Eastern Service Center.

[FR Doc. E8–6330 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Parts 10, 163, and 178

[Docket Number USCBP–2007–0001; CBP Dec. 08–03]

RIN 1505–AB75

United States-Jordan Free Trade Agreement

AGENCIES: Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Final rule.

SUMMARY: This document adopts as a final rule, without change, interim amendments to title 19 of the Code of Federal Regulations which were published in the **Federal Register** on June 27, 2007, as CBP Dec. 07–50 to implement the preferential tariff treatment and other customs-related provisions of the United States-Jordan Free Trade Agreement signed by the United States and the Hashemite Kingdom of Jordan.

DATES: Final rule effective April 30, 2008.

FOR FURTHER INFORMATION CONTACT: *Operational Aspects:* Heather Sykes, Trade Policy and Programs, Office of International Trade (202–863–6099).

Legal Aspects: Karen Greene, Regulations and Rulings, Office of International Trade (202–572–8838).

SUPPLEMENTARY INFORMATION: On October 24, 2000, the United States and the Hashemite Kingdom of Jordan (the ''Parties'') signed the U.S.-Jordan Free Trade Agreement (''US–JFTA''), which is designed to eliminate tariffs and other trade barriers between the two countries. The provisions of the US–JFTA were adopted by the United States with the enactment on September 28, 2001, of the United States-Jordan Free Trade Area Implementation Act (the ''Act''), Public Law 107–43, 115 Stat. 243 (19 U.S.C. 2112 note). On December 7, 2001, the President signed Proclamation 7512 to implement the provisions of the US–JFTA. The Proclamation, which was published in the **Federal Register** on December 13, 2001 (66 FR 64497), modified the Harmonized Tariff Schedule of the United States (''HTSUS'') as set forth in Annexes I and II of the Proclamation. The modifications to the HTSUS included the addition of new General Note 18, the incorporation of the

relevant US–JFTA rules of origin as set forth in the Act, and the insertion throughout the HTSUS of the preferential duty rates applicable to individual products under the US–JFTA where the special program indicator ''JO'' appears in parenthesis in the ''Special'' rate of duty subcolumn.

Article 2 and Annex 2.2 of the US–JFTA set forth the rules of origin and documentary requirements that apply for purposes of obtaining preferential treatment under the US–JFTA. Annex 2.1 of the US–JFTA sets forth the terms for the immediate elimination or staged reduction of duties on products of Jordan, with all products to become duty free within a ten-year period (by the year 2010).

Under Annex 2.2 of the US–JFTA and § 102 of the Act, to be eligible for reduced or duty-free treatment under the US–JFTA, a good imported into the United States from Jordan must meet three basic requirements: (1) It must be imported directly from Jordan into the customs territory of the United States; (2) it must be a product of Jordan, *i.e.*, it must be either wholly the growth, product, or manufacture of Jordan or a new or different article of commerce that has been grown, produced, or manufactured in Jordan; and (3) if it is a new or different article of commerce, it must have a minimum domestic content, *i.e.*, at least 35 percent of its appraised value must be attributed to the cost or value of materials produced in Jordan plus the direct costs of processing operations performed in Jordan. Annex 2.2 of the US–JFTA further provides that: (1) The cost or value of U.S.-produced materials may be counted toward the Jordanian domestic content requirement to a maximum of 15 percent of the appraised value of the imported good; and (2) simple combining or packaging operations or mere dilution with water or another substance will confer neither Jordanian origin on an imported good nor Jordanian or U.S. origin on a constituent material of an imported good.

In addition, for purposes of demonstrating compliance with the origin criteria, Annex 2.2 of the US–JFTA establishes the requirements for submitting a declaration, when requested by Customs and Border Protection (''CBP''), that provides all pertinent information concerning the production or manufacture of an imported good.

CBP is responsible for administering the provisions of the US–JFTA and the Act that relate to the importation of goods into the United States from Jordan. On June 27, 2007, CBP published CBP Dec. 07–50 in the **Federal Register** (72 FR 35154), setting forth interim amendments to implement the preferential tariff treatment and customs-related provisions of the US–JFTA. In order to provide transparency and facilitate their use, the majority of the US–JFTA implementing regulations set forth in CBP Dec. 07–50 were included within new Subpart K in Part 10 of title 19 of the Code of Federal Regulations (19 CFR Subpart K, Part 10). However, in those cases in which US–JFTA implementation was more appropriate in the context of an existing regulatory provision, the US–JFTA regulatory text was incorporated in an existing part within the CBP regulations.

The U.S.–JFTA implementing regulations set forth in CBP Dec. 07–50 pertain specifically to US–JFTA customs-related provisions, such as the rules of origin, that govern the duty-free or reduced-duty treatment of products imported into the United States from Jordan. These rules do not confer origin or establish a criterion for determining the origin of imported goods for any other purpose. For example, origin determinations for country of origin marking purposes under 19 U.S.C. 1304 are not affected.

Although the interim regulatory amendments were promulgated without prior public notice and comment procedures and took effect on June 27, 2007, CBP Dec. 07–50 provided for the submission of public comments that would be considered before adopting the interim regulations as a final rule. The prescribed public comment period closed on August 27, 2007. No comments were received in response to the solicitation of public comments in CBP Dec. 07–50.

Conclusion

Accordingly, CBP has decided to adopt the interim rule published on June 27, 2007, without change.

Executive Order 12866

CBP has determined that this document is not a regulation or rule subject to the provisions of Executive Order 12866 of September 30, 1993 (58 FR 51735, October 1993), because it pertains to a foreign affairs function of the United States and implements an international agreement and, therefore, is specifically exempted by section 3(d)(2) of Executive Order 12866.

Regulatory Flexibility Act

The regulations to implement the preferential tariff treatment and other customs-related provisions of the US–JFTA were previously published in CBP Dec. 07–50 as interim regulations. CBP issued the regulations as an interim rule because, as noted above, they pertained to a foreign affairs function of the United States and implemented an international agreement. Because no notice of proposed rulemaking was required, the provisions of the Regulatory Flexibility Act, as amended (5 U.S.C. 601 *et seq.*), do not apply. Accordingly, this final rule is not subject to the regulatory analysis requirements or other requirements of 5 U.S.C. 603 and 604.

Paperwork Reduction Act

The collection of information in this final rule has previously been reviewed and approved by the Office of Management and Budget in accordance with the requirements of the Paperwork Reduction Act (44 U.S.C. 3507) under control number 1651–0128.

The collections of information in these regulations are in §§ 10.703 and 10.704. This information is required in connection with claims for preferential tariff treatment and for the purpose of the exercise of other rights under the US–JFTA and the Act and will be used by CBP to determine eligibility for a tariff preference or other rights or benefits under the US–JFTA and the Act. The likely respondents are business organizations including importers, exporters, and manufacturers.

The estimated average annual burden associated with the collection of information in this final rule is 0.2 hours per respondent or record keeper. Comments concerning the accuracy of this burden estimate and suggestions for reducing that burden, should be directed to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to the Trade and Commercial Regulations Branch, Regulations and Rulings, Customs and Border Protection, 1300 Pennsylvania Avenue, NW. (Mint Annex), Washington, DC 20229.

Signing Authority

This document is being issued in accordance with section 0.1(a)(1) of the CBP Regulations (19 CFR 0.1(a)(1)) pertaining to the authority of the Secretary of the Treasury (or his/her delegate) to approve regulations related to certain customs revenue functions.

List of Subjects

19 CFR Part 10

Customs duties and inspection, Exports, Imports, Preference programs, Reporting and recordkeeping requirements, Trade agreements (United States-Jordan Free Trade Agreement).

19 CFR Part 163

Administrative practice and procedure, Customs duties and inspection, Exports, Imports, Reporting and recordkeeping requirements, Trade agreements.

19 CFR Part 178

Administrative practice and procedure, Exports, Imports, Reporting and recordkeeping requirements.

Amendments to the CBP Regulations

■ Accordingly, the interim rule amending Parts 10, 163, and 178 of the CBP regulations (19 CFR parts 10, 163, and 178), which was published at 72 FR 35154 on June 27, 2007, is adopted as a final rule without change.

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

Approved: March 25, 2008.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. E8–6511 Filed 3–28–08; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Penicillin G Benzathine and Penicillin G Procaine Suspension

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by IVX Animal Health, Inc. The supplemental NADA provides for changing scientific nomenclature for a bovine pathogen on labeling for penicillin G benzathine and penicillin G procaine injectable suspension.

DATES: This rule is effective March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8341, e-mail: *cindy.burnsteel@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th Street Ter., St. Joseph, MO 64503, filed a supplement to NADA 65–498 for PEN BP–48 (penicillin G benzathine and penicillin G procaine) injectable suspension used for the treatment of animal diseases associated with several bacterial pathogens. The supplemental NADA provides for changing a bovine pathogen name from *Corynebacterium pyogenes* to *Actinomyces pyogenes* on product labeling. The supplemental NADA is approved as of February 22, 2008, and the regulations in 21 CFR 522.1696a are amended to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1696a [Amended]

■ 2. In § 522.1696a, in paragraph (d)(2)(ii)(A), remove ''*Corynebacterium pyogenes*'' and ''(*C. pyogenes*)'' and in their places add ''*Actinomyces pyogenes*'' and ''(*A. pyogenes*)''.

Dated: March 21, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–6603 Filed 3–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feed; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Intervet Inc. The NADA provides for use of approved, single-ingredient Type A medicated articles containing zilpaterol hydrochloride and melengestrol acetate in two-way combination Type B and Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Gerald L. Rushin, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8103, e-mail: *gerald.rushin@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Intervet Inc., P.O. Box 318, 29160 Intervet Lane, Millsboro, DE 19966, filed NADA 141–284 that provides for use of ZILMAX (zilpaterol hydrochloride) and MGA (melengestrol acetate) Type A medicated articles to make dry and liquid two-way combination Type B and Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and for suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 20 to 40 days on feed. The NADA is approved as of February 29, 2008, and the regulations in 21 CFR 558.665 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,

neither an environmental assessment nor environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.665, add paragraph (e)(2) to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(e) * * *

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
* *	*	*	* *	*
(2) 6.8 to provide 60 to 90 mg/ head/day	Melengestrol acetate to provide 0.25 to 0.5 mg/ head/day	Heifers fed in confinement for slaughter: As in paragraph (e)(1) of this section; and for suppression of estrus (heat).	As in paragraph (e)(1) of this section; see paragraph §§ 558.342(d) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	057926
* *	*	*	* *	*

Dated: March 21, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–6601 Filed 3–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 41

[T.D. TTB–68; Re: T.D. ATF–444 and Notice No. 912]

RIN 1513–AB38

Puerto Rican Tobacco Products and Cigarette Papers and Tubes Shipped From Puerto Rico to the United States (2007R–368P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule (Treasury decision).

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau is adopting as a final rule, with some clarifying changes and editorial corrections, the temporary regulations set forth in T.D. ATF–444. These temporary regulations eliminated the onsite preshipment inspection of, and the requirement to complete several ATF forms for, shipments to the United States of tobacco products and cigarette papers and tubes manufactured in Puerto Rico.

DATES: *Effective Date:* March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Amy R. Greenberg, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street, NW., Suite 200E, Washington, DC 20220; telephone 202–927–8210; or e-mail *Amy.Greenberg@ttb.gov*.

SUPPLEMENTARY INFORMATION:

Background

Chapter 52 of the Internal Revenue Code of 1986 (IRC) pertains to the Federal excise tax on tobacco products and cigarette papers and tubes. Section 5701 of the IRC (26 U.S.C. 5701) imposes a tax on such products manufactured in, or imported into, the United States. Section 7652(a) of the IRC (26 U.S.C. 7652(a)) imposes the same tax, with certain exceptions not pertinent here, on articles of merchandise of Puerto Rican manufacture coming into the United States and withdrawn for consumption or sale. The Alcohol and Tobacco Tax and Trade Bureau (TTB) is responsible for administering the provisions of chapter 52 and section 7652(a) of the IRC as they pertain to the tax on tobacco products and cigarette papers and tubes, including promulgating regulations concerning payment and collection of the tax and other requirements that protect the revenue. Prior to January 24, 2003, our predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF) administered these regulations.

On March 8, 2001, ATF published in the **Federal Register** (66 FR 13849) a temporary rule, T.D. ATF–444, amending the regulations in 27 CFR part 275 to eliminate certain regulatory requirements related to the shipment of tobacco products and cigarette papers and tubes of Puerto Rican manufacture from Puerto Rico to the United States. Specifically, ATF amended §§ 275.105, 275.106, 275.110, and 275.111 to eliminate the requirement that persons who ship tobacco products and cigarette papers and tubes of Puerto Rican manufacture from Puerto Rico to the United States notify ATF prior to the shipment, and to eliminate the requirements that an ATF officer: (1) Inspect each shipment of such articles; (2) certify that the amount of tax on the articles has been calculated correctly; and (3) release each shipment. The amended regulations set forth recordkeeping requirements in place of the former processes of notification, physical inspection, certification, and release. Under the temporary rule, persons who ship Puerto Rican tobacco products and cigarette papers and tubes to the United States must keep and maintain records to show that the amount of tax is correctly calculated, paid (where applicable), and recorded for audit and examination purposes.

The temporary rule amendments to §§ 275.106, 275.110, and 275.111 also eliminated the requirements for the completion of four specific forms. Two forms, ATF forms 2987 (5210.8) and 3075 (5200.9), were required to be submitted to ATF by the company shipping the products to the United States, and contained information readily available from common commercial records. The elimination of these forms was intended to relieve the taxpayer of a duplicative recordkeeping requirement. The other two forms, ATF forms 2989 and 3074 (5200.6), were certificates which were prepared by ATF officers and affixed to the outside

of each shipping container, affirming that the appropriate tax had been paid. These forms were eliminated because ATF determined that they were not necessary to protect the Federal excise tax revenue due on tobacco products and cigarette papers and tubes.

T.D. ATF–444 also included some technical corrections to the regulations, including updating the delegation order numbers appearing in §§ 275.11 and 275.29.

On the same day that T.D. ATF–444 was published, ATF also published in the **Federal Register** (66 FR 13864), a notice of proposed rulemaking (NPRM), (Notice No. 912) soliciting comments on the regulatory amendments contained in T.D. ATF–444. ATF did not receive any comments in response to Notice No. 912 by the close of the public comment period.

Since the publication of T.D. ATF–444, ATF and then TTB continued to conduct audits of the commercial records of companies that ship Puerto Rican tobacco products or cigarette papers and tubes from Puerto Rico to the United States. These audits have demonstrated that the elimination of the required inspection prior to shipment, the elimination of certain forms, and the replacement of other forms with the requirement to maintain records, have allowed TTB and the regulated industry members to avoid unnecessary administrative burdens without creating any jeopardy to the revenue.

Subsequent Regulatory Changes

Following the publication of T.D. ATF–444, 27 CFR part 275 was recodified as 27 CFR part 41 pursuant to T.D. TTB–16, published in the **Federal Register** (69 FR 52421) on August 26, 2004. Thus, all provisions of the temporary rule identified as sections in part 275 appear in this final rule as sections in part 41.

Adoption of Final Rule

Based on the background information provided above, TTB has determined that the temporary regulations published in T.D. ATF–444, recodified and updated pursuant to T.D. TTB–16, should be adopted as a final rule with only minor organizational, plain language, and editorial changes. We have made such changes to §§ 41.105, 41.106, 41.110, 41.111, and 41.121 to enhance their clarity and readability without substantively affecting their texts. We have modified the section headings to §§ 41.106 and 41.111 to more clearly reflect the content of these provisions. We have also updated the Office of Management and Budget (OMB) control numbers for §§ 41.105, 41.106, 41.110, and 41.121.

Inapplicability of Delayed Effective Date

Pursuant to the provisions of 5 U.S.C. 553(d)(1) and (d)(3), we are issuing these regulations without a delayed effective date. This rule finalizes regulations which provided relief from regulatory restrictions by eliminating several administrative burdens on industry members associated with onsite preshipment inspection of, and the requirement to complete several ATF forms for, shipments to the United States of tobacco products and cigarette papers and tubes manufactured in Puerto Rico. By eliminating these administrative burdens, these final regulations fit within the meaning of the relief from a restriction standard in section 553(d)(1). Furthermore, TTB has determined that good cause exists in accordance with section 553(d)(3) to finalize these regulations immediately, and without delayed effective date, in order to continue the alleviation of these administrative burdens on the industry.

Regulatory Flexibility Act

Pursuant to the requirements of the Regulatory Flexibility Act (5 U.S.C. chapter 6), we certify that these regulations will not have a significant economic impact on a substantial number of small entities. These regulations relieve and simplify certain administrative obligations. Primarily, the regulations replace onsite, preshipment inspections with less burdensome, periodic recordkeeping and audit requirements. The regulations also eliminate four reporting forms in further reducing administrative and recordkeeping burdens. Accordingly, these regulations will not have a significant economic impact on a substantial number of small entities and a regulatory flexibility analysis is not required. Pursuant to 26 U.S.C. 7805(f), the temporary regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses, and we received no comments.

Executive Order 12866

It has been determined that this rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, a regulatory assessment is not required.

Paperwork Reduction Act

The collections of information in the regulations contained in this final rule have been previously reviewed and approved by Office of Management and Budget (OMB) in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3504(h)) and assigned control numbers 1513–0083, 1513–0090, and 1513–0108. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB. Although sections of the regulations covered by these approvals are amended for clarity, this final rule imposes no new or revised collection of information, and does not change the reporting or recordkeeping burden.

Comments concerning suggestions for reducing the burden of the collections of information should be directed to Mary A. Wood, Alcohol and Tobacco Tax and Trade Bureau, at any of these addresses:

- P.O. Box 14412, Washington, DC 20044–4412;
- 202–927–8525 (facsimile); or
- *formcomments@ttb.gov* (e-mail).

Drafting Information

Amy R. Greenberg of the Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, drafted this document.

List of Subjects in 27 CFR Part 41

Administrative practice and procedure, Authority delegations, Cigarette papers and tubes, Claims, Electronic fund transfer, Customs duties and inspection, Excise taxes, Imports, Labeling, Packaging and containers, Penalties, Reporting requirements, Seizures and forfeitures, Surety bonds, Tobacco products, U.S. possessions, Warehouses.

Amendments to the Regulations

■ Accordingly, for the reasons set forth in the preamble, the temporary rule published on March 8, 2001, at 66 FR 13849, is adopted as a final rule with the changes as discussed above and set forth below.

PART 41—IMPORTATION OF TOBACCO PRODUCTS AND CIGARETTE PAPERS AND TUBES

■ 1. The authority citation for part 41 continues to read as follows:

Authority: 18 U.S.C. 2342; 26 U.S.C. 5701, 5703, 5704, 5705, 5708, 5712, 5713, 5721, 5722, 5723, 5741, 5754, 5761, 5762, 5763, 6301, 6302, 6313, 6404, 7101, 7212, 7342, 7606, 7651, 7652, 7805; 31 U.S.C. 9301, 9303, 9304, 9306.

■ 2. Section 41.105 is revised to read as follows:

§ 41.105 Prepayment of tax.

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

7652(a) on tobacco products and cigarette papers and tubes of Puerto Rican manufacture to be shipped to the United States, the shipper must file, or cause to be filed, a tax return, TTB F 5000.25, with full remittance of the tax which will become due on those products.

(Approved by the Office of Management and Budget under control number 1513–0090)

■ 3. Section 41.106 is revised to read as follows:

§ 41.106 Record of shipment by taxpayer.

(a) *Shipments other than noncommercial mail shipments.* The taxpayer must ensure that the tax has been prepaid on the tobacco products and cigarette papers and tubes in each shipment. The taxpayer must identify the tobacco products or cigarette papers or tubes by including on the bill of lading or similar record accompanying the shipment the following information:

(1) The marks and numbers on the shipping containers;

(2) The number of containers to be shipped;

(3) The kind of taxable article(s) to be shipped and the rate of tax applicable to each kind of article, as specified in §§ 41.30 through 41.35;

(4) The number of small cigarettes, large cigarettes, or small cigars to be shipped;

(5) The number and total sale price of large cigars having a sale price of not more than $235.294 per thousand to be shipped;

(6) The number of large cigars having a sale price equal to or more than $235.294 per thousand to be shipped;

(7) The pounds and ounces of chewing tobacco or snuff to be shipped;

(8) The pounds and ounces of pipe tobacco or roll-your-own tobacco to be shipped;

(9) The number of cigarette papers or tubes to be shipped;

(10) The amount of the tax paid for each kind of article under this subpart;

(11) The name and address of the consignee in the United States to whom the products are to be shipped; and

(12) A notation identifying the particular TTB F 5000.25 by which the taxes were prepaid.

(b) *Noncommercial mail shipments.* Noncommercial mail shipments of tobacco products and cigarette papers and tubes to the United States are exempt from the requirements of paragraph (a) of this section, except that the taxpayer must provide a copy of the TTB F 5000.25 upon the request of an appropriate TTB officer.

(Approved by the Office of Management and Budget under control number 1513–0108)

■ 4. Section 41.110 is revised to read as follows:

§ 41.110 Record of tax computation and shipment by bonded manufacturer under deferred taxpayment.

Where tobacco products or cigarette papers or tubes are to be shipped to the United States with deferred taxpayment, the bonded manufacturer must calculate the tax prior to shipment. The tax calculation must conform to the information on the bill of lading or a similar record accompanying the shipment, and the date of completing the bill of lading or similar record accompanying the shipment will be treated as the date of computation of the tax. Tobacco products or cigarette papers or tubes may be shipped to the United States in accordance with the provisions of this section only after computation of the tax. The bill of lading or similar record accompanying the shipment must include the following information:

(a) The marks and numbers on the shipping containers;

(b) The number of containers to be shipped;

(c) The kind of taxable article(s) to be shipped and the rate of tax applicable to each kind of article, as specified in §§ 41.30 through 41.35;

(d) The number of small cigarettes, large cigarettes, or small cigars to be shipped;

(e) The number and total sale price of large cigars having a sale price of not more than $235.294 per thousand to be shipped;

(f) The number of large cigars having a sale price equal to or more than $235.294 per thousand to be shipped;

(g) The pounds and ounces of chewing tobacco or snuff to be shipped;

(h) The pounds and ounces of pipe tobacco or roll-your-own tobacco to be shipped;

(i) The number of cigarette papers or tubes to be shipped;

(j) The amount of the tax to be paid for each kind of article under this subpart; and

(k) The name and address of the consignee in the United States to whom the products are to be shipped.

(Approved by the Office of Management and Budget under control number 1513–0108)

■ 5. Section 41.111 is revised to read as follows:

§ 41.111 Verification of bond and agreement to pay tax.

(a) *Verification of bond.* Prior to shipment of tobacco products or cigarette papers or tubes to the United States, the manufacturer must verify:

(1) That there is no default in payment of tax chargeable against the manufacturer's bond on TTB F 2986 (5210.12); and

(2) That the amount of the manufacturer's bond is sufficient or is in the maximum penal sum to cover the tax that will become due on the shipment.

(b) *Agreement to pay tax.* The shipment of tobacco products or cigarette papers or tubes by the bonded manufacturer serves as an agreement by the manufacturer to pay the tax on that shipment.

■ 6. Section 41.121 is revised to read as follows:

§ 41.121 Amount and account of bond.

(a) *Bond amount.* Except for the maximum and minimum amounts stated in this paragraph, the total amount of the bond or bonds required under this subpart must be in an amount not less than the amount of unpaid tax chargeable at any one time against the bond or bonds. The maximum and minimum amounts of such bond or bonds are as follows:

Taxable article	Bond amount maximum (in dollars)	Bond amount minimum (in dollars)
(1) Cigarettes	250,000	1,000
(2) Any combination of taxable articles	250,000	1,000
(3) One kind of taxable article other than cigarettes	150,000	1,000

(b) *Bond account.* Where the amount of a bonded manufacturer's bond is less than the maximum amount prescribed in paragraph (a) of this section, the bonded manufacturer must maintain an account reflecting all outstanding taxes for which the manufacturer's bond is chargeable. A manufacturer must debit that account with the amount of tax that was agreed to be paid under § 41.111 or that is otherwise chargeable against the bond and then must credit the account for the amount paid on TTB F 5000.25 or other TTB-prescribed document, at the time it is filed. A manufacturer who will defer payment of tax for a shipment of tobacco products or cigarette papers or tubes under this subpart must have sufficient credit in this account to cover the taxes prior to making the shipment to the United States.

(Approved by the Office of Management and Budget under control number 1513–0108)

Signed: January 17, 2008.

John J. Manfreda,

Administrator.

Approved: February 27, 2008.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

[FR Doc. E8–6513 Filed 3–28–08; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2007–0096]

RIN 1625–AA09

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Mile 113, St. Petersburg Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the operating regulations governing the Pinellas Bayway Structure ''E'' (SR 679 Bridge), Gulf Intracoastal Waterway, mile 113, St. Petersburg Beach, Pinellas County, Florida. This rule will provide vehicular traffic relief during heavy vehicular traffic periods flowing into a nearby county park and will meet the reasonable needs of navigation.

DATES: This rule is effective April 30, 2008.

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 [Docket No. USCG–2007–0096] and are available online at *www.regulations.gov.* This material is also available for inspection or copying at two locations: the Docket Management Facility (M30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays and at Commander (dpb), Seventh Coast Guard District, 909 S.E. 1st Avenue, Room 432, Miami, Florida 33131–3028 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Michael Lieberum, Seventh Coast Guard District, Bridge Administration Branch, telephone 305–415–6744. If you have questions on viewing the docket, call Renee W. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On December 4, 2007, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Gulf Intracoastal Waterway, mile 113, St. Petersburg Beach, FL in the **Federal Register**. 72 FR 68116. We have received no comments on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The Pinellas Bayway Structure ''E'' (SR 679) Bridge, Gulf Intracoastal Waterway mile 113, St. Petersburg Beach, Pinellas County, Florida, currently opens on signal; except that, from 9 a.m. to 7 p.m. the draw need only open on the hour, 20 minutes after the hour, and 40 minutes after the hour. The bridge provides vehicular access into and out of a popular county park.

At the request of Florida State Representative Frishe's office, who is acting on behalf of local citizens, the Coast Guard is changing this regulation which will require the Pinellas Bayway ''E'' Bridge to open on signal, except that from 7 a.m. to 9 p.m. the bridge will open on the hour and half-hour. Public vessels of the United States, tugs with tows and vessels in distress shall be allowed to pass at any time.

Discussion of Comments and Changes

The Coast Guard received no comments in response to the notice of proposed rulemaking (NPRM). For this reason no changes were made to the proposals for this final rule.

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.

This rule allows for scheduled bridge openings, and all waterway restrictions or closure times are published, giving adequate time for mariners to plan accordingly.

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.

For the reason stated above, 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.

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 the 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 actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about the rule or any policy or action of the Coast Guard.

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 an 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 an economically significant rule and would not create an environmental risk to health or risk to safety that might 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

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 (32)(e) of the Instruction, from further environmental documentation. Under figure 2–1, paragraph (32)(e), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.287(d)(4) to read as follows:

§ 117.287 Gulf Intracoastal Waterway.

* * * * *

(d)(4) Pinellas Bayway Structure ''E'' (SR 679) bridge, mile 113.0 at St. Petersburg Beach. The draw shall open on signal, except that from 9 a.m. to 7 p.m. the draw need open only on the hour and 30 minutes past the hour.

* * * * *

Dated: March 13, 2008.

W.D. Lee,

Captain, U.S. Coast Guard, Acting Commander, Seventh Coast Guard District.

[FR Doc. E8–6481 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2008–0117]

RIN 1625–AA09

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Bradenton Beach, FL, Schedule Change

AGENCY: Coast Guard, DHS.

ACTION: Temporary rule.

SUMMARY: The Coast Guard is changing the operating regulations governing the Cortez bridge mile 87.4 and the Anna Maria bridge mile 89.2 across the Gulf Intracoastal Waterway to allow for the rehabilitation of the Anna Maria Bridge. This rule will allow each bridge to open on a twice an hour schedule, except that they will be closed to navigation in the evening; also each bridge will open once every hour during the 45 day vehicle closure period on the Anna Maria Bridge. This action is necessary for worker safety and will assist in expediting the rehabilitation of the Anna Maria Bridge.

DATES: This temporary final rule is effective from 7 a.m. March 15, 2008 through 7 p.m. December 31, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0117 and are available online at

www.regulations.gov. They are also available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and Commander (dpb), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, Florida 33131–3028 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call Mr. Michael Lieberum, Bridge Branch, Seventh Coast Guard District, at 305–415–6744. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The final pre-construction and construction schedule were not provided to the Coast Guard with sufficient time to publish an NPRM and receive public comment before work began. The mayors of the surrounding cities, in coordination with the bridge owner, the contractor and local marinas in the area provided the Coast Guard with a finalized work schedule and suggested change in the bridges operations that would best serve the concerns of the surrounding communities and the contractor. In addition, the communities in the vicinity of the Anna Maria and Cortez bridges were informed of the bridge rehabilitation and proposed restrictions through the use of the local media. Furthermore this regulation is necessary for workers safety and will assist in expediting the rehabilitation of the Anna Maria Bridge. Therefore publishing an NPRM and delaying the start date of the rehabilitation project is contrary to the public interest and unnecessary.

Under 5 U.S.C. 553(d)(3), for the same reasons articulated in the preceding paragraph, the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**.

Background and Purpose

Due to the planned extensive rehabilitation of the Anna Maria Bridge across the Gulf Intracoastal Waterway mile 89.2, Bradenton Beach, Florida, the contractor requested that the Coast Guard change the current operation of the Anna Maria Bridge and the Cortez Bridge. The contractor also advised that it was necessary to start preparatory work as soon as possible in order to complete some of the work prior to the scheduled 45 days closure period to vehicular traffic. The Anna Maria Bridge would be closed to vehicle traffic for 45 days starting on September 29, 2008 and all vehicle traffic would be detoured to the Cortez Bridge across the Gulf Intracoastal Waterway mile 87.4, Bradenton Beach, Florida. The mayors of the surrounding cities requested a meeting with all concerned to discuss alternative solutions to alleviate possible vehicle traffic problems that could disrupt the flow of vehicles transiting to and from Anna Maria Island. The meeting sponsored by the local mayors was and held on November 28, 2007, and allowed the Coast Guard to hear the concerns of the mayors and the School Board which assisted in drafting this temporary rule.

The current operating regulation for the Cortez Bridge 33 CFR 117.287(d)(1) states: Cortez (SR 684) Bridge, mile 87.4. The draw shall open on signal, except that from 6 a.m. to 7 p.m., the draw need only open on the hour, 20 minutes after the hour and forty minutes after the hour. From January 15 to May 15, from 6 a.m. to 7 p.m., the draw need only open on the hour and half-hour.

The current operating regulation for the Anna Maria Bridge 33 CFR 117.287(d)(2) states: Anna Maria (SR 64) (Manatee Avenue West) Bridge, mile 89.2. The draw shall open on signal, except that from 6 a.m. to 7 p.m., the draw need only open on the hour, 20 minutes after the hour and forty minutes after the hour. From January 15 to May 15, from 6 a.m. to 7 p.m., the draw need only open on the hour and half-hour.

Based on the information received, the Coast Guard is changing the regulations for these bridges so that they will remain on a twice an hour schedule throughout the length of the rehabilitation, except they will be closed to navigation in the evening and will open once an hour during the day during the 45 day vehicle closure period. This action is necessary to assist the local communities' vehicle traffic flow and the contractor in completing the scheduled work in a timely manner.

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. The major impact of this rulemaking will occur during the off season so as to have the least impact on the local communities. Additionally, there is an alternate route available for the majority of vessels to avoid the construction area.

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 will not have a significant economic impact on a substantial number of small entities. This action will not have a significant economic impact on a substantial number of small entities as there is an alternate route available for the majority of vessels to avoid the construction area.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can 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 actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

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 an 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 an economically significant rule and would not create an environmental risk to health or risk to safety that might 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

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 (32)(e) of the Instruction, from further environmental documentation.

Under figures 2–1, paragraph (32)(e), of the Instruction, an ''Environmental Analysis Check List'' and a ''Categorical Exclusion Determination'' are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. From 7 a.m. on March 15, 2008, through 7 p.m. on December 31, 2008, § 117.287(d)(1) and § 117.287(d)(2) are temporarily suspended and temporary § 117.287(d)(5) and temporary § 117.287(d)(6) are added to read as follows:

§ 117.287 Gulf Intracoastal Waterway.

(d)(5) Cortez (SR 684) Bridge, mile 87.4. The draw shall open on signal; except that from 6 a.m. to 7 p.m., the draw shall open on the hour and half-hour.

From September 29, 2008 to November 13, 2008, the Cortez Bridge will remain closed to navigation from 5:35 a.m. to 9:25 a.m., 1:35 p.m. to 4:25 p.m. and 8 p.m. to 4:25 a.m. At all other times, this bridge will open once an hour on the bottom of the hour.

(6) The Anna Maria (SR 64) (Manatee Avenue West) Bridge, mile 89.2. The draw shall open a single-leaf on signal; except that from 6 a.m. to 7 p.m., the draw shall open on the hour and half-hour. A double-leaf opening will be available with a one-hour notice to the bridge tender. From September 29, 2008 to November 13, 2008, the Anna Maria Bridge will remain closed to navigation from 6 a.m. to 9 a.m., 2 p.m. to 5 p.m. and 8 p.m. to 5 a.m., at all other times, this bridge will open once an hour on the top of the hour.

* * * * *

Dated: March 12, 2008.

W.D. Lee,

Captain, U.S. Coast Guard, Commander Seventh Coast Guard District, Acting.

[FR Doc. E8–6483 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2008–0184]

RIN 1625–AA09

Drawbridge Operation Regulations; Intracoastal Waterway (ICW); Atlantic City, NJ, Air Show Event

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the US40–322 (Albany

Avenue) Bridge, at ICW mile 70.0, across Inside Thorofare at Atlantic City, NJ. This deviation is necessary to facilitate traffic control during the Atlantic City Air Show. This deviation will cause the bridge to be maintained in the closed-to-navigation position.

DATES: This deviation is effective from 10 a.m. to 5 p.m. on August 20, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0184 and are available online at *http://www.regulations.gov*. They are also available for inspection or copying at two locations: the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and the Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, VA 23704–5004 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mrs. Sandra S. Elliott, Bridge Management Specialist, Fifth Coast Guard District, at (757) 398–6557.

SUPPLEMENTARY INFORMATION: To facilitate traffic control for the Atlantic City Air Show, the US40–322 (Albany Avenue) Bridge will be maintained in the closed-to-navigation position from 10 a.m. to 5 p.m. on August 20, 2008.

The Greater Atlantic City Chamber of Commerce on behalf of the bridge owner, the New Jersey Department of Transportation (NJDOT), has requested a temporary deviation for the current operating regulation set out in 33 CFR 117.733 (f) to close the US40–322 (Albany Avenue) Bridge to navigation for the sole purpose of traffic control before, during and after the Atlantic City Air Show display, scheduled for Wednesday, August 20, 2008, from 10 a.m. to 5 p.m.

The US40–322 (Albany Avenue Bridge) at ICW mile 70.0, across Inside Thorofare at Atlantic City, NJ, a lift drawbridge, has a vertical clearance in the closed position to vessels of 10 feet, above mean high water. The current operating regulation set out in 33 CFR 117.733 (f) requires the draw shall open on signal except that: Year-round from 11 p.m. to 7 a.m. and from November 1 through March 31 from 3 p.m. to 11 p.m., the draw need only open if at least four hours notice is given; From June 1 through September 30: from 9 a.m. to 4 p.m. and from 6 p.m. to 9 p.m., the draw need only open on the hour and half hour; and from 4 p.m. to 6 p.m., the draw need not open.

During the event, vessel operators with mast height lower than 10 feet will continue to be able to transit through the drawbridge. The Atlantic Ocean is an alternate route for vessels with a mast height greater than 10 feet.

The Coast Guard reviewed the bridge logs provided by NJDOT for August 2007 which revealed that vessel traffic is primarily recreational and the number of bridge openings on weekdays averages about three openings per day. In addition, qualified personnel will be on-site to open the drawbridge for vessels in the event of an emergency.

The Coast Guard will inform the users of the waterway via maritime advisories of the closure period for the bridge so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 19, 2008.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch, Fifth Coast Guard District.

[FR Doc. E8–6475 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2008–0174]

Drawbridge Operation Regulations; Sacramento River, Rio Vista, CA, Drawbridge Maintenance

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Rio Vista Drawbridge across the Sacramento River, mile 12.8, at Rio Vista, CA. The deviation is necessary to allow the bridge owner, the California Department of Transportation (Caltrans), to conduct required maintenance of the drawspan. This deviation allows for a 4-hour notice for openings during nighttime.

DATES: This deviation is effective between 9 p.m. and 5 a.m., from March 24, 2008 through April 24, 2008.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2008–0174 and are available online at *http://www.regulations.gov*. They are also available for inspection or copying two locations: The Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays, and Commander (dpw), Eleventh Coast Guard District, Building 50–2, Coast Guard Island, Alameda, CA 94501–5100, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437–3516.

SUPPLEMENTARY INFORMATION: Caltrans requested a temporary change to the operation of the Rio Vista Drawbridge, mile 12.8, Sacramento River, at Rio Vista, CA. The Rio Vista Drawbridge navigation span provides a vertical clearance of 17 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal as required by 33 CFR 117.5. Navigation on the waterway consists of both commercial and recreational vessels.

The 4-hour notice for openings during the maintenance period, between 9 p.m. and 5 a.m., from March 24, 2008 through April 24, 2008, will allow Caltrans to clear the drawspan of maintenance equipment so as not to delay approaching vessels. This temporary deviation has been coordinated with all affected waterway users. No objections to the proposed temporary deviation were raised.

Vessels that can transit the bridge, while in the closed-to-navigation position, may continue to do so at any time.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: March 20, 2008.

C.E. Bone,

Rear Admiral, U.S. Coast Guard Commander, Eleventh Coast Guard District.

[FR Doc. E8–6473 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[ET Docket No. 03–201; FCC 07–56]

Equipment Approval of Modular Transmitters

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of three years, the information collection requirements contained in the ''Unlicensed Devices and Equipment Approval,'' *Report and Order*. These new rules required modification of the Form 731 Application for Equipment Authorization, and contained information collection requirements subject to the Paperwork Reduction Act of 1995 that were not effective until after approval by the Office of Management and Budget (OMB).

DATES: The effective date for the rule contained in § 15.212 published in the **Federal Register** on May 23, 2007 at 72 FR 28889 is April 15, 2008.

FOR FURTHER INFORMATION CONTACT: Nancy Brooks, Office of Engineering and Technology, (202) 418–2454, e-mail: *eapninquiry@fcc.gov*.

SUPPLEMENTARY INFORMATION:

1. In a *Report and Order*, released on April 23, 2007, FCC 07–56, published in the **Federal Register** on May 23, 2007, 72 FR 28889, the Federal Communications Commission adopted new rules that required modification of the Form 731 Application for Equipment Authorization, and contained information collection requirements subject to the Paperwork Reduction Act of 1995 that were not effective until after approval by the Office of Management and Budget (OMB). On March 10, 2008, OMB approved the new modified information collection requirements contained in 47 CFR 15.212. This information collection is assigned OMB Control Number 3060–0057.

2. The Report and Order amended parts 2 and 15 of the Commission's rules for unlicensed devices and equipment approval of both existing modular transmitter devices and emerging partitioned (or ''split'') modular transmitter devices. In addition to obtaining approval from OMB as noted, these new rules required software development to modify the Form 731 Application for Equipment Authorization. Software development to implement the new requirements has been completed, and the revised electronic Form 731 approved by OMB can be accessed on the effective date of implementation at *https://fjallfoss.fcc.gov/oetcf/eas/index.cfm* (applications filed directly with the FCC) or at *https://fjallfoss.fcc.gov/tcb/index.html* (applications filed by a Telecommunications Certification Body acting on behalf of the FCC). The public may continue to access the FCC database of authorized equipment via the Internet using options presented in the Reports section at *https://fjallfoss.fcc.gov/oetcf/eas/index.cfm*. Users experiencing problems in accessing the database via the Internet may contact OET at *easthelp@fcc.gov*

3. This publication satisfies the statement that the Commission would publish a document announcing the effective date of the rule changes requiring OMB approval.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E8–6556 Filed 3–28–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 15, 27, 54, 73 and 76

[MB Docket No. 07–148; FCC 08–56]

DTV Consumer Education Initiative

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved, for a period of six months under its emergency processing rules (5 CFR 1320.13), the information collection(s) associated with the Commission's 2008 Report and Order concerning DTV Consumer Education Initiative. This notice is consistent with the Report and Order, which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of the rules.

DATES: Sections 15.124, 27.20, 73.674, 73.3526(e)(11)(iv) and 73.3527(e)(13), published at 73 FR 15431, March 24, 2008, are effective March 31, 2008; and Sections 54.418 and 76.1630, also published at 73 FR 15431, March 24, 2008, are effective April 30, 2008.

FOR FURTHER INFORMATION CONTACT: Lyle Elder, *Lyle.Elder@fcc.gov* or 202–418–2120.

SUPPLEMENTARY INFORMATION: This document announces that, on March 27, 2008, OMB approved, for a period of six months under its emergency processing rules (5 CFR 1320.13), the information collection requirements contained in the Commission's Report and Order concerning *DTV Consumer Education Initiative,* FCC 08–56, published at 73 FR 15431, March 24, 2008. The OMB Control Numbers that are assigned to these information collections are 3060–1115 and 3060–0214. The Commission publishes this notice as announcement of the effective date of the rules and announcement of OMB approval for information collections. If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554. Please include the OMB Control Numbers, 3060–1115 and 3060–0214, in your correspondence. The Commission will also accept your comments via the Internet if you send them to *PRA@fcc.gov*.

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the FCC is notifying the public that it received OMB approval on March 27, 2008, for the information collection requirements contained in the Commission's rules at 47 CFR 15.124, 54.418, 27.20, 73.674, 73.3526(e)(11)(iv), 73.3527(e)(13) and 76.1630. The OMB Control Number assigned is 3060–1115 for all of the information collection requirements contained in 47 CFR 15.124, 54.418, 27.20, 73.674, and 76.1630. The OMB Control Number assigned is 3060–0214 for information collection requirements contained in 47 CFR 73.3526(e)(11)(iv) and 73.3527(e)(13). The total annual reporting burden for respondents for the collections contained in OMB Control Number 3060–1115 is estimated to be: 11,022 respondents; 70,026 responses; and a total annual burden hours of 156,069 hours; there is no annual cost associated with this information collection. The total annual recordkeeping burden for respondents for the collections contained in OMB Control Number 3060–0214 is estimated to be: 52,285 respondents; 52,285 responses; and a total annual burden hours of 1,831,706 hours; there is no

cost associated with this information collection.

Under 5 CFR 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid OMB Control Number.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E8–6683 Filed 3–28–08; 8:45 am]

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DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

48 CFR Parts 212, 225, and 252

RIN 0750–AF25

Defense Federal Acquisition Regulation Supplement; Contractor Personnel Authorized To Accompany U.S. Armed Forces (DFARS Case 2005–D013)

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: DoD has adopted as final, with changes, an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) to implement DoD policy regarding contractor personnel authorized to accompany U.S. Armed Forces deployed outside the United States.

DATES: *Effective Date:* March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Williams, Defense Acquisition Regulations System, OUSD (AT&L) DPAP (DARS), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062. Telephone 703–602–0328; facsimile 703–602–7887. Please cite DFARS Case 2005–D013.

SUPPLEMENTARY INFORMATION:

A. Background

DoD published an interim rule at 71 FR 34826 on June 16, 2006, to implement policy found in DoD Instruction 3020.41, Contractor Personnel Authorized to Accompany the U.S. Armed Forces. In addition, changes to the Federal Acquisition Regulation (FAR) were proposed at 71 FR 40681 on July 18, 2006, and finalized at 73 FR 10943 on February 28, 2008, to address the issues of contractor personnel that are providing support to the U.S. Government outside the United States but are not covered by the DFARS rule. Since the FAR and the DFARS rules are similar in many respects, the following discussion of comments received on the DFARS rule also includes relevant issues raised with regard to the FAR rule.

1. Right to Self-Defense (252.225–7040(b)(3)(i))

a. Distinction Between Self-Defense and Combat Operations

Comment: One respondent stated that there is an inherently vague line between what constitutes ''defense'' and ''attack,'' which is plainly crossed when the terms are applied in asymmetric warfare; and that contractors employing ''self-defense'' measures would have to undertake a wide array of combat activities to ensure their safety.

DoD Response: The DFARS rule recognizes that individuals have an inherent right to self-defense. It does not require self-defense, but authorizes it when necessary. In addition, the rule does not authorize preemptive measures. To the contrary, it recognizes that the actual conduct of an individual cannot be controlled, only governed, by contract terms and, therefore, emphasizes the consequences for the inappropriate use of force (252.225–7040(c)(3)(iii)).

b. Whether the Right of Self-Defense Should be Modified to ''Personal'' Self-Defense

Comment: One respondent recommended insertion of the word ''personal'' before ''self-defense,'' stating that this will clarify that civilians accompanying the force are authorized to use deadly force only in defense of themselves, rather than the broader concept of unit self-defense or preemptive self-defense.

DoD Response: DoD does not concur with this recommendation. The meaning of the term ''self-defense'' may vary depending on a person's duties and the country or designated operational area in which the duties are being performed.

c. Whether the Right of Self-Defense Should be Extended to Defense Against Common Criminals

Comment: One respondent stated that, since the rule will apply in innumerable asymmetrical environments, the phrase ''against enemy armed forces'' should be deleted, asserting that the right of self-defense should extend beyond enemy armed forces, since such defensive actions may be needed as protection against common criminals.

DoD Response: The final rule removes the phrase ''against enemy armed forces'' from paragraph (b)(3)(i) of the DFARS clause. DoD believes that it is more useful to the contractor to make an overall statement as to what is allowed with regard to use of deadly force in self-defense, than to focus on the law of war authorities with regard to enemy armed forces. There are legitimate situations that may also require a reasonable exercise of self-defense against other than enemy armed forces, e.g., defense against common criminals or terrorists. When facing an attacker, it will often not be possible for the contractor to ascertain whether the attacker is technically an ''enemy armed force.'' A cross-reference has been added in paragraph (b)(3)(iii) of the clause, with regard to the limitations on the use of force specified in paragraphs (d) and (j)(3) of the clause.

2. Role of Private Security Contractors (252.225–7040(b)(3)(ii))

a. Whether a Separate Category for Private Security Contractors Is Necessary

Comment: One respondent stated there is no need for private security contractors as a separate category if private security contractors (like other contractors) can only use deadly force in self-defense.

DoD Response: While the right to self-defense applies to all contractors, the rule recognizes that private security contractors have been given a mission to protect other assets/persons. Therefore, it is important that the rule reflect the broader authority of private security contractors with regard to use of deadly force, consistent with the terms and conditions of the contract.

b. Hiring Private Security Contractors as Mercenaries Violates the Constitution, Law, Regulations, Policy, and American Core Values

Comment: Several respondents commented that, by allowing contractors to assume combat roles, the Government is allowing mercenaries in violation of the Constitution, the laws of the United States, and core American values. One law specifically identified was 5 U.S.C. 3108, Employment of detective agencies; restrictions (the ''Anti-Pinkerton Act''). Also identified were the DoD Manpower Mix Criteria and the Federal Activities Inventory Reform (FAIR) Act of 1998, which

preclude contracting out core inherently governmental functions, especially combat functions.

DoD Response: While not disputing the many prohibitions against the use of mercenaries, private security contractors are not mercenaries and they are not part of the armed forces. The Government is not contracting out combat functions. The Government has the authority to hire security guards worldwide. In accordance with OMB Circular A–76, protection of property and persons is not an inherently governmental function. Private security contractors may be persons accompanying the armed forces within the meaning of Article 4A(4) of the Geneva Convention III.

In *Brian X. Scott,* Comp. Gen. Dec. B–298370 (Aug. 18, 2006), the Comptroller General of the United States concluded that solicitations for security services in and around Iraq violated neither the Anti-Pinkerton Act, nor DoD policies regarding contractor personnel, because the services required are not ''quasi-military armed forces'' activities. The Comptroller General also relied on the language of the interim DFARS rule, which prohibits contractor personnel from participating in direct combat activities, as well as the provisions of DoD Instruction 3020.41, which makes it the responsibility of the combatant commander to ensure that private security contract mission statements do not authorize the performance of any inherently governmental military functions. The Comptroller General concluded that ''* * * the services sought under the solicitations appear to comport with the DoD policies and regulations which state that security contractors are not allowed to conduct direct combat activities or offensive operations.''

c. Whether the Standard for Use of Deadly Force Should be Modified to One of ''Reasonableness''

Comment: Paragraph (b)(3)(ii) of the DFARS clause uses ''only when necessary'' as the standard for describing the use of deadly force by security contractors. DoD Directive 5210.56, Use of Deadly Force and the Carrying of Firearms by DoD Personnel Engaged in Law Enforcement and Security Duties (E2.1.2.3.1), uses the standard of ''reasonably appears necessary.'' The respondent stated that, while deadly force is to be avoided, the ''only when necessary'' standard in the interim rule fails to recognize the ''reasonably appears necessary'' standard that is critical to split-second decisions, particularly in a war zone.

DoD Response: DoD agrees that the DFARS rule should be consistent with the cited DoD Directive and has incorporated the ''reasonably appears necessary'' standard into the final rule.

d. Whether Protected Assets/Persons for Private Security Contractors Should be Limited to Non-Military Objectives

Comment: One respondent stated the rule should be clarified to limit private security contractor personnel to protecting assets/persons that are non-military objectives. This omission from the interim rule seems to conflict with Army Field Manual No. 3–100.21, which prohibits the use of contractors in a force protection role. The respondent also expressed concern about how to craft statements of work for private security contractors that do not assign inherently governmental functions to contractors.

DoD Response: It is not possible to know in advance of an actual conflict what may become a military objective. Almost anything worth protecting could become a military target in wartime. As stated in paragraph 2 above, the Government is not contracting out combat functions. The United States Government has the authority to hire security guards worldwide. According to OMB Circular A–76, Performance of Commercial Activities, protection of property and persons is not an inherently governmental function (see FAR 7.503(d)(19)). DoD Instruction 3020.41 provides limitations and safeguards for private security contracts, including legal review on a case-by-case basis. Paragraph 6.3.5 of that Instruction states that, ''Whether a particular use of contract security personnel to protect military assets is permissible is dependent on the facts and requires legal analysis.'' The DoD Instruction also states in paragraph 6.3.5.2, ''Contracts shall be used cautiously in contingency operations where major combat operations are ongoing or imminent. In these situations, contract security services will not be authorized to guard U.S. or coalition military supply routes, military facilities, military personnel, or military property except as specifically authorized by the geographic Combatant Commander (non-delegable).'' Since these requirements must be fulfilled before the private security contract is entered into, it is not necessary or appropriate to include these requirements in the DFARS rule.

e. Use of the Term ''Mission Statement''

Comments: Paragraph (b)(3)(ii) of the DFARS clause authorizes private security contractor personnel to use deadly force only when ''necessary to execute their security mission to protect assets/persons, consistent with the mission statement contained in their contract.'' Several respondents stated that the use of the term ''mission statement'' in that sentence caused confusion and should be clarified. One respondent noted that not all contracts for security services will contain a ''mission statement'' as such. Statements of work may contain sections entitled ''objectives,'' ''purpose,'' or ''scope of work,'' which may or may not contain the equivalent of a mission statement. The respondent further noted that the need to deploy security personnel quickly could result in a mission statement (or its equivalent) that may not be as precise as desired and, therefore, ill-suited to serve as part of a standard for when deadly force is authorized.

Other respondents requested clarification as to whether subcontractors would be considered private security contractors, or whether the term ''private security contractor'' was limited to contractors that have a contract directly with the Government. One respondent stated there is no guidance as to who would qualify as private security contractor personnel, creating uncertainty as to whether private security companies retained by a prime contractor would be covered if the prime contractor drafted a mission statement for its private security subcontractor.

DoD Response: DoD agrees that the term ''mission statement'' could cause confusion and has replaced ''mission statement'' with ''terms and conditions'' in paragraph (b)(3)(ii) of the clause. DoD does not believe that any clarification with regard to subcontractors is necessary. When a clause flows down to subcontractors, the terms are changed appropriately to reflect the relationship of the parties. Nothing in the rule indicates that private security contractors cannot be subcontractors.

f. Authority of Combatant Commander To ''Create Missions''

Comment: One respondent stated that the rule delegates extensive authority to combatant commanders to direct contractor actions under both support and security contracts. The respondent further stated that granting such nearly unlimited authority to combatant commanders to create missions is inconsistent with laws and regulations that convey such authority to contracting officers and serves to undermine their authority.

DoD Response: The combatant commander is not authorized to create

missions for private security contractors. A contractor must perform in accordance with the terms and conditions of the contract. The combatant commander is responsible for reviewing/approving any contractor request to carry weapons and evaluating whether the planned use of such weapons is appropriate.

g. Approval of Private Security Contractors

Comment: One respondent questioned whether there will be a vetting process and a list of approved Private Security Contractors from which DoD contractors or their subcontractors may acquire services.

DoD Response: Contractors are responsible for providing their own security support and for the selection and performance of subcontractors. However, the Government may reserve the right to approve subcontracts.

h. Definition of ''Private Security Contractor''

Comment: Several respondents requested a definition of ''private security contractor.'' One respondent noted that DoD Instruction 3020.41 uses the term ''security services.''

DoD Response: DoD considered defining ''private security contractor'' to mean ''a contractor that has been hired to provide security, either by the Government or as a subcontractor.'' However, in considering this definition, DoD realized that, in some circumstances, a contractor whose primary function is not security may directly hire a few personnel to provide security, rather than subcontracting to a private security contractor. The authority for use of deadly force ultimately rests with the individuals who are providing the security, whether as direct hires or as employees of a subcontractor. Therefore, the final rule amends paragraph (b)(3)(ii) of the contract clause to replace the term ''private security contractor personnel'' with ''contractor personnel performing security functions.'' In addition, since some contractor personnel performing security functions are employees, rather than hired by contract, paragraph (b)(3)(ii) of the clause has been further amended to address execution of the security mission by such personnel consistent with their job description and terms of employment.

i. Coordination and Communication With Private Security Contractors

Comment: One respondent stated that DoD is coordinating responsibilities and functions among the military and contractor security forces in Iraq and requested that the DFARS state that DoD will similarly coordinate security efforts in future theaters of operation. In addition, the respondent stated that the DFARS should name an organization to coordinate the overall activities of the private security contractors to meet U.S. tactical and strategic goals and that DoD should have a process by which it communicates and receives threat information to and from contractors operating in the field, as required by DoD Instruction 3020.41. Further, DoD Instruction 3020.41, paragraph 6.3.5.3.3, also requires a plan as to how appropriate assistance will be provided to contractor security personnel who become engaged in hostile situations.

DoD Response: Such plans for coordination and communication are the responsibility of the combatant commander and are outside the scope of this DFARS rule. These issues must be addressed before the combatant commander approves the arming of contingency contractor personnel to provide security services. Once approved, the terms and conditions of the contract will reflect these requirements as appropriate.

3. Consequences of Inappropriate Use of Force (252.225–7040(b)(3)(iii))

a. Loss of ''Law of War'' Protection From Direct Attack

Comment: The statement in paragraph (b)(3)(iii) of the contract clause, that civilians lose their law of war protection from direct attack if and for such time as they take a direct part in hostilities, raised numerous questions regarding its meaning. One respondent considered this to be a correct statement under the international law of war, but that it may call into question the foundation for the global war on terrorism and targeting ''unlawful combatants'' when they are not taking a direct part in hostilities.

DoD Response: The statement in question has been excluded from the final rule. DoD considered the statement to be unnecessary and potentially confusing. Paragraph (b)(3)(i) of the clause establishes the right to self-defense. Paragraph (b)(3)(ii) sets forth a limited right for some contractor personnel to protect assets/persons. A new paragraph (b)(3)(iii) has been added to address the consequences of the inappropriate use of force.

b. Consequences Other Than ''Law of War'' Consequences

Comment: Several respondents stated that the notice to contractors relating to the personal and legal impact of directly participating in hostilities is incomplete. Without including the cautionary language of DoD Instruction 3020.41 relating to possible criminal and civil liability, civilians accompanying the armed forces might erroneously believe the only impact of their direct participation is that they would be lawful targets during such time that they are participating in hostilities. One respondent was also concerned that, by not mentioning potential immunity, it could be argued that the clause waives otherwise available immunities. The respondents suggested addition of language stating that, ''Since civilians accompanying the force do not have combatant immunity, unless immune from host nation jurisdiction by virtue of an international agreement or international law, contingency contractor personnel are advised that inappropriate use of force could subject them to U.S. or host nation prosecution and civil liability.''

DoD Response: The new paragraph (b)(3)(iii) in the contract clause incorporates the information found in DoD Instruction 3020.41 relating to possible immunity and possible criminal and civil liability for contractor personnel who inappropriately use force.

4. Contractors Are Not Active Duty (252.225–7040(b)(4))

Comment: One respondent was concerned about paragraph (b)(4) of the contract clause, which states, ''Service performed by Contractor personnel subject to this clause is not active duty or service under 38 U.S.C. 106.'' The respondent stated that the Note under 38 U.S.C. 106 explains that the Secretary of Defense is to determine what constitutes active duty or service under this statute for Women's Air Forces Service Pilots who were attached to the Army Air Corps during World War II and persons in similarly situated groups who rendered services in a capacity considered civilian employment or contractual service. The respondent stated that the determination can only be made retrospectively.

DoD Response: Paragraph (b)(4) of the clause correctly states the terms of service for Defense and non-Defense contractors. Contractors should hold no expectations under this clause that their service will qualify as ''active duty or service.'' The Note under 38 U.S.C. 106 requires that determinations for any applicant group be based on (1) regulations prescribed by the Secretary, and (2) a full review of the historical records and any other evidence pertaining to the service of any such group. In promulgating the DFARS, DoD has issued a regulation prescribed by

the Secretary. This DoD regulation establishes the historical record that shall be used in future review of the historical evidence surrounding a contractor's service under this clause. DoD policy is that contractors operating under this clause shall not be attached to the armed forces in a way similar to the Women's Air Forces Service Pilots of World War II. Contractors today are not being called upon to obligate themselves in the service of the country in the same way as the Women's Air Forces Service Pilots or any of the other groups listed in 38 U.S.C. 106.

5. Weapons (252.225–7040(j))

a. Nature of the Authorized Weapons

Comment: One respondent stated there is no reasonable limitation on the nature of the weapons that a contractor is to handle, whether as a ''self-defense'' contractor or a private security contractor. This range could include anything from small arms to major weapons systems.

DoD Response: The possible situations are too numerous to permit prescription of specific weapons for each situation. However, it is unlikely that a contractor would attempt to bring a major weapon system onto the battlefield, or that the combatant commander would authorize such weapons.

b. Combatant Commander Rules on the Use of Force

Comment: One respondent stated that there is no reasonable means by which a combatant commander can generate rules regarding the use of force by contractors. The respondent further stated that the rules must be related to doctrine, dogma, rules of engagement, etc., and these are formulated well above the level of the combatant commander. Since the rules may be different, contractor personnel would be subject to a range of serious risks and liabilities.

DoD Response: It is the authority of the combatant commander to perform those functions of command over assigned forces involving organizing and employing commands and forces; assigning tasks; designating objectives; and giving authoritative direction over all aspects of military operations, joint training, and logistics necessary to accomplish the missions assigned. Operational control is inherent in combatant command (command authority) and, therefore, provides full authority to organize and employ commands and forces as the combatant commander considers necessary to accomplish assigned missions. The combatant commander also establishes rules of engagement in the designated operational area, and does take into consideration many influences such as doctrine. The combatant commander will seek advice from experts in areas such as law and security before making such decisions. Since the rules regarding contractor authorization to carry firearms will vary according to the phase of the conflict, the combatant commander is the most informed and able individual to determine whether a contractor should carry weapons.

c. Law of Armed Conflict Issues

Comment: One respondent stated that the notion that the Government assumes no responsibility whatsoever for the use of weapons on a battlefield by a contractor authorized and required to use such weapons, as the practical effect of the contract requirements, makes no sense and is certain to cause contractual law of armed conflict and other problems.

DoD Response: There have been no issues on the law of armed conflict for contractors carrying weapons, because in the current conflicts there are no enemy armed forces that are lawful combatants and no enemy government to provide them prisoner of war status and protections if captured. DoD also notes that, at the beginning of the current conflict, contractors were not permitted to carry weapons at all. During the post-major operations phase, civilian contractors that have been brought in for a variety of security operations are authorized (and required) to provide their own weapons. The obvious safety/security issues connected with carrying a weapon far outweigh any theoretical issues.

d. Liability for Use of Weapons

Comment: Several respondents expressed concern that the Government authorizes and sometimes requires contractor personnel to carry weapons, but that it places sole liability for the use of weapons on contractors and contractor personnel, even if the contractor was acting in strict accordance with the contract statement of work or under specific instructions from the contracting officer or the combatant commander (252.225–7040(j)(4)). One respondent considered that statement to be inconsistent with prior regulatory history, citing the statement in the preamble to the final DFARS rule published on May 5, 2005 (70 FR 23792), that ''risk associated with inherently Governmental functions will remain with the Government.''

DoD Response: While a contractor may be authorized to carry and use weapons, the contractor remains responsible for the performance and conduct of its personnel. A contractor has discretion in seeking authority for any of its employees to carry and use a weapon. The contractor is responsible for ensuring that its personnel who are authorized to carry weapons are adequately trained to carry and use them safely, adhere to the rules on the use of force, comply with law and agreements, and are not barred from possession of a firearm. Inappropriate use of force could subject a contractor or its subcontractors or employees to prosecution or civil liability under the laws of the United States and the host nation. The Government cannot indemnify a contractor and its personnel against claims for damages or injury or grant immunity from prosecution associated with the use of weapons. With regard to the statement on inherently governmental functions, this rule does not authorize contractors to perform any inherently governmental functions.

6. Risk/Liability to Third Parties/ Indemnification (252.225–7040(b)(2))

Comment: Many respondents expressed concern that the DFARS rule shifts to contractors all risks associated with performing the contract, and may lead courts to deny contractors certain defenses in tort litigation. The respondents cited decisions by State and Federal courts arising out of injuries or deaths to third parties, including military members and civilians. Generally, the courts absolved contractors of liability to third parties where the Government carried ultimate responsibility for the operation. For example—

○ In *Smith* v. *Halliburton Co.,* No. H–06–0462, 2006 WL 1342823 (S.D. Tex. May 16, 2006) and *Whitaker* v. *Kellogg Brown & Root, Inc.,* No. 05–CV–78, 2006 WL 1876922 (M.D. Ga. July 6, 2006), the courts found there was no risk and no liability associated with contractor performance when active duty military members were injured in situations where the military (or the injured member himself) was responsible for force protection of military members.

○ In *Koohi* v. *United States,* 976 F.2d 1328 (9th Cir. 1992), the contractor bore no risk and no liability for military decisions aboard the U.S.S. Vincennes to shoot down an approaching aircraft during a time of war, and the contractor had no responsibility to design or manufacture the Aegis weapon system to prevent such use by military members.

Some respondents expressed concern that the acceptance of risk may preclude

grants of indemnification. One respondent stated that the rule could adversely affect indemnification that would otherwise be available. The clause at FAR 52.228–7, Insurance-Liability to Third Persons, provides limited indemnification, but provides that contractors shall not be reimbursed for liabilities for which the contractor is otherwise responsible under the express terms of any clause specified in the Schedule or elsewhere in the contract. The respondent also stated that the provisions requiring the contractor to accept certain risks and liabilities could also be the basis to deny pre- or post-award requests for indemnification under Public Law 85–804. Another respondent cited a decision by a DoD Contract Appeals Board in which the Board declined a contractor's request for indemnification under Public Law 85–804 because, according to the Board, contractors should not be able to deliberately enter into contractual arrangements with full knowledge that a risk is involved and yet propose unrealistically low prices on the hopes they may later gain indemnification. The respondents recommended that the United States either identify, quantify, and accept all the risk or insert language that would immunize contractors from tort liability. Specifically, several respondents recommended adding the statement, ''Notwithstanding any other clause in this contract, nothing in this clause should be interpreted to affect any defense or immunity that may be available to the contractor in connection with third-party claims, or to enlarge or diminish any indemnification a contractor may have under this contract or as may be available under the law.'' There was also concern that, by accepting all risks of performance, contractors would not be able to obtain workers compensation insurance or reimbursement under the Defense Base Act. One respondent recommended that the contractor's share of risk in the rule be revised as follows: ''Except as otherwise provided in the contract, the Contractor accepts the risks associated with required contract performance in such operations.''

DoD Response: DoD believes that the rule adequately allocates risks, allows for equitable adjustments, and permits contractors to defend against potential third-party claims. Contractors are in the best position to plan and perform their duties in ways that avoid injuring third parties. Contractors are equally or more responsible to research host nation laws and proposed operating environments and to negotiate and price the terms of each contract effectively. Accordingly, the clause retains the current rule of law, holding contractors accountable for the negligent or willful actions of their employees, officers, and subcontractors. This is consistent with existing laws and rules, including the clause at FAR 52.228–7, Insurance-Liability to Third Persons, and FAR Part 50, Extraordinary Contractual Actions, as well as the court and board decisions cited in the comments. The current law regarding the Government Contractor Defense (e.g., the line of cases following *Boyle* v. *United Technologies,* 487 U.S. 500, 108 S. Ct. 2510 (1988)) extends to manufacturers immunity when the Government prepares or approves relatively precise design or production specifications after making sovereign decisions balancing known risks against Government budgets and other factors in control of the Government. This rule covers service contracts, not manufacturing, and it makes no changes to existing rules regarding liability. The public policy rationale behind *Boyle* does not apply when a performance-based statement of work is used in a services contract, because the Government does not, in fact, exercise specific control over the actions and decisions of the contractor or its employees or subcontractors. Asking a contractor to ensure its employees comply with host nation law and other authorities does not amount to the precise control that would be requisite to shift away from a contractor's accountability for its own actions. Contractors will still be able to defend themselves when injuries to third parties are caused by the actions or decisions of the Government. However, to the extent that contractors are currently seeking to avoid accountability to third parties for their own actions by raising defenses based on the sovereignty of the United States, this rule should not send a signal that would invite courts to shift the risk of loss to innocent third parties. The language in the clause is intended to encourage contractors to properly assess the risks involved and take proper precautions. However, to preclude the misunderstanding that asking the contractor to ''accept all risks'' is an attempt to shift all risk of performance to the contractor without regard to specific provisions in the contract, the statement in the rule regarding risk has been amended to add the lead-in phrase, ''Except as otherwise provided in the contract''.

7. Definition of Terms (252.225–7040(a))

a. Theater of Operations

Comment: One respondent stated that the term ''theater of operations'' is unwarranted by any legitimate purposes suggested by the rule, and that this term, if defined at all, should rest in the hands of the President or the Secretary of Defense.

DoD Response: The term was included in the interim rule because it defined the geographic area to which the clause was applicable. The combatant commander has the authority to define a ''theater of operations'' within the geographic area for which the combatant commander is responsible. However, consistent with DoD Joint Publication 3–0, Joint Operations, DoD has determined that the term ''designated operational area'' is more appropriate to describe the applicability of the rule, as this term includes the theater of operations as well as such descriptors as theater of war, joint operations area, amphibious objective area, joint special operations area, and area of operations. Therefore, the term ''theater of operations'' has been replaced with the term ''designated operational area'' throughout the rule.

b. Other Military Operations

Comment: Two respondents noted that the term ''other military operations'' is very broadly defined. One respondent stated that the term is either over-expansive, or unnecessary, because it is so inclusive as to suggest nearly any type of military engagement likely to be carried out in the first half of the current century.

DoD Response: DoD agrees that the definition was very broad, because it was intended to cover every type of military operation. Since the final rule applies to ''other military operations'' only when designated by the combatant commander, definition of this term is no longer necessary and has been excluded from the final rule.

8. Terms Not Defined

a. Enemy Armed Forces

Comment: Two respondents objected to the use of the term ''enemy armed forces'' in the rule without definition.

DoD Response: The term ''enemy armed forces'' has been excluded from the final rule.

b. ''Law of War,'' ''Law of War Protections,'' and ''Take Direct Part in Hostilities''

Comment: One respondent stated that terms of art such as ''law of war,'' ''law of war protections,'' and ''take direct part in hostilities'' are not defined in the

rule and likely cannot be defined satisfactorily in the DFARS. The respondent further stated that understanding the concepts underlying these terms is crucial to preparing statements of work for and administering contracts that will send contractor employees into hostile environments. Therefore, the respondent recommended that the DFARS text include some discussion of these terms and the need for contracting personnel to seek advice when dealing with these terms.

DoD Response: DoD agrees that these terms cannot be defined satisfactorily in the DFARS and has removed the terms from the final DFARS rule. However, DoD is developing law of war training that will be available to contractor personnel.

c. ''Mission Essential,'' ''Essential Contractor Services,'' ''Security Support,'' ''Security Mission,'' ''Security Plan,'' ''Mandatory Evacuation,'' and ''Non-Mandatory Evacuation''

Comment: Two respondents stated that the interim rule used these terms, which are not defined, and, except for ''essential contractor services'' and ''security plan,'' are not used in DoD Instruction 3020.41. The respondents considered these terms critical to the contractor in determining and pricing its obligations under a solicitation and resulting contract.

DoD Response: ''Mission essential'' is the term used in DoD Instruction 3020.37, Continuation of Essential DoD Contractor Services During Crises. ''Essential contractor services'' is defined in DoD Instruction 3020.41. The Government identifies the mission essential personnel and essential contractor services to the contractor, so it is unnecessary to define these terms in the DFARS. ''Security support'' and ''security mission'' are used with their common dictionary meaning; however, the terms and conditions of the contract will define the mission and will also specify if security support will be provided. DoD Instruction 3020.41, paragraph 6.3.4, addresses the requirements for a security plan. Since the combatant commander prepares the security plan, these requirements do not need to be repeated in the DFARS. It is also unnecessary to define ''mandatory evacuation'' and ''non-mandatory evacuation'' in the DFARS, as these terms are used with their common dictionary meaning, and the Government will identify any evacuation order as mandatory or non-mandatory. The contractor will be given appropriate instructions in the event an evacuation order is issued.

9. Scope of Application

a. Commercial Items

Comment: One respondent expressed concern that DFARS 212.301(f) requires application of the contract clause across-the-board to commercial items. The respondent recommended that the clause apply only if the acquisition of commercial items is for performance of contractor personnel outside the United States in a covered theater of operations.

DoD Response: DoD agrees that the clause should apply only if the acquisition of commercial items is for performance of contractor personnel outside the United States in a designated operational area. However, the respondent has misinterpreted the requirement at DFARS 212.301(f)(vii). This paragraph states that the clause at DFARS 252.225–7040 is to be used in accordance with the prescription at DFARS 225.7402–4, which specifies the criteria for use of the clause.

b. Military Operations and exercises

Comment: One respondent expressed concern regarding application of the rule to a wide range of military operations and exercises that do not require special treatment. The rule prescribes use of the clause when contractor personnel will be required to perform outside the United States in a theater of operations during ''other military operations'' or ''military exercises designated by the combatant commander.'' The respondent recommended that the final rule include criteria for when the combatant commander should invoke the authority to require use of the clause.

DoD Response: DoD has amended the rule to clarify that ''designated by the combatant commander'' applies to military operations as well as military exercises. However, DoD does not consider it appropriate for the DFARS to prescribe criteria to the combatant commander for use of the clause. The combatant commander is in the best position to determine whether the circumstances in a designated operational area warrant use of the clause. In addition, the final rule clarifies that any of the types of military operations covered by the scope of the rule may include stability operations.

c. Designation of Specific Geographic Area

Comment: One respondent questioned whether the combatant commander should designate a specific geographic area for applicability of the clause.

DoD Response: DoD believes that the scope of the DFARS clause sufficiently defines the area of applicability. The designated operational area is a specific geographic area, defined by the combatant commander or the subordinate joint force commander for the conduct or support of specified military operations.

10. Logistical and Security Support (225.7402–3 and 252.225–7040(C))

a. Lack of Force Protection Represents a Change in Policy

Comment: Two respondents stated that the lack of committed force protection represents a drastic change in policy for contractors accompanying U.S. Armed Forces. Another respondent considered that this is the penultimate paragraph in the transfer of responsibility for force protection from the military to contractors, and that it is ill-considered. One of the respondents noted that, prior to the interim rule, the DFARS required the combatant commander to develop a security plan for protection of contractor personnel through military means unless the terms of the contract placed the responsibility with another party. That respondent strongly opposed the changes made by the interim rule, which limit the requirement for the combatant commander to develop a security plan to those locations where there is not sufficient or legitimate civil authority and where the commander decides the provision of security is in the interests of the Government. The respondent stated that this reversal of policy will—

(1) Have a significant impact on the ability of contractors to provide future support to DoD (bid/proposal costs will reflect higher costs related to the contractor's assumption of security costs);

(2) Have a direct effect on systems contractors supporting major weapons systems; and

(3) Substantially increase contract prices.

The respondent also cited DoD Joint Publication 4–0, Chapter V, and Enclosure 2 to DoD Instruction 3020.41 as support for the statements that DoD affirmatively had the obligation to provide force protection for contractors providing direct support to the military. Another of the respondents questioned how the decision that DoD presumably will not provide a security plan is consistent with protecting contractor resources vital to accomplishing the U.S. mission.

DoD Response: In most areas of the world, it is the responsibility of the host nation to provide protection for civilians working in their country. It is clearly unnecessary for the combatant commander to prepare a security plan in

locations where there is sufficient legitimate civil authority. The added provisions are from DoD Instruction 3020.41, which provides that the combatant commander must decide that to provide security is in the interests of the Government. The combatant commander is in the best position to judge the circumstances in the designated operational area and what resources are available to him and to the contractors. The writers of the regulations cannot commit the U.S. Armed Forces to provide protection to contractor personnel performing in areas of conflict, beyond what is provided for in DoD Instruction 3020.41. With regard to the reference to DoD Joint Publication 4–0, Chapter V, this chapter (paragraph 13a.) specifically states that force protection responsibility for DoD contractor employees is a contractor responsibility, unless valid contract terms place that responsibility with another party. With regard to the reference to Enclosure 2 to DoD Instruction 3020.41, the definition of ''Contractors Deploying with the Force'' in Enclosure 2 states that contractors deploying with the force usually receive Government-furnished support similar to DoD civilians. This statement addresses logistics support, not force protection.

The rule does not state that the combatant commander will not provide a security plan. The rule specifically states that the combatant commander will provide a security plan for protection of contractor personnel in locations where there is not sufficient legitimate civil authority and the combatant commander decides it is in the interests of the Government to provide security, especially if threat conditions necessitate security through military means. The rule focuses the application of limited resources in those situations where most needed.

b. Timing of Disclosure

Comment: One respondent stated that timing of the disclosure of agency support could impact an offeror's proposal costs and recommended that, at a minimum, agencies be required to include support information, not just in the contract, but also in the solicitation. Another respondent stated that the solicitation should specify whether DoD will provide a security plan. Contractors need sufficient time to decide whether they want to bear the additional risk of performance or make suitable arrangements with a private security firm or its own personnel. A third respondent requested that the final rule clarify whether a security plan, if any, will be developed prior to the release of the solicitation.

DoD Response: DoD agrees that the timing of the disclosure of the agency's decision to provide or not provide support could have an impact on proposal costs. Therefore, DFARS 225.7402–3(c) has been amended to add a requirement for identification of this information in the solicitation.

c. Changes in Government-Provided Support

Comment: One respondent recommended that any changes to Government-provided security support should expressly require an equitable adjustment to the contract.

DoD Response: DoD does not believe it is necessary to expressly address this issue in the DFARS rule. Any need for equitable adjustment will be evaluated in accordance with the Changes clause included in the contract.

d. Agency/Combatant Commander Cannot Know if Adequate Support is Available

Comment: One respondent commented that one of the conditions precedent to Government support is a determination by the Government that adequate support cannot be obtained by the contractor from other sources. The respondent stated that, whether or not competitors can obtain adequate support from other sources is outside of an agency's knowledge and that this kind of knowledge involved marketplace issues that vary significantly by the size and experience of the contractor. The respondent also stated that two of the three key elements of the combatant commander's decision required by the DFARS rule are outside of his expertise and scope of knowledge—namely whether the specific contractor can obtain effective security services and whether effective security services are available at a reasonable price.

DoD Response: DoD does not agree that the Government would not be able to determine whether the contractor was able to obtain adequate support from other sources. The Government official/combatant commander would not be making a decision in a vacuum, but would have staff to perform necessary market research and consult with the contractor as necessary. The final rule contains an amendment at 225.7402–3(b)(2) to include ''reasonable cost'' as a criterion for contractor-obtained support, consistent with the language at 252.225–7040(c)(1)(i)(B).

e. Security Costs Should Be a Cost-Reimbursement Line Item

Comment: One respondent stated that security costs should be a cost-reimbursement line item, even in a fixed-price contract, or should provide for equitable adjustment to reflect material changes in the threat environment.

DoD Response: In accordance with FAR 16.103, selecting the appropriate contract type is generally a matter of negotiation and requires the exercise of sound judgment. The contractor's responsibility for the performance costs and the profit/fee incentives offered are tailored to the uncertainties involved in contract performance. While DoD acknowledges that there may be a high degree of uncertainty in the costs for security, the determination of how to handle that uncertainty is a matter of negotiation rather than regulation.

f. Shift Mid-Stream

Comment: One respondent stated that existing contracts with military force protection could be impacted midstream by the DFARS rule and that contractors will be required to either shift their work plan and price such changes accordingly or decline the work.

DoD Response: This rule does not impact existing contracts. DoD does not plan to retroactively modify contracts. If the combatant commander has established a security plan and is currently providing force protection, there is no reason to believe that this rule would result in a change to the existing arrangements.

g. Firms Unwilling To Bid

Comment: One respondent stated that many firms, aware that they might no longer be provided military force protection, might decline new overseas DoD work due to the often dangerous or austere conditions.

DoD Response: The conditions are often dangerous or austere, and military protection may not be available. If firms are unwilling to cope with such conditions, they should not bid.

h. Insufficient Infrastructure

Comment: Regarding non-security support, one respondent noted that paragraph (c)(3) of the DFARS clause states that, unless specified elsewhere in the contract, the contractor is responsible for all other support required for its personnel engaged in a theater of operations. The respondent further noted that, in some theaters of operations, the local infrastructure might be insufficient or the military situation may limit or restrict the

contractor's ability to provide such support.

DoD Response: Because of such difficulties, the DFARS clause provides for logistical support when such support is needed to ensure continuation of essential contractor services and the contractor cannot obtain adequate services. However, the contractor cannot assume that such services will be provided unless it has been arranged and is specified in the contract.

i. Provision of Care

Comment: One respondent noted that paragraph (c)(2)(i) of the DFARS clause states that all contractor personnel ''may be provided'' certain types of care. The respondent expressed concern that this paragraph implies there is discretion not to provide such care, but with no guidance as to how this discretion is to be exercised. The respondent recommended revision of the phrase ''may be provided'' to ''are authorized to receive.''

DoD Response: There was no intent to imply that access to such care would be denied, but rather that DoD could not commit to providing it in all circumstances. The phrase has been revised as recommended by the respondent.

11. Compliance With Laws, Regulations, Directives (252.225–7040(d))

a. Lack of Access to Necessary Information on Laws, Regulations, and Directives

Paragraph (d) of the DFARS clause requires the contractor to comply with, and ensure that its deployed personnel are familiar with and comply with, all applicable laws, rules, and regulations, including those of the host country, all treaties and international agreements, all U.S. regulations, and all orders, directives, and instructions issued by the combatant commander.

Comment: One respondent stated that rarely will contractors, let alone offerors, have access to any (and certainly not all) relevant orders, directives, instructions, policies, and procedures of the combatant commander, even in those narrow functional areas specified in the clause. The respondent also states that frequently a contractor is asked to deploy to countries or areas of the world on short notice without extended advance notice and without meaningful access to information on relevant foreign and local laws.

DoD Response: Paragraph (d) of the DFARS clause reinforces the existing obligation for contractor personnel to comply with the laws and regulations applicable to the contract. Contractors have access to all of these laws and regulations, and country studies are available online at *http://www.state.gov.* Therefore, a contractor may ascertain on its own the laws and regulations necessary to comply with paragraph (d) of the clause. In addition, a contractor supporting contingency operations should have access to any orders, directive, instructions, policies, and procedures of the combatant commander that affect contract performance in the designated operational area. The Web site at *http://www.acq.osd.mil/dpap/pacc/cc/areas_of_responsibility.html* links directly to individual combatant commands and countries to provide the information necessary for operating in that area.

b. Varying Need for Extensive Information

Comment: One respondent stated that deployed employees may have no need for certain types of information that are unrelated to their specific work assignments.

DoD Response: The DFARS clause only requires knowledge of applicable laws and regulations. If certain laws or regulations are not applicable to particular employees, the information provided to those employees should be tailored as appropriate.

c. Inconsistency Between U.S. Laws and Host or Third Country National Laws

Comment: One respondent recommended that the DFARS clause address how U.S. contractors are to resolve conflicts between compliance with U.S. law and any inconsistent host or third country national laws. Another respondent recommended establishment of an order of precedence among the contract, statement of work, DFARS clauses, DoD instructions and directives, and combatant commander orders (written or oral).

DoD Response: DoD does not agree with the recommended changes. The resolution of conflicts between U.S. and host or third country national laws must be analyzed on a case-by-case basis and, therefore, is beyond the scope and intent of the regulations. Also, paragraph (d) of the DFARS clause is a reminder of the existing obligation to comply with the applicable laws, regulations, and international agreements specified therein. It is the contractor's responsibility to make the best possible interpretations and determinations when deciding which law or regulation takes precedence in the event of a conflict. With regard to the orders of the combatant commander, see the following paragraph.

d. Authority of the Combatant Commander

Comment: One respondent expressed concern that the broad authority in paragraph (d)(4) of the DFARS clause would allow the combatant commander to become unduly involved in the contracting process. In addition, this paragraph could be interpreted as empowering combatant commanders to issue instructions for individual contracts on a wide spectrum of matters.

DoD Response: Paragraph (d)(4) of the clause is a reminder of the existing obligation for contractor personnel to comply with laws and regulations applicable to the contract. It does not provide new authority for combatant commanders to direct the contracting activities of other Government agencies. However, paragraph (d)(4) has been amended to clarify that only the contracting officer is authorized to modify the terms and conditions of the contract.

e. Ensure That the Statement of Work Does Not Violate Host Nation or International Law

Comment: One respondent stated that the rule should direct the contracting officer to ensure that the statement of work does not require the contractor to violate host nation or international law. This would be consistent with many provisions in DoD Instruction 3020.41 that the DFARS rule omits.

DoD Response: The requiring activity and the combatant commander have primary responsibility for the statement of work, and they must follow the requirements of DoD Instruction 3020.41. Therefore, it is unnecessary to repeat this requirement in the DFARS.

12. Preliminary Personnel Requirements (252.225–7040(e))

a. Immunizations

Comment: One respondent recommended that contractors be required to comply with immunization requirements to the ''best of their knowledge'' rather than requiring that they be aware of all such requirements, since they may not have ready access to all of the vaccines, documents, and medical and physical requirements that may be applicable to a specific deployment.

DoD Response: Contractors should be aware of all immunization requirements, since the Government is required to provide specific information in the contract regarding those requirements.

b. Foreign Visas

Comment: One respondent stated that contractors should not have to obtain foreign government approval through entrance or exit visas before implementing a contract.

DoD Response: DoD does not have the authority to waive the visa requirements of foreign governments. If a contractor is experiencing problems obtaining any necessary visas, it should advise the contracting officer so that the U.S. Government can assist if possible.

c. Isolated Personnel Training

Comment: One respondent requested explanation of the phrase ''isolated personnel training.''

DoD Response: ''Isolated personnel training'' refers to training for military or civilian personnel who may be separated from their unit or organization in an environment requiring them to survive, evade, or escape while awaiting rescue or recovery. For additional clarity, paragraph (e)(1)(vi) of the DFARS clause has been amended to add a reference to DoD Instruction 1300.23, Isolated Personnel Training for DoD Civilian and Contractors.

13. Personnel Data List (252.225–7040(g))

Comment: One respondent questioned whether the Privacy Act will apply to the implementation of a personnel database.

DoD Response: The Privacy Act (5 U.S.C. 552a) applies to any system of records established by the Government. The final rule designates the Synchronized Predeployment and Operational Tracker (SPOT) as the applicable system for maintaining data on deployed personnel. The **Federal Register** notice for the SPOT system, as required by the Privacy Act, was published at 70 FR 56646 on September 28, 2005.

14. Changes (252.225–7040(p))

a. Expansion of Changes Clause

Comment: One respondent stated that paragraph (p) of the DFARS clause represented an unnecessary sweeping expansion of the standard FAR ''Changes'' clause; and that the standard clause is limited for important reasons, one of which is to ensure that Government contracts remain within clearly defined scopes. Another respondent stated that inclusion of change in place of performance in paragraph (p) could be interpreted to require a contractor to move from Iraq to Kuwait or from East Timor to Lebanon. Although the respondent strongly supported the premise that changes are subject to the Changes clause and, therefore, subject to equitable adjustment when appropriate, the respondent also recommended that an equitable adjustment be explicitly required.

DoD Response: DoD does not consider paragraph (p) of the DFARS clause to be a sweeping change, since it is patterned after the standard Changes clause for construction contracts, which includes changes in site performance. Because this DFARS clause is not limited to construction contracts, the more generic term ''place of performance'' was substituted for ''site.'' The Changes clause requires that changes be within the scope of the contract and that equitable adjustment be provided when appropriate. Since paragraph (p) of the DFARS clause states that any change order will be subject to the Changes clause, it is not necessary to repeat the principles of the Changes clause in the DFARS clause.

b. Interim Rule Preamble

Comment: One respondent stated that the description of the changes to paragraph (p) of the DFARS clause, in the preamble to the interim rule published at 71 FR 34826 on June 16, 2006, was not accurate, because it only addressed place of performance, when the changes also included Government-furnished facilities, equipment, material, and services.

DoD Response: The preamble accurately described the changes made by the interim rule published on June 16, 2006. The references to Government-furnished facilities, equipment, material, and services were already in the clause prior to the interim rule.

15. Subcontract Flowdown (252.225–7040(q))

a. Obligation and Role of the Parties

Comment: Two respondents recommended that the Government more clearly state what parts of the clause are to flowed down and whether, for each provision, the contractor is to act in the Government's stead.

DoD Response: The language in paragraph (q) of the DFARS clause is consistent with the language normally included in FAR/DFARS clauses requiring flowdown of requirements to subcontractors. The specific language ''shall incorporate the substance of this clause'' is intended to allow latitude in correctly stating the relationship of the parties. The Government does not have privity of contract with subcontractors.

b. Flowdown of Support

Comment: One respondent, while not objecting to the policy for subcontract flowdown, questions the ability of the prime contractor to flow down provisions to subcontractors that have the effect of committing the Government to undertake affirmative support of each subcontractor (including third country national firms) retained to provide support.

DoD Response: The provision for flowdown of the clause to all subcontracts where subcontractor personnel are authorized to accompany U.S. Armed Forces outside the United States reflects the intent that resuscitative care, stabilization, hospitalization at level III military treatment facilities, and assistance with patient movement in certain emergencies is authorized for such subcontractor personnel. The Government has no privity of contract with subcontractors. Therefore, all parts of the clause should be flowed down to subcontractors to ensure that subcontractors supporting deployed forces receive appropriate coverage. With regard to other types of support, the contract will specify what support will be provided and to whom.

c. Flowdown to Private Security Contractors

Comment: One respondent expressed concern that flowing down the clause to private security contractors means that a prime contractor can authorize a subcontractor to use deadly force.

DoD Response: Although the prime contractor flows down clause requirements, use of deadly force is always subject to the authority of the combatant commander, who authorizes the possession of weapons and the rules for their use.

16. Defense Base Act

Comment: One respondent stated that ''self-defense contracts'' and private security contracts continue, as a matter of law, to include compliance with the Defense Base Act; and that, with the interim rule's expansion of the functions to be performed by contractor personnel, it becomes unclear that coverage under the Defense Base Act will be available to contractors.

DoD Response: The DFARS rule does not expand functions to be performed by contractor personnel. In addition, the courts have determined that the Defense Base Act applies to any overseas contract that has a nexus to either a national defense activity or a facility construction or improvement project. DoD's private security contracts fall within Defense Base Act coverage, as they are services to be performed outside the United States and relate to national defense activities. DoD

includes the clause at FAR 52.228–3, Workers' Compensation Insurance (Defense Base Act), in all service contracts to be performed entirely or in part outside the United States and in supply contracts that require the performance of employee services overseas. Defense Base Act coverage exists as long as contract performance falls within the scope of the statutory requirements. This DFARS rule does not change or preclude Defense Base Act coverage. If there is concern about the unavailability of Defense Base Act coverage because of the high cost of insurance or unwillingness of insurance providers when high risk is involved, activities such as the Army Corps of Engineers have negotiated arrangements with insurance companies to make insurance available to contractors. Also, the Government will reimburse insurance companies for expenses incurred relating to war hazards, the biggest risk.

Comment: One respondent expressed concern that, by accepting all risks of performance, contractors would not be able to obtain workers compensation insurance or reimbursement under the Defense Base Act.

DoD Response: The statement regarding risk at 252.225–7040(b)(2) was intended to reinforce the general rule that the contractor is responsible for fulfilling its contractual obligations, even in dangerous and austere conditions. It was not intended to conflict with any other provisions of the contract. For clarity, the introductory phrase, ''Except as provided elsewhere in the contract,'' has been added to the statement as requested by the respondent.

17. Basis and Need for DFARS Rule

a. DoD Instruction 3020.41, Contractor Personnel Authorized To Accompany the U.S. Armed Forces

Comment: One respondent considered that the interim DFARS rule was written in response to DoD Instruction 3020.41, but that the legal and policy predicate of the instruction is unclear. The instruction follows by only 5 months the predecessor DFARS rule. In turn, the earlier changes had themselves been predicated on DoD Instruction 3020.37, Continuation of Essential DoD Contractor Services During Crises.

DoD Response: The predecessor DFARS rule was published at 70 FR 23790 on May 5, 2005, and was not predicated on DoD Instruction 3020.37. That rule was developed by DoD specialists familiar with the problems occurring with contracts requiring contractor personnel to accompany U.S. Armed Forces deployed overseas. When the DFARS rule was published on May 5, 2005, DoD Instruction 3020.41 was still in draft form. The drafters of the DFARS rule worked closely with the drafters of DoD Instruction 3020.41 to achieve maximum consistency. When DoD Instruction 3020.41 was published on October 3, 2005, it contained changes that had not been anticipated when the DFARS rule was published. Therefore, DoD issued an interim DFARS rule on June 16, 2006, to incorporate the additional changes included in DoD Instruction 3020.41.

b. DoD Directive 2311.01E, DoD Law of War Program

Comment: One respondent stated that the DFARS rule is not consistent with DoD Directive 2311.01E, particularly sections 5.7.2 and 5.7.4.

DoD Response: DoD has reviewed these sections of the DoD Instruction and has found no inconsistencies. Section 5.7.2 requires heads of DoD components to institute and implement effective programs to prevent violations of the law of war. Section 5.7.4 requires that contract work statements for contractors comply with DoD Directive 2311.01E and DoD Instruction 3020.41 and require contractors to institute and implement effective programs to prevent violations of the law of war by their employees and subcontractors, including law of war training. DoD is presently preparing training for contractors law of war and is drafting DFARS changes to incorporate contractor training requirements (73 FR 1853, January 10, 2008).

c. Need for Separate DFARS Rule With Unique Requirements

Comment: One respondent stated that there should be a single coherent regulation generated that does not devolve combat activities on civilian contractors. In addition, the respondent stated that the fact that the DFARS changes have been made effective in advance of the proposed FAR changes suggest that the deviation requirements of FAR Subpart 1.4 may have been violated. Another respondent stated that there are inconsistencies between the requirement applicable to contractors accompanying the U.S. Armed Forces and those for all other contractors.

DoD Response: Neither the FAR nor the DFARS rule devolves combat activities on civilian contractors. Both rules are needed because of essential differences between contractors that are authorized to accompany the U.S. Armed Forces deployed outside the United States and all other contractors that are performing in a designated operational area or supporting a diplomatic or consular mission, whether under contract with DoD or a civilian agency. In addition, the requirements of FAR Subpart 1.4 have not been violated. In accordance with FAR 1.401(f), deviation requirements do not apply to policies or procedures that have been incorporated into agency acquisition regulations in accordance with 1.301(a).

d. Need for Interim DFARS Rule

Comment: Several respondents questioned the need for an interim rule, providing no opportunity for public comment prior to putting these changes into effect. One respondent added that, to the extent that any of the protocols specified in the interim rule have become essential, there is considerable evidence that those protocols have been in use for two or more years.

DoD Response: DoD considered it imperative to amend the DFARS rule to correct the inconsistencies with DoD Instruction 3020.41. Also, the fact that personnel are finding it necessary to take action without regulatory coverage provides more, not less, reason to issue the regulations necessary to provide structure and boundaries for such activities.

18. Information Collection Requirements

Comment: One respondent stated that the rule would impose substantial information collection requirements on the contracting communities, suggesting that transmogrification of battlefield contractors into combatants portends huge increases in their information collection and management responsibilities that are anything but usual and customary and are well outside the normal course of business.

DoD Response: DoD does not agree that the rule provides for transmogrification of battlefield contractors into combatants or requires huge increases in their information collection and management responsibilities. Although the rule requires contractors to establish and maintain a current list of contractor personnel in the area of performance with a designated Government official, such information should be routinely maintained by the contractor as part of the contractor's personnel data base.

19. Additional Changes

The final rule also includes the following changes:

○ Addition of Subpart 225.3 to supplement the final FAR rule published at 73 FR 10943 on February 28, 2008. The DFARS subpart: (1) Clarifies the meaning of the term

''performance in a designated operational area''; (2) specifies that, for DoD, FAR 25.301 also applies to personal services contracts, since DoD does not have the same authorities as the civilian agencies with regard to personal services contractors; (3) provides that the clause at FAR 52.225–19 will not be used in solicitations and contracts when all contractor personnel performing outside the United States will be covered by the clause at 252.225–7040; and (4) specifies the automated system for use in maintaining DoD contractor personnel data under the clause at FAR 52.225–19.

○ At 225.7402–4(a), clarification that the contract clause applies to solicitations and contracts that ''authorize'' contractor personnel to accompany U.S. Armed Forces deployed outside the United States. This is consistent with the terminology used in 225.7402–1, Scope.

○ Revision of 252.225–7040(e)(2)(iv) to reflect the provisions of Section 552 of the National Defense Authorization Act for Fiscal Year 2007 (Pub. L. 109–364), which amended 10 U.S.C. 802(a)(10) to make the Uniform Code of Military Justice applicable to persons accompanying the U.S. Armed Forces in a contingency operation.

○ Amendment of 252.225–7040(h)(1) to clarify that the contracting officer may direct the contractor to remove and replace contractor personnel who fail to comply with or violate applicable contract requirements.

This rule was not subject to Office of Management and Budget review under Executive Order 12866, dated September 30, 1993.

B. Regulatory Flexibility Act

DoD has prepared a final regulatory flexibility analysis consistent with 5 U.S.C. 604. A copy of the analysis may be obtained from the point of contact specified herein. The analysis is summarized as follows:

This rule amends the DFARS to implement DoD Instruction 3020.41, Contractor Personnel Authorized to Accompany the U.S. Armed Forces. The objective is to provide consistent policy and a standard clause applicable to DoD contracts that authorize contractor personnel to accompany U.S. Armed Forced deployed outside the United States. Application of the rule is limited to entities with DoD contracts that authorize contractor personnel to accompany U.S. Armed forces deployed outside the United States in contingency operations, humanitarian or peacekeeping operations, or other military operations or military exercises when designated by the combatant commander. The rule requires contractors to maintain data on its personnel that are authorized to accompany U.S. Armed Forces deployed outside the United States, and designates the Synchronized Predeployment and Operational Tracker (SPOT) web-based system for entering of the data. No special skills are required for use of the SPOT system, and the information that must be entered into the system is of the type that a contractor would normally maintain with regard to its personnel.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply, because the rule does not impose any 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 212, 225, and 252

Government procurement.

Michele P. Peterson,

Editor, Defense Acquisition Regulations System.

■ Accordingly, the interim rule amending 48 CFR parts 212, 225, and 252, which was published at 71 FR 34826 on June 16, 2006, is adopted as a final rule with the following changes:

■ 1. The authority citation for 48 CFR parts 212, 225, and 252 continues to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 225—FOREIGN ACQUISITION

■ 2. Subpart 225.3 is added to read as follows:

Subpart 225.3—Contracts Performed Outside the United States

Sec.

225.301 Contractor personnel in a designated operational area or supporting a diplomatic or consular mission outside the United States.
225.301–1 Scope.
225.301–4 Contract clause.

Subpart 225.3—Contracts Performed Outside the United States

225.301 Contractor personnel in a designated operational area or supporting a diplomatic or consular mission outside the United States.

225.301–1 Scope.

(a) *Performance in a designated operational area*, as used in this section, means performance of a service or construction, as required by the contract. For supply contracts, the term includes services associated with the acquisition of supplies (e.g., installation or maintenance), but does not include production of the supplies or associated overhead functions.

(c) For DoD, this section also applies to all personal services contracts.

225.301–4 Contract clause.

(1) Use the clause at FAR 52.225–19, Contractor Personnel in a Designated Operational Area or Supporting a Diplomatic or Consular Mission Outside the United States, in accordance with the prescription at FAR 25.301–4, except that—

(i) The clause shall also be used in personal services contracts with individuals; and

(ii) The clause shall not be used when all contractor personnel performing outside the United States will be covered by the clause at 252.225–7040.

(2) When using the clause at FAR 52.225–19, the contracting officer shall inform the contractor that the Synchronized Predeployment and Operational Tracker (SPOT) is the appropriate automated system to use for the list of contractor personnel required by paragraph (g) of the clause. Information on the SPOT system is available at *http://www.dod.mil/bta/products/spot.html*.

■ 3. Sections 225.7402 through 225.7402–4 are revised to read as follows:

225.7402 Contractor personnel authorized to accompany U.S. Armed Forces deployed outside the United States.

For additional information on contractor personnel authorized to accompany the U.S. Armed Forces, see PGI 225.7402.

225.7402–1 Scope.

(a) This section applies to contracts that involve contractor personnel authorized to accompany U.S. Armed Forces deployed outside the United States in—

(1) Contingency operations;

(2) Humanitarian or peacekeeping operations; or

(3) Other military operations or military exercises, when designated by the combatant commander.

(b) Any of the types of operations listed in paragraph (a) of this subsection may include stability operations such as—

(1) Establishment or maintenance of a safe and secure environment; or

(2) Provision of emergency infrastructure reconstruction, humanitarian relief, or essential governmental services (until feasible to transition to local government).

225.7402–2 Definition.

See PGI 225.7402–2 for additional information on designated operational areas.

225.7402–3 Government support.

(a) Government support that may be authorized or required for contractor personnel performing in a designated operational area may include, but is not limited to, the types of support listed in PGI 225.7402–3(a).

(b) The agency shall provide logistical or security support only when the appropriate agency official, in accordance with agency guidance, determines in coordination with the combatant commander that—

(1) Such Government support is available and is needed to ensure continuation of essential contractor services; and

(2) The contractor cannot obtain adequate support from other sources at a reasonable cost.

(c) The contracting officer shall specify in the solicitation and contract—

(1) Valid terms, approved by the combatant commander, that specify the responsible party, if a party other than the combatant commander is responsible for providing protection to the contractor personnel performing in the designated operational area as specified in 225.7402–1;

(2) If medical or dental care is authorized beyond the standard specified in paragraph (c)(2)(i) of the clause at 252.225–7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States; and

(3) Any other Government support to be provided, and whether this support will be provided on a reimbursable basis, citing the authority for the reimbursement.

(d) The contracting officer shall provide direction to the contractor, if the contractor is required to reimburse the Government for medical treatment or transportation of contractor personnel to a selected civilian facility in accordance with paragraph (c)(2)(ii) of the clause at 252.225–7040.

(e) Contractor personnel must have a letter of authorization (LOA) issued by a contracting officer in order to process through a deployment center or to travel to, from, or within the designated operational area. The LOA also will identify any additional authorizations, privileges, or Government support that the contractor personnel are entitled to under the contract. For a sample LOA, see PGI 225.7402–3(e).

225.7402–4 Contract clauses.

(a) Use the clause at 252.225–7040, Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States, instead of the clause at FAR 52.225–19, Contractor Personnel in a Designated Operational Area or Supporting a Diplomatic or Consular Mission Outside the United States, in solicitations and contracts that authorize contractor personnel to accompany U.S. Armed Forces deployed outside the United States in—

(1) Contingency operations;

(2) Humanitarian or peacekeeping operations; or

(3) Other military operations or military exercises, when designated by the combatant commander.

(b) For additional guidance on clauses to consider when using the clause at 252.225–7040, see PGI 225.7402–4(b).

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 4. Section 252.225–7040 is revised to read as follows:

252.225–7040 Contractor Personnel Authorized to Accompany U.S. Armed Forces Deployed Outside the United States.

As prescribed in 225.7402–4(a), use the following clause:

CONTRACTOR PERSONNEL AUTHORIZED TO ACCOMPANY U.S. ARMED FORCES DEPLOYED OUTSIDE THE UNITED STATES (MAR 2008)

(a) *Definitions.* As used in this clause—

Combatant Commander means the commander of a unified or specified combatant command established in accordance with 10 U.S.C. 161.

Designated operational area means a geographic area designated by the combatant commander or subordinate joint force commander for the conduct or support of specified military operations.

Subordinate joint force commander means a sub-unified commander or joint task force commander.

(b) *General.*

(1) This clause applies when Contractor personnel are authorized to accompany U.S. Armed Forces deployed outside the United States in—

(i) Contingency operations;

(ii) Humanitarian or peacekeeping operations; or

(iii) Other military operations or military exercises, when designated by the Combatant Commander.

(2) Contract performance in support of U.S. Armed Forces deployed outside the United States may require work in dangerous or austere conditions. Except as otherwise provided in the contract, the Contractor accepts the risks associated with required contract performance in such operations.

(3) Contractor personnel are civilians accompanying the U.S. Armed Forces.

(i) Except as provided in paragraph (b)(3)(ii) of this clause, Contractor personnel are only authorized to use deadly force in self-defense.

(ii) Contractor personnel performing security functions are also authorized to use deadly force when such force reasonably appears necessary to execute their security mission to protect assets/persons, consistent with the terms and conditions contained in their contract or with their job description and terms of employment.

(iii) Unless immune from host nation jurisdiction by virtue of an international agreement or international law, inappropriate use of force by contractor personnel authorized to accompany the U.S. Armed Forces can subject such personnel to United States or host nation prosecution and civil liability (see paragraphs (d) and (j)(3) of this clause).

(4) Service performed by Contractor personnel subject to this clause is not active duty or service under 38 U.S.C. 106 note.

(c) *Support.* (1)(i) The Combatant Commander will develop a security plan for protection of Contractor personnel in locations where there is not sufficient or legitimate civil authority, when the Combatant Commander decides it is in the interests of the Government to provide security because—

(A) The Contractor cannot obtain effective security services;

(B) Effective security services are unavailable at a reasonable cost; or

(C) Threat conditions necessitate security through military means.

(ii) The Contracting Officer shall include in the contract the level of protection to be provided to Contractor personnel.

(iii) In appropriate cases, the Combatant Commander may provide security through military means, commensurate with the level of security provided DoD civilians.

(2)(i) Generally, all Contractor personnel authorized to accompany the U.S. Armed Forces in the designated operational area are authorized to receive resuscitative care, stabilization, hospitalization at level III military treatment facilities, and assistance with patient movement in emergencies where loss of life, limb, or eyesight could occur. Hospitalization will be limited to stabilization and short-term medical treatment with an emphasis on return to duty or placement in the patient movement system.

(ii) When the Government provides medical treatment or transportation of Contractor personnel to a selected civilian facility, the Contractor shall ensure that the Government is reimbursed for any costs associated with such treatment or transportation.

(iii) Medical or dental care beyond this standard is not authorized unless specified elsewhere in this contract.

(3) Unless specified elsewhere in this contract, the Contractor is responsible for all other support required for its personnel engaged in the designated operational area under this contract.

(4) Contractor personnel must have a letter of authorization issued by the Contracting Officer in order to process through a deployment center or to travel to, from, or within the designated operational area. The

letter of authorization also will identify any additional authorizations, privileges, or Government support that Contractor personnel are entitled to under this contract.

(d) *Compliance with laws and regulations.* The Contractor shall comply with, and shall ensure that its personnel authorized to accompany U.S. Armed Forces deployed outside the United States as specified in paragraph (b)(1) of this clause are familiar with and comply with, all applicable—

(1) United States, host country, and third country national laws;

(2) Treaties and international agreements;

(3) United States regulations, directives, instructions, policies, and procedures; and

(4) Orders, directives, and instructions issued by the Combatant Commander, including those relating to force protection, security, health, safety, or relations and interaction with local nationals. However, only the Contracting Officer is authorized to modify the terms and conditions of the contract.

(e) *Pre-deployment requirements.* (1) The Contractor shall ensure that the following requirements are met prior to deploying personnel in support of U.S. Armed Forces. Specific requirements for each category may be specified in the statement of work or elsewhere in the contract.

(i) All required security and background checks are complete and acceptable.

(ii) All deploying personnel meet the minimum medical screening requirements and have received all required immunizations as specified in the contract. The Government will provide, at no cost to the Contractor, any theater-specific immunizations and/or medications not available to the general public.

(iii) Deploying personnel have all necessary passports, visas, and other documents required to enter and exit a designated operational area and have a Geneva Conventions identification card, or other appropriate DoD identity credential, from the deployment center. Any Common Access Card issued to deploying personnel shall contain the access permissions allowed by the letter of authorization issued in accordance with paragraph (c)(4) of this clause.

(iv) Special area, country, and theater clearance is obtained for personnel. Clearance requirements are in DoD Directive 4500.54, Official Temporary Duty Abroad, and DoD 4500.54–G, DoD Foreign Clearance Guide. Contractor personnel are considered non-DoD personnel traveling under DoD sponsorship.

(v) All personnel have received personal security training. At a minimum, the training shall—

(A) Cover safety and security issues facing employees overseas;

(B) Identify safety and security contingency planning activities; and

(C) Identify ways to utilize safety and security personnel and other resources appropriately.

(vi) All personnel have received isolated personnel training, if specified in the contract, in accordance with DoD Instruction 1300.23, Isolated Personnel Training for DoD Civilian and Contractors.

(2) The Contractor shall notify all personnel who are not a host country national, or who are not ordinarily resident in the host country, that—

(i) Such employees, and dependents residing with such employees, who engage in conduct outside the United States that would constitute an offense punishable by imprisonment for more than one year if the conduct had been engaged in within the special maritime and territorial jurisdiction of the United States, may potentially be subject to the criminal jurisdiction of the United States in accordance with the Military Extraterritorial Jurisdiction Act of 2000 (18 U.S.C. 3621, *et seq.*);

(ii) Pursuant to the War Crimes Act (18 U.S.C. 2441), Federal criminal jurisdiction also extends to conduct that is determined to constitute a war crime when committed by a civilian national of the United States;

(iii) Other laws may provide for prosecution of U.S. nationals who commit offenses on the premises of U.S. diplomatic, consular, military or other U.S. Government missions outside the United States (18 U.S.C. 7(9)); and

(iv) In time of declared war or a contingency operation, Contractor personnel authorized to accompany U.S. Armed Forces in the field are subject to the jurisdiction of the Uniform Code of Military Justice under 10 U.S.C. 802(a)(10).

(f) *Processing and departure points.* Deployed Contractor personnel shall—

(1) Process through the deployment center designated in the contract, or as otherwise directed by the Contracting Officer, prior to deploying. The deployment center will conduct deployment processing to ensure visibility and accountability of Contractor personnel and to ensure that all deployment requirements are met, including the requirements specified in paragraph (e)(1) of this clause;

(2) Use the point of departure and transportation mode directed by the Contracting Officer; and

(3) Process through a Joint Reception Center (JRC) upon arrival at the deployed location. The JRC will validate personnel accountability, ensure that specific designated operational area entrance requirements are met, and brief Contractor personnel on theater-specific policies and procedures.

(g) *Personnel data.* (1) The Contractor shall enter before deployment and maintain data for all Contractor personnel that are authorized to accompany U.S. Armed Forces deployed outside the United States as specified in paragraph (b)(1) of this clause. The Contractor shall use the Synchronized Predeployment and Operational Tracker (SPOT) web-based system, at *http://www.dod.mil/bta/products/spot.html*, to enter and maintain the data.

(2) The Contractor shall ensure that all employees in the database have a current DD Form 93, Record of Emergency Data Card, on file with both the Contractor and the designated Government official. The Contracting Officer will inform the Contractor of the Government official designated to receive this data card.

(h) *Contractor personnel.* (1) The Contracting Officer may direct the Contractor, at its own expense, to remove and replace any Contractor personnel who jeopardize or interfere with mission accomplishment or who fail to comply with or violate applicable requirements of this contract. Such action may be taken at the Government's discretion without prejudice to its rights under any other provision of this contract, including the Termination for Default clause.

(2) The Contractor shall have a plan on file showing how the Contractor would replace employees who are unavailable for deployment or who need to be replaced during deployment. The Contractor shall keep this plan current and shall provide a copy to the Contracting Officer upon request. The plan shall—

(i) Identify all personnel who are subject to military mobilization;

(ii) Detail how the position would be filled if the individual were mobilized; and

(iii) Identify all personnel who occupy a position that the Contracting Officer has designated as mission essential.

(i) *Military clothing and protective equipment.* (1) Contractor personnel are prohibited from wearing military clothing unless specifically authorized in writing by the Combatant Commander. If authorized to wear military clothing, Contractor personnel must—

(i) Wear distinctive patches, arm bands, nametags, or headgear, in order to be distinguishable from military personnel, consistent with force protection measures; and

(ii) Carry the written authorization with them at all times.

(2) Contractor personnel may wear military-unique organizational clothing and individual equipment (OCIE) required for safety and security, such as ballistic, nuclear, biological, or chemical protective equipment.

(3) The deployment center, or the Combatant Commander, shall issue OCIE and shall provide training, if necessary, to ensure the safety and security of Contractor personnel.

(4) The Contractor shall ensure that all issued OCIE is returned to the point of issue, unless otherwise directed by the Contracting Officer.

(j) *Weapons.* (1) If the Contractor requests that its personnel performing in the designated operational area be authorized to carry weapons, the request shall be made through the Contracting Officer to the Combatant Commander, in accordance with DoD Instruction 3020.41, paragraph 6.3.4.1 or, if the contract is for security services, paragraph 6.3.5.3. The Combatant Commander will determine whether to authorize in-theater Contractor personnel to carry weapons and what weapons and ammunition will be allowed.

(2) If the Contracting Officer, subject to the approval of the Combatant Commander, authorizes the carrying of weapons—

(i) The Contracting Officer may authorize the Contractor to issue Contractor-owned weapons and ammunition to specified employees; or

(ii) The *[Contracting Officer to specify the appropriate individual, e.g., Contracting Officer's Representative, Regional Security*

Officer] may issue Government-furnished weapons and ammunition to the Contractor for issuance to specified Contractor employees.

(3) The Contractor shall ensure that its personnel who are authorized to carry weapons—

(i) Are adequately trained to carry and use them—

(A) Safely;

(B) With full understanding of, and adherence to, the rules of the use of force issued by the Combatant Commander; and

(C) In compliance with applicable agency policies, agreements, rules, regulations, and other applicable law;

(ii) Are not barred from possession of a firearm by 18 U.S.C. 922; and

(iii) Adhere to all guidance and orders issued by the Combatant Commander regarding possession, use, safety, and accountability of weapons and ammunition.

(4) Whether or not weapons are Government-furnished, all liability for the use of any weapon by Contractor personnel rests solely with the Contractor and the Contractor employee using such weapon.

(5) Upon redeployment or revocation by the Combatant Commander of the Contractor's authorization to issue firearms, the Contractor shall ensure that all Government-issued weapons and unexpended ammunition are returned as directed by the Contracting Officer.

(k) *Vehicle or equipment licenses.* Contractor personnel shall possess the required licenses to operate all vehicles or equipment necessary to perform the contract in the designated operational area.

(l) *Purchase of scarce goods and services.* If the Combatant Commander has established an organization for the designated operational area whose function is to determine that certain items are scarce goods or services, the Contractor shall coordinate with that organization local purchases of goods and services designated as scarce, in accordance with instructions provided by the Contracting Officer.

(m) *Evacuation.* (1) If the Combatant Commander orders a mandatory evacuation of some or all personnel, the Government will provide assistance, to the extent available, to United States and third country national Contractor personnel.

(2) In the event of a non-mandatory evacuation order, unless authorized in writing by the Contracting Officer, the Contractor shall maintain personnel on location sufficient to meet obligations under this contract.

(n) *Next of kin notification and personnel recovery.* (1) The Contractor shall be responsible for notification of the employee-designated next of kin in the event an employee dies, requires evacuation due to an injury, or is isolated, missing, detained, captured, or abducted.

(2) In the case of isolated, missing, detained, captured, or abducted Contractor personnel, the Government will assist in personnel recovery actions in accordance with DoD Directive 2310.2, Personnel Recovery.

(o) *Mortuary affairs.* Mortuary affairs for Contractor personnel who die while accompanying the U.S. Armed Forces will be handled in accordance with DoD Directive 1300.22, Mortuary Affairs Policy.

(p) *Changes.* In addition to the changes otherwise authorized by the Changes clause of this contract, the Contracting Officer may, at any time, by written order identified as a change order, make changes in the place of performance or Government-furnished facilities, equipment, material, services, or site. Any change order issued in accordance with this paragraph (p) shall be subject to the provisions of the Changes clause of this contract.

(q) *Subcontracts.* The Contractor shall incorporate the substance of this clause, including this paragraph (q), in all subcontracts when subcontractor personnel are authorized to accompany U.S. Armed Forces deployed outside the United States in—

(1) Contingency operations;

(2) Humanitarian or peacekeeping operations; or

(3) Other military operations or military exercises, when designated by the Combatant Commander.

(End of clause).

[FR Doc. E8–6582 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 071106671–8010–02]

RIN 0648–XG73

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in Statistical Area 620 in the Gulf of Alaska

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for pollock in Statistical Area 620 in the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the B season allowance of the 2008 total allowable catch (TAC) of pollock for Statistical Area 620 in the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 26, 2008, through 1200 hrs, A.l.t., August 25, 2008.

FOR FURTHER INFORMATION CONTACT: Jennifer Hogan, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (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 B season allowance of the 2008 TAC of pollock in Statistical Area 620 of the GOA is 7,576 metric tons (mt) as established by the 2008 and 2009 harvest specifications for groundfish of the GOA (73 FR 10562, February 27, 2008).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the A season allowance of the 2008 TAC of pollock in Statistical Area 620 of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 7,566 mt, and is setting aside the remaining 10 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for pollock in Statistical Area 620 of the GOA.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

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) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of pollock in Statistical Area 620 of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of March 25, 2008.

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.

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

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

Dated: March 25, 2008.

Alan D. Risenhoover

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

[FR Doc. 08–1082 Filed 3–26–08; 11:15 am]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register
Vol. 73, No. 62
Monday, March 31, 2008

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 HOMELAND SECURITY

U.S. Citizenship and Immigration Services

8 CFR Parts 214, 215 and 274a

[CIS No. 2428–07; Docket No. USCIS–2007–0055]

RIN 1615–AB65

Changes to Requirements Affecting H–2A Nonimmigrants: Extending the Public Comment Period

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Proposed rule: extending the public comment period.

SUMMARY: U.S. Citizenship and Immigration Services (USCIS) announces the extension of the public comment period for the proposed rule entitled ''Changes to Requirements Affecting H–2A Nonimmigrants.'' The proposed rule was published in the **Federal Register** on February 13, 2008. Written comments on the proposed rule were to be submitted to USCIS on or before March 31, 2008 (a 45-day comment period) in order to be assured of consideration. USCIS has decided to accept comments from the public through April 14, 2008.

DATES: The comment period for the proposed rule published at 73 FR 8230, February 13, 2008, is extended through April 14, 2008. Comments received by USCIS after this date will not be considered.

ADDRESSES: You may submit comments, identified by DHS Docket No. USCIS–2007–0055, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, Department of Homeland Security, 111 Massachusetts Avenue, NW., 3rd Floor, Washington, DC 20529. To ensure proper handling, please reference DHS Docket No. USCIS–2007–0055 on your correspondence. This mailing address may also be used for paper, disk, or CD–ROM submissions.
- *Hand Delivery/Courier:* Regulatory Management Division, U.S. Citizenship and Immigration Services, Department of Homeland Security, 111 Massachusetts Avenue, NW., 3rd Floor, Washington, DC 20529. Contact Telephone Number (202) 272–8377.

FOR FURTHER INFORMATION CONTACT: Hiroko Witherow, Service Center Operations, U.S. Citizenship and Immigration Services, Department of Homeland Security, 111 Massachusetts Avenue, NW., Suite 3000, Washington, DC 20529, telephone (202) 272–8410.

SUPPLEMENTARY INFORMATION: On February 13, 2008, the Department of Homeland Security (DHS) published a proposed rule in the **Federal Register** entitled ''Changes to Requirements Affecting H–2A Nonimmigrants'' at 73 FR 8230. This rule proposed amendments to DHS regulations affecting temporary and seasonal agricultural workers within the H–2A nonimmigrant classification and their U.S. employers. You may view a copy of the February 13, 2008, proposed rule at: *http://a257.g.akamaitech.net/7/257/2422/01jan20081800/edocket.access.gpo.gov/2008/pdf/E8-2532.pdf*

USCIS has decided to extend the comment period through April 14, 2008. Comments received by USCIS after April 14, 2008, will not be considered in drafting the final rule.

Dated: March 26, 2008.

Emilio T. Gonzalez,

Director, U.S. Citizenship and Immigration Services.

[FR Doc. E8–6605 Filed 3–28–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0367; Directorate Identifier 2007–CE–089–AD]

RIN 2120–AA64

Airworthiness Directives; Viking Air Limited Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

> Service experience indicates that as aircraft become older, they are more likely to exhibit indications of corrosion.

Additionally, the FAA has reviewed the service experience and finds this action to be necessary based upon that service experience. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by April 30, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Richard Beckwith, Aerospace Engineer, FAA, New York Aircraft Certification Office,1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228–7302; fax: (516) 568–2716.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0367; Directorate Identifier 2007–CE–089–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada, which is the aviation authority for Canada, has issued AD No. CF–94–12R1, dated April 13, 1999; and AD No. CF–99–11, dated May 28, 1999 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> Service experience indicates that as aircraft become older, they are more likely to exhibit indications of corrosion. Transport Canada, in conjunction with other airworthiness authorities, has committed itself to ensuring that additional maintenance programs for older aircraft are developed and implemented to minimize and control corrosive deterioration that could jeopardize airworthiness. Bombardier Inc., as manufacturer of the DHC–6 aircraft, has developed a Corrosion Prevention and Control Program which identifies specific areas that must be inspected to ensure the structural integrity of the DHC–6 fleet.

Additionally, the FAA has reviewed the service experience of the Viking Air Limited Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes and finds this action to be necessary based upon that service experience.

The MCAI requires that you do the corrosion tasks required by the corrosion prevention and control program. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Viking Air Limited has issued DHC–6 Twin Otter (Series 100/200/300) Corrosion Prevention and Control Manual PSM 1–6–5, Revision 3, dated January 15, 2007; Viking Temporary Revision, C57–10–18 (TR 2–2), dated December 19, 2007; Viking Temporary Revision, Part 3, Supplement 1 (TR 3–2), dated December 19, 2007; Viking Temporary Revision, Part 3, Supplement 1 (TR 3–3), dated December 19, 2007; and Viking Temporary Revision, Part 3, Supplement 1, (TR 3–4), dated December 19, 2007. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above together with the fact that the FAA has reviewed the service experience and finds this action to be necessary based upon that service experience. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

We estimate that this proposed AD would affect about 162 products of U.S. registry. We also estimate that it would take about 40 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $518,400, or $3,200 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Viking Air Limited: Docket No. FAA–2008–0367; Directorate Identifier 2007–CE–089–AD.

Comments Due Date

(a) We must receive comments by April 30, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes, serial numbers (SNs) 001 through 844, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 51: Structures.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

Service experience indicates that as aircraft become older, they are more likely to exhibit indications of corrosion. Transport Canada, in conjunction with other airworthiness authorities, has committed itself to ensuring that additional maintenance programs for older aircraft are developed and implemented to minimize and control corrosive deterioration that could jeopardize airworthiness. Bombardier Inc., as manufacturer of the DHC–6 aircraft, has developed a Corrosion Prevention and Control Program which identifies specific areas that must be inspected to ensure the structural integrity of the DHC–6 fleet.

Additionally, the FAA has reviewed the service experience of the Viking Air Limited Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes and finds this action to be necessary based upon that service experience. The MCAI requires that you do the corrosion tasks (CTs) required by the corrosion prevention and control program.

Actions and Compliance

(f) Unless already done, do the following actions:

(1) Within the next 90 days after the effective date of this AD, develop a schedule for doing the initial and repeat CTs required in paragraph (f)(2) and (f)(3) of this AD.

(2) Initially, do all of the seven basic CTs defined at paragraph 3.0 of Part 3 of DHC–6 Twin Otter (Series 100/200/300) Corrosion Prevention and Control Manual PSM 1–6–5, Revision 3, dated January 15, 2007; and the temporary revisions listed in Table 1, *Viking Temporary Revisions,* of this AD:

TABLE 1.—VIKING TEMPORARY REVISIONS

Temporary revision no. and date
(i) Viking Temporary Revision, C57–10–18 (TR 2–2), dated December 19, 2007.
(ii) Viking Temporary Revision, Part 3, Supplement 1 (TR 3–2), dated December 19, 2007.
(iii) Viking Temporary Revision, Part 3, Supplement 1 (TR 3–3), dated December 19, 2007.
(iv) Viking Temporary Revision, Part 3, Supplement 1, (TR 3–4), dated December 19, 2007.

Determine corrosion level following the definitions contained in the introduction section of DHC–6 Twin Otter (Series 100/200/300) Corrosion Prevention and Control Manual PSM 1–6–5, Revision 3, dated January 15, 2007. The initial accomplishment deadlines are specified in Table 2, *Initial Accomplishment Deadline,* of this AD:

TABLE 2.—INITIAL ACCOMPLISHMENT DEADLINE

Applicable airplane serial numbers	Initial accomplishment deadline for all airplanes in applicable S/N range
(i) 001 through 199	15 months after the effective date of this AD.
(ii) 200 through 439	27 months after the effective date of this AD.
(iii) 440 through 659	51 months after the effective date of this AD.
(iv) 660 through 844	63 months after the effective date of this AD.

(3) After the initial completion of each CT, repeat each CT at the repeat interval (R) specified in the manual. Determine corrosion level following the definitions contained in the introduction section of DHC–6 Twin Otter (Series 100/200/300) Corrosion Prevention and Control Manual PSM 1–6–5, Revision 3, dated January 15, 2007.

(4) If any corrosion is found during any action required by this AD, before further flight, address corrosion following paragraph 4.0 of Part 3 of DHC–6 Twin Otter (Series 100/200/300) Corrosion Prevention and Control Manual PSM 1–6–5, Revision 3, dated January 15, 2007. All repairs are to be done following a method approved by the Manager, New York Aircraft Certification Office or Transport Canada Civil Aviation (or its delegated agent).

(5) Within 21 days after the finding of Level 3 corrosion, submit a plan to the FAA to identify a schedule for accomplishing the applicable CTs on the remainder of the airplanes in the operator's fleet that are subject to this AD or data substantiating that the Level 3 corrosion that was found is an isolated case. The FAA may impose a schedule other than proposed in the plan upon finding that a change to the schedule is needed to ensure that any other Level 3 corrosion is detected in a timely manner. For the purposes of this paragraph, the FAA is defined as the cognizant principal maintenance inspector (PMI) for operators that are assigned a PMI (e.g., part 121, 125, and 135 operators) and the cognizant flight standards district office for other operators (e.g., part 91 operators).

(6) If any Level 3 corrosion is found while doing any action required by this AD, within 21 days after the finding of Level 3 corrosion, report the finding on the form in Figure 1 of this AD and send it to Viking Air Limited, VP Engineering, 9574 Hampden Road, Sidney, British Columbia, Canada V8L 5V5.

(7) Incorporation of the initial and repeat CTs into your FAA-approved maintenance program constitutes terminating action for this AD. If this AD is terminated in this way, then the maintenance program must be in accordance with this AD.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Richard Beckwith, Aerospace Engineer, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228–7302; fax: (516) 568–2716. Before using any approved AMOC on any airplane to which the AMOC applies, notify your

appropriate PMI in the FAA Flight Standards District Office (FSDO), or lacking a PMI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

DOCKET NO. FAA–2008–0367
INSPECTION REPORT
[Report only if you find level 3 corrosion]

1. Operator:	2. Telephone:
3. Airplane Model Number:	4. Airplane Serial Number:
5. Airplane Tail Number:	6. Date of Inspection:
7. Corrosion Task:	
8. Description & Specific Location of Findings:	
9. Additional Comments of Owner/Operator:	
Send to: Viking Air Limited VP Engineering 9574 Hampden Road Sidney, British Columbia, Canada V8L 5V5 Telephone: 250.656.7227 Fax: 250.656.9702	

Figure 1.

Related Information

(h) Refer to MCAI Transport Canada AD No. CF–94–12R1, dated April 13, 1999; and Transport Canada AD No. CF–99–11, dated May 28, 1999; and DHC–6 Twin Otter (Series 100/200/300) Corrosion Prevention and Control Manual PSM 1–6–5, Revision 3, dated January 15, 2007; and the temporary revisions listed in Table 1—*Viking Temporary Revisions*, of this AD, for related information.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–6468 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0368; Directorate Identifier 2008–CE–007–AD]

RIN 2120–AA64

Airworthiness Directives; Viking Air Limited Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

There have been reports of inter-rivet cracking on several wing front spar adapter assemblies (P/N C6WM1027–1) on the horizontal and vertical flanges. It was determined that the cracking was caused by stress corrosion in the short transverse grain initiated by local riveting induced stresses.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by April 30, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.

- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov*; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Pong Lee, Aerospace Engineer, FAA, New York Aircraft Certification Office, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228–7324; fax: (516) 794–5531.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0368; Directorate Identifier 2008–CE–007–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

Transport Canada, which is the aviation authority for Canada, has issued AD No. CF–2007–31, dated December 17, 2007 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

There have been reports of inter-rivet cracking on several wing front spar adapter assemblies (P/N C6WM1027–1) on the horizontal and vertical flanges. It was determined that the cracking was caused by stress corrosion in the short transverse grain initiated by local riveting induced stresses. This directive mandates modification and inspection of the wing front spar adapter fitting and replacement of cracked fittings.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Viking Air Limited has issued the following DHC–6 Twin Otter Service Bulletins:

- No. V6/540, dated October 1, 2007;
- No. V6/541, dated October 1, 2007; and
- No. V6/542, dated October 1, 2007.

R.W. Martin, Inc. has issued Service Bulletin No. 00160/2, Revision A, dated November 15, 2007.

The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 157 products of U.S. registry. We also estimate that it would take about 18 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $226,080 or $1,440 per product.

In addition, we estimate that any necessary follow-on actions would take about 200 work-hours and require parts costing $3,696 for a cost of $19,696 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with

this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Viking Air Limited: Docket No. FAA–2008–0368; Directorate Identifier 2008–CE–007–AD.

Comments Due Date

(a) We must receive comments by April 30, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Models DHC–6–1, DHC–6–100, DHC–6–200, and DHC–6–300 airplanes, all serial numbers, that are:

(1) Equipped with wing boxes, part numbers (P/Ns) C6W1002–1, C6W1002–3, WR6–1002–59, or WR6–1002–61, that incorporate a P/N C6WM1027–1 front spar adapter assembly with 10 or more years of service; and

(2) Certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 57: Wings.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

There have been reports of inter-rivet cracking on several wing front spar adapter assemblies (P/N C6WM1027–1) on the horizontal and vertical flanges. It was determined that the cracking was caused by stress corrosion in the short transverse grain initiated by local riveting induced stresses. This directive mandates modification and inspection of the wing front spar adapter fitting and replacement of cracked fittings.

Actions and Compliance

(f) Unless already done, do the following actions:

(1) Within the next 180 days after the effective date of this AD, install inspection holes in the left-hand (LH) and right-hand (RH) lower wing skins following Viking DHC–6 Twin Otter Service Bulletin Number V6/541, dated October 1, 2007.

(2) Before further flight after installing the inspection holes required in paragraph (f)(1) of this AD, inspect the LH and RH front spar adapter assemblies for cracks. For wing box P/Ns C6W1002–1 and C6W1002–3, inspect following Viking DHC–6 Twin Otter Service Bulletin Number V6/540, dated October 1, 2007. For wing box P/Ns WR6–1002–59 and WR6–1002–61, inspect following R.W. Martin, Inc. Service Bulletin No. 00160/2, Revision A, dated November 15, 2007. Repetitively inspect all affected wing box P/Ns thereafter at intervals not to exceed 1,200 hours time-in-service or 12 months, whichever occurs first, until the replacement required in paragraph (f)(3) of this AD is done.

(3) Before further flight after doing any inspection required in paragraph (f)(2) of this AD where cracks are found, replace the cracked front spar adapter assembly with a front spar adapter assembly, P/N C6WM1027–3. Do the replacement following Viking DHC–6 Twin Otter Service Bulletin Number V6/542, dated October 1, 2007. This replacement terminates the repetitive inspections required in paragraph (f)(2) of this AD for the replaced front spar adapter assembly.

(4) As a terminating action for the repetitive inspections required in paragraph (f)(2) of this AD, at any time after the initial inspection required in paragraph (f)(2) of this AD, you may replace P/N C6WM1027–1 with P/N C6WM1027–3.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: (1) MCAI Transport Canada AD No. CF–2007–31, dated December 17, 2007, requires incorporating task C57–10–18 of the DHC–6 Corrosion Prevention and Control Manual (CPCM), PSM 1–6–5, within 90 days after the effective date of this AD.

(2) We are not incorporating task C57–10–18 of the DHC–6 CPCM, PSM 1–6–5, into this AD because we are currently examining Transport Canada AD No. CF–94–12R1, dated April 13, 1999; and AD No. CF–99–11, dated May 28, 1999. Transport Canada issued these ADs to incorporate a Corrosion Prevention and Control Program that identifies specific areas that must be inspected to ensure the structural integrity of the DHC–6 fleet.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Pong Lee, Aerospace Engineer, FAA, New York Aircraft Certification Office,1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone: (516) 228–7324; fax: (516) 794–5531. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI Transport Canada AD No. CF–2007–31, dated December 17, 2007; Viking DHC–6 Twin Otter Service Bulletins No. V6/540, dated October 1, 2007; No. V6/541, dated October 1, 2007; and No. V6/542, dated October 1, 2007; and R.W. Martin, Inc. Service Bulletin No. 00160/2, Revision A, dated November 15, 2007, for related information.

Issued in Kansas City, Missouri, on March 8, 2008.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–6469 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0365; Directorate Identifier 2007–NM–274–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Mystère-Falcon 900 and Falcon 900EX Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

This Airworthiness Directive (AD) is issued following the discovery of a potential chafing between the feeder bundle and the right side partition wall separating the cabin from the lavatory at frames 22/23. This chafing may damage the feeder bundle and cause a sustained smoke-generating short-circuit between the feeder and the partition

wall made of resistive composite material. Strong smoke and a difficult-to-localize short-circuit may result in a hazardous situation.

The unsafe condition is sustained smoke in the cabin, which may lead to reduced ability of the flightcrew to operate the airplane. The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by April 30, 2008.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- *Hand Delivery:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0365; Directorate Identifier 2007–NM–274–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2006–0270, dated September 4, 2006 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> This Airworthiness Directive (AD) is issued following the discovery of a potential chafing between the feeder bundle and the right side partition wall separating the cabin from the lavatory at frames 22/23. This chafing may damage the feeder bundle and cause a sustained smoke-generating short-circuit between the feeder and the partition wall made of resistive composite material. Strong smoke and a difficult-to-localize short-circuit may result in a hazardous situation.

The unsafe condition is sustained smoke in the cabin, which may lead to reduced ability of the flightcrew to operate the airplane. Corrective actions include inspecting for damage of the feeder cables, repairing any damaged feeder cable, installing a protective Teflon tube over the feeder cable bundle, and modifying the partition wall. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Dassault has issued the service information described in the following table.

DASSAULT SERVICE INFORMATION

Airplane model	Service Bulletin	Revision level	Dated
Falcon 900EX	F900EX–241	1	July 19, 2006.
Falcon 900EX	F900EX–251	1	July 19, 2006.
Mystère-Falcon 900	F900–358	1	July 19, 2006.
Mystère-Falcon 900	F900–359	1	July 19, 2006.

The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 38 products of U.S. registry. We also estimate that it would take about 3 work-hours per product to comply with the basic requirements of this proposed AD. The average labor

rate is $80 per work-hour. Required parts would cost about $34 per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $10,412, or $274 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Dassault Aviation: Docket No. FAA–2008–0365; Directorate Identifier 2007–NM–274–AD.

Comments Due Date

(a) We must receive comments by April 30, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to the Dassault airplanes described in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category.

(1) Model Mystère-Falcon 900 airplanes, serial numbers 188 through 202 inclusive, except those on which both Dassault Service Bulletins F900–358 and F900–359 have already been implemented, or Modification M3891 has already been implemented.

(2) Model Falcon 900EX airplanes, serial numbers 82 through 146 inclusive, except those on which both Dassault Service Bulletins F900EX–241 and F900EX–251 have already been implemented, or Modification M3891 has already been implemented.

Subject

(d) Air Transport Association (ATA) of America Code 24: Electrical Power.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

This Airworthiness Directive (AD) is issued following the discovery of a potential chafing between the feeder bundle and the right side partition wall separating the cabin from the lavatory at frames 22/23. This chafing may damage the feeder bundle and cause a sustained smoke-generating short-circuit between the feeder and the partition wall made of resistive composite material. Strong smoke and a difficult-to-localize short-circuit may result in a hazardous situation.

The unsafe condition is sustained smoke in the cabin, which may lead to reduced ability of the flightcrew to operate the airplane. Corrective actions include inspecting for damage of the feeder cables, repairing any damaged feeder cable, installing a protective Teflon tube over the feeder cable bundle, and modifying the partition wall.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) For Model Mystère-Falcon 900 airplanes: Do the actions specified in paragraphs (f)(1)(i) and (f)(1)(ii) of this AD.

(i) Within 330 flight hours or 7 months after the effective date of this AD, whichever occurs first, inspect for damage of the feeder cable bundle at the right side partition wall at frames 22/23, and, if no damage of any feeder cable is found, before further flight, install a protective Teflon tube over the feeder cable bundle; in accordance with the Accomplishment Instructions of Dassault Service Bulletin F900–358, Revision 1, dated July 19, 2006. If chafing or damage of any feeder cable is found, before further flight, repair the feeder cable in accordance with the Accomplishment Instructions of Dassault Service Bulletin F900–359, Revision 1, dated July 19, 2006; and install a protective Teflon tube over the feeder cable bundle in accordance with Dassault Service Bulletin F900–359, Revision 1, or Dassault Service Bulletin F900–358, Revision 1.

(ii) Within 3,750 flight cycles or 74 months after the effective date of this AD, whichever occurs first, modify the right side partition wall at frames 22/23; in accordance with the Accomplishment Instructions of Dassault Service Bulletin F900–359, Revision 1, dated July 19, 2006. Implementation of both Dassault Service Bulletin F900–358 and Dassault Service Bulletin F900–359, both Revision 1, both dated July 19, 2006, terminates the requirements of this AD for Model Mystère-Falcon 900 airplanes.

(2) For Model Falcon 900EX airplanes: Do the actions specified in paragraphs (f)(2)(i) and (f)(2)(ii) of this AD.

(i) Within 330 flight hours or 7 months after the effective date of this AD, whichever occurs first, inspect for damage of the feeder cable bundle at the right side partition wall at frames 22/23, and, if no such damage of any feeder cable is found, before further flight, install a protective Teflon tube over the feeder cable bundle; in accordance with the Accomplishment Instructions of Dassault Service Bulletin F900EX–241, Revision 1, dated July 19, 2006. If any damage of any feeder cable is found, before further flight, repair the feeder cable in accordance with the Accomplishment Instructions of Dassault Service Bulletin F900EX–251, Revision 1, dated July 19, 2006; and install a protective Teflon tube over the feeder cable bundle in accordance with Dassault Service Bulletin F900EX–251, Revision 1, or Dassault Service Bulletin F900EX–241, Revision 1.

(ii) Within 3,750 flight cycles or 74 months after the effective date of this AD, whichever occurs first, modify the right side partition wall at frames 22/23, in accordance with the Accomplishment Instructions of Dassault Service Bulletin F900EX–251, Revision 1, dated July 19, 2006. Implementation of both Dassault Service Bulletin F900EX–241 and Dassault Service Bulletin F900EX–251, both Revision 1, both dated July 19, 2006, terminates the requirements of this AD for Model Falcon 900EX airplanes.

Actions Accomplished According to Previous Issue of Service Bulletin

(g) Actions accomplished before the effective date of this AD, in accordance with the service information described in Table 1 of this AD, are considered acceptable for compliance with the corresponding actions specified in this AD.

TABLE 1.—PREVIOUS SERVICE INFORMATION

Airplane model	Dassault Service Bulletin	Dated
Falcon 900EX	F900EX–241	October 19, 2005.
Falcon 900EX	F900EX–251	October 19, 2005.
Mystère-Falcon 900	F900–358	October 19, 2005.
Mystère-Falcon 900	F900–359	October 19, 2005.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(h) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(i) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2006–0270, dated September 4, 2006, and the service bulletins described in Table 2 of this AD, for related information.

TABLE 2.—DASSAULT SERVICE INFORMATION

Service Bulletin	Revision level	Dated
F900EX–241	1	July 19, 2006.
F900EX–251	1	July 19, 2006.
F900–358	1	July 19, 2006.
F900–359	1	July 19, 2006.

Issued in Renton, Washington, on March 21, 2008.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–6522 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0364; Directorate Identifier 2006-NM–281–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Model Falcon 2000EX Airplanes and Model Falcon 900EX Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

During a flight test performed on an EASy aircraft, subsequently to an air data probe failure, the crew realized that the Flight path vectors and the Vertical speeds that were displayed on pilot's and co-pilot's PDU (primary display unit) were identically wrong.

A review of the EASy architecture reveals that * * * One single ADS unflagged air data error may lead to the computation and display on both pilot's and co-pilot's display units of unnoticed and misleading flight information.

At take-off or during go-around this situation might considerably reduce flight safety.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by April 30, 2008.

ADDRESSES: You may send comments by any of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Fax: (202) 493–2251.
- Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- Hand Delivery: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–40, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Operations office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the

ADDRESSES section. Include ''Docket No. FAA–2008–0364; Directorate Identifier 2006–NM–281–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA Airworthiness Directive 2006–0157, dated June 7, 2006 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> During a flight test performed on an EASy aircraft, subsequently to an air data probe failure, the crew realized that the Flight path vectors and the Vertical speeds that were displayed on pilot's and co-pilot's PDU (primary display unit) were identically wrong.
>
> A review of the EASy architecture reveals that the current wiring of Air Data System (ADS) and IRS (inertial reference system) units is not compliant with the certified safety objectives. All IRS primary inputs are wired to the same General Purpose (GP) Bus and thus basic requirements for ADS segregation are not met. One single ADS unflagged air data error may lead to the computation and display on both pilot's and co-pilot's display units of unnoticed and misleading flight information.
>
> At take-off or during go-around this situation might considerably reduce flight safety.
>
> This AD mandates a wiring modification of IRS [no.] 2 and a test of General Purpose bus IRS entry per application of SB-F2000EX–89 on Falcon 2000EX EASy and per application of SB-F900EX–274 on Falcon 900EX EASy.
>
> Furthermore in order to maintain ADS parameter segregation against possible failures, this AD also requires F2000EX EASy and F900EX EASy operators to comply with the modifications made to the respective Chapter 5.40 of the Aircraft Maintenance Manuals that contain an additional periodic functional test of the IRS GP Bus I/O (input/output).
>
> Dispatch conditions under MMEL (master minimum equipment list) in case of an IRS2 failure are modified after implementation of the wiring change.

The corrective actions involve checking the integrity of the GP bus and IRS2, and repairing them as applicable. You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

Dassault has issued Service Bulletins F2000EX–89, dated March 17, 2006, and F900EX–274, dated March 17, 2006. Dassault has also issued Section 34–209, dated March 2007, of the Dassault Falcon 900EX EASY/900DX Maintenance Manual; and section 34–209, dated May 2007, of the Dassault Falcon 2000EX EASy Maintenance Manual. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with the State of Design Authority, we have been notified of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all pertinent information and determined an unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 62 products of U.S. registry. We also estimate that it would take about 3 work-hours per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour. Required parts would cost a negligible amount per product. Where the service information lists required parts costs that are covered under warranty, we have assumed that there will be no charge for these costs. As we do not control warranty coverage for affected parties, some parties may incur costs higher than estimated here. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $14,880, or $240 per product.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator,

the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

Dassault Aviation: Docket No. FAA–2008–0364; Directorate Identifier 2006–NM–281–AD.

Comments Due Date

(a) We must receive comments by April 30, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Dassault Model Falcon 2000EX airplanes, serial number (S/N) 6, and S/N 28 and subsequent; and Model Falcon 900EX airplanes, S/N 97, S/N 120 and subsequent; certificated in any category.

Subject

(d) Air Transport Association (ATA) of America Code 34: Navigation.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

During a flight test performed on an EASy aircraft, subsequently to an air data probe failure, the crew realized that the Flight path vectors and the Vertical speeds that were displayed on pilot's and co-pilot's PDU (primary display unit) were identically wrong.

A review of the EASy architecture reveals that the current wiring of Air Data System (ADS) and IRS (inertial reference system) units is not compliant with the certified safety objectives. All IRS primary inputs are wired to the same General Purpose (GP) Bus and thus basic requirements for ADS segregation are not met. One single ADS unflagged air data error may lead to the computation and display on both pilot's and co-pilot's display units of unnoticed and misleading flight information.

At take-off or during go-around this situation might considerably reduce flight safety.

This AD mandates a wiring modification of IRS [no.] 2 and a test of General Purpose bus IRS entry per application of SB–F2000EX–89 on Falcon 2000EX EASy and per application of SB–F900EX–274 on Falcon 900EX EASy.

Furthermore in order to maintain ADS parameter segregation against possible failures, this AD also requires F2000EX EASy and F900EX EASy operators to comply with the modifications made to the respective Chapter 5.40 of the Aircraft Maintenance Manuals that contain an additional periodic functional test of the IRS GP Bus I/O (input/output).

Dispatch conditions under MMEL (master minimum equipment list) in case of an IRS2 failure are modified after implementation of the wiring change.

The corrective actions involve checking the integrity of the GP bus and IRS2, and repairing them as applicable.

Actions and Compliance

(f) Unless already done, do the following actions.

(1) For Model Falcon 2000EX airplanes without Dassault Modification M2758 and Model Falcon 900EX airplanes without Dassault Modification M5143 in the applicability range: Within 3 months after the effective date of this AD, do the IRS2 wiring modification and test the GP (general purpose) bus IRS entry. Do all actions in accordance with the Accomplishment Instructions of Dassault Service Bulletin F2000EX–89, dated March 17, 2006; or Dassault Service Bulletin F900EX–274, dated March 17, 2006; as applicable. Repeat the test at intervals not to exceed 5,000 flight hours. If the GP bus IRS entry fails any test, before further flight, do all applicable corrective actions in accordance with the procedures in Section 34–209, dated March 2007, of the Dassault Falcon 900EX EASY/900DX Maintenance Manual; or Section 34–209, dated May 2007, of the Dassault Falcon 2000EX EASy Maintenance Manual; as applicable.

(2) For Model Falcon 2000EX airplanes with Dassault Modification M2758 and Model Falcon 900EX airplanes with Dassault Modification M5143 in the applicability range: Within 5,000 flight hours after date of issuance of the original French standard airworthiness certificate or the date of issuance of the original French export certificate of airworthiness, or within 3 months after the effective date of this AD, whichever occurs later, do a test of the GP bus IRS entry in accordance with the Accomplishment Instructions of Dassault Service Bulletin F2000EX–89, dated March 17, 2006; or Dassault Service Bulletin F900EX–274, dated March 17, 2006; as applicable. Repeat the test at intervals not to exceed 5,000 flight hours. If the GP bus IRS entry fails any test, before further flight, do the corrective actions in accordance with the procedures in Section 34–209, dated March 2007, of the Dassault Falcon 900EX EASY/900DX Maintenance Manual; or Section 34–209, dated May 2007, of the Dassault Falcon 2000EX EASy Maintenance Manual; as applicable.

FAA AD Differences

Note: This AD differs from the MCAI and/or service information as follows:

(1) Where the MCAI specifies to do a test of the GP bus IRS entry in accordance with Chapter 5.40 of the applicable Dassault Maintenance Manual and does not specify a corrective action, we require those corrective actions to be done in accordance with Section 34–209, dated March 2007, of the Dassault Falcon 900EX EASY/900DX Maintenance Manual; or Section 34–209, dated May 2007, of the Dassault Falcon 2000EX EASy Maintenance Manual; as applicable.

(2) The MCAI specified to revise the applicable Dassault MMEL by incorporating Dassault Temporary Change 4, dated June 15, 2006, to the Dassault Falcon 2000EX EASy MMEL (for Model F2000EX EASy airplanes); and Dassault Temporary Change 3, dated June 15, 2006, to the Dassault Falcon 900EX EASy MMEL (for Model F900EX EASy airplanes); as applicable. However, the FAA-approved MMEL (which is required to be used by operators) has been revised to include the information specified in the Dassault temporary changes. Therefore, we have not included a requirement for this revision in this AD.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act, the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) Airworthiness Directive 2006–0157, dated June 7, 2006; Section 34–209, dated March 2007, of the Dassault Falcon 900EX EASY/900DX Maintenance Manual; Section 34–209, dated May 2007, of the Dassault Falcon 2000EX EASy Maintenance Manual; and Dassault Service Bulletins F2000EX–89 and F900EX–274, both dated March 17, 2006; for related information.

Issued in Renton, Washington, on March 21, 2008.

Dionne Palermo,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–6521 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2008–0369; Directorate Identifier 2008–CE–015–AD]

RIN 2120–AA64

Airworthiness Directives; British Aerospace Regional Aircraft Model HP. 137 Jetstream MK 1, Jetstream Series 200, 3100, and 3200 Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for the products listed above. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as:

A failure mode has been identified following the examination of parts from another aircraft type (Jetstream 4100 series) that can lead to the loss of a nose-wheel. The Jetstream (HP.137) Mk1, 200, 3100 and 200 series use a similar method for retaining the wheel assemblies on the landing gear axle and can therefore experience the same type of failure, i.e. a combination of excessive wear and/or adverse tolerances on the axle inner cone, outer cone or wheel hub splined sleeve cones resulting in the loss of the critical gap between the inner flange face of the wheel outer cone and the axle end face. If this gap is lost, it results in the wheel having free play along the length of the axle. This condition, if not corrected, can cause the wheel nut lock plate to break, leading to the wheel retention nut unscrewing and subsequent separation of the nose wheel from the landing gear axle.

The proposed AD would require actions that are intended to address the unsafe condition described in the MCAI.

DATES: We must receive comments on this proposed AD by April 30, 2008.

ADDRESSES: You may send comments by any of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Fax: (202) 493–2251.
- Mail: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590.
- Hand Delivery: U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at http://www.regulations.gov; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Taylor Martin, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4138; fax: (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2008–0369; Directorate Identifier 2008–CE–015–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No: 2008–0037, dated February 22, 2008 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

A failure mode has been identified following the examination of parts from another aircraft type (Jetstream 4100 series) that can lead to the loss of a nose-wheel. The Jetstream (HP.137) Mk1, 200, 3100 and 3200 series use a similar method for retaining the wheel assemblies on the landing gear axle and can therefore experience the same type of failure, i.e. a combination of excessive wear and/or adverse tolerances on the axle inner cone, outer cone or wheel hub splined sleeve cones resulting in the loss of the critical gap between the inner flange face of the wheel outer cone and the axle end face. If this gap is lost, it results in the wheel having free play along the length of the axle. This condition, if not corrected, can cause the wheel nut lock plate to break, leading to the wheel retention nut unscrewing and subsequent separation of the nose wheel from the landing gear axle.

For the reasons described above, this AD requires repetitive inspections of the nose landing gear to ensure that the wheels are correctly retained and, depending on findings, replacement of worn parts.

You may obtain further information by examining the MCAI in the AD docket.

Relevant Service Information

British Aerospace Regional Aircraft has issued British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA070241, dated July 13, 2007. The actions described in this service information are intended to correct the unsafe condition identified in the MCAI.

FAA's Determination and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to our bilateral agreement with this State of Design Authority, they have notified us of the unsafe condition described in the MCAI and service information referenced above. We are proposing this AD because we evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Differences Between This Proposed AD and the MCAI or Service Information

We have reviewed the MCAI and related service information and, in general, agree with their substance. But we might have found it necessary to use different words from those in the MCAI to ensure the AD is clear for U.S. operators and is enforceable. In making these changes, we do not intend to differ substantively from the information provided in the MCAI and related service information.

We might also have proposed different actions in this AD from those in the MCAI in order to follow FAA policies. Any such differences are highlighted in a NOTE within the proposed AD.

Costs of Compliance

We estimate that this proposed AD will affect 190 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is $80 per work-hour.

Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $15,200, or $80 per product.

In addition, we estimate that any necessary follow-on actions would take about 1 work-hour and require parts costing $250, for a cost of $330 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and

3. 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.

We prepared a regulatory evaluation of the estimated costs to comply with this proposed AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

2. The FAA amends § 39.13 by adding the following new AD:

British Aerospace Regional Aircraft: Docket No. FAA–2008–0369; Directorate Identifier 2008–CE–015–AD.

Comments Due Date

(a) We must receive comments by April 30, 2008.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Model HP. 137 Jetstream MK 1, Jetstream Series 200, 3100, and 3200 airplanes, all serial numbers, certificated in any category.

Subject

(d) Air Transport Association of America (ATA) Code 32: Landing Gear.

Reason

(e) The mandatory continuing airworthiness information (MCAI) states:

A failure mode has been identified following the examination of parts from another aircraft type (Jetstream 4100 series) that can lead to the loss of a nose wheel. The Jetstream (HP.137) Mk1, 200, 3100 and 3200 series use a similar method for retaining the wheel assemblies on the landing gear axle and can therefore experience the same type of failure, i.e. a combination of excessive wear and/or adverse tolerances on the axle inner cone, outer cone or wheel hub splined sleeve cones resulting in the loss of the critical gap between the inner flange face of the wheel outer cone and the axle end face. If this gap is lost, it results in the wheel having free play along the length of the axle. This condition, if not corrected, can cause the wheel nut lock plate to break, leading to the wheel retention nut unscrewing and subsequent separation of the nose wheel from the landing gear axle.

For the reasons described above, this AD requires repetitive inspections of the nose landing gear to ensure that the wheels are correctly retained and, depending on findings, replacement of worn parts.

Actions and Compliance

(f) Unless already done, do the following actions:

(1) Within the next 3 months after the effective date of this AD, initially inspect the left and right nose wheel attachments to the axle following British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA070241, dated July 13, 2007.

(2) Repetitively thereafter inspect the left and right nose wheel attachments to the axle at the intervals specified in Table 1 of this AD following British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA070241, dated July 13, 2007. If during any repetitive inspection the gap measurement changes from the previous inspection measurement, adjust the repetitive inspection interval as necessary based on Table 1 of this AD.

TABLE 1.—REPETITIVE INSPECTION INTERVALS

If the measured gap size is:	Then repetitively inspect at the following intervals:
0.002 to 0.005 inches (0.05 to 0.13 mm).	Within 500 hours TIS.
More than 0.005 to 0.010 inches (0.13 to 0.25 mm).	Within 1,000 hours TIS.
More than 0.010 to 0.020 inches (0.25 to 0.51 mm).	Within 2,000 hours TIS.
More than 0.020 inches (0.51 mm).	Within 3,000 hours TIS.

(3) Before further flight, if during any of the inspections required in paragraphs (f)(1) or (f)(2) of this AD you find the gap between the inner flange of the outer cone and the axle end face is less than 0.002 inches (0.05 mm), replace all worn parts.

Note 1: Replacement of parts does not constitute terminating action for the inspection requirements of this AD.

FAA AD Differences

Note 2: This AD differs from the MCAI and/or service information as follows: No differences.

Other FAA AD Provisions

(g) The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Taylor Martin, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4138; fax: (816) 329–4090. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these

actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(3) *Reporting Requirements:* For any reporting requirement in this AD, under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.), the Office of Management and Budget (OMB) has approved the information collection requirements and has assigned OMB Control Number 2120–0056.

Related Information

(h) Refer to MCAI European Aviation Safety Agency (EASA) AD No: 2008–0037, dated February 22, 2008; and British Aerospace Jetstream Series 3100 and 3200 Service Bulletin 32–JA070241, dated July 13, 2007, for related information.

Issued in Kansas City, Missouri, on March 21, 2008.

David R. Showers,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–6509 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2008–0171; Airspace Docket No. 08–AAL–5]

Proposed Revision of Class E Airspace; Deadhorse, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to revise Class E airspace at Deadhorse, AK. Eight Standard Instrument Approach Procedures (SIAPs) and a textual Departure Procedure (DP) are being amended for the Deadhorse Airport at Deadhorse, AK. Adoption of this proposal would result in revision of Class E airspace upward from the surface, and from 700 feet (ft.) and 1,200 ft. above the surface at the Deadhorse Airport, Deadhorse, AK.

DATES: Comments must be received on or before May 15, 2008.

ADDRESSES: Send comments on the proposal to the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001. You must identify the docket number FAA–2008–0171/ Airspace Docket No. 08–AAL–5, at the beginning of your comments. You may also submit comments on the Internet at *http://www.regulations.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.

An informal docket may also be examined during normal business hours at the office of the Manager, Safety, Alaska Flight Service Operations, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number (907) 271–5898; fax: (907) 271–2850; e-mail: *gary.ctr.rolf@faa.gov*. Internet address: *http://www.alaska.faa.gov/at*.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments 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–2008–0171/Airspace Docket No. 08–AAL–5.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of Notice of Proposed Rulemaking's (NPRM's)

An electronic copy of this document may be downloaded through the Internet at *http://www.regulations.gov*. Recently published rulemaking documents can also be accessed through the FAA's Web page at *http://www.faa.gov* or the Superintendent of Document's Web page at *http://www.access.gpo.gov/nara/index.html*.

Additionally, any person may obtain a copy of this notice by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591 or by calling (202) 267–8783. Communications must identify both docket numbers for this notice. Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, to request a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is considering an amendment to the Code of Federal Regulations (14 CFR part 71), which would revise Class E airspace at the Deadhorse Airport, in Deadhorse, AK. The intended effect of this proposal is to revise Class E airspace upward from the surface, and from 700 ft. and 1,200 ft. above the surface to contain Instrument Flight Rules (IFR) operations at the Deadhorse Airport, Deadhorse, AK.

The FAA Instrument Flight Procedures Production and Maintenance Branch has amended eight SIAPs and a DP for the Deadhorse Airport. The approaches are (1) the Area Navigation (RNAV) Global Positioning System (GPS) Runway (RWY) 05, Amendment (Amdt) 1, (2) the RNAV (GPS) RWY 23, Amdt 1, (3) the Localizer (LOC)/Distance Measuring Equipment (DME) Backcourse (BC) RWY 23, Amdt 11, (4) the Instrument Landing System (ILS) or LOC/DME RWY 05, Amdt 2, (5) the Very High Frequency Omni-directional Range (VOR)/DME RWY 05, Amdt 2, (6) the VOR/DME RWY 23, Amdt 4, (7) the VOR RWY 05, Amdt 4, and (8) the VOR RWY 23, Amdt 6. Textual DP's are unnamed and are published in the front of the U.S. Terminal Procedures for Alaska. Class E controlled airspace extending upward from the surface, and from 700 ft. and 1,200 ft. above the surface in the

Deadhorse Airport area would be established by this action. The proposed airspace is sufficient in size to contain aircraft executing the instrument procedures at the Deadhorse Airport, Deadhorse, AK.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as surface areas are published in paragraph 6002 of FAA Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 in FAA Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document would be published subsequently in the Order.

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

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it proposes to create Class E airspace sufficient in size to contain aircraft executing instrument procedures at the Deadhorse Airport, AK, and represents the FAA's continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 14 CFR 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 7400.9R, Airspace Designations and Reporting Points, signed August 15, 2007, and effective September 15, 2007, is to be amended as follows:

* * * * *

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

AAL AK E2 Deadhorse, AK [Revised]

Deadhorse, Deadhorse Airport, AK
(Lat. 70°11′41″ N., long. 148°27′55″ W.)

Within a 4.1-mile radius of the Deadhorse Airport, and within 2.4 miles either side of the 035° (T)/ 058°(M) bearing from the Deadhorse Airport extending from the 2.4-mile radius to 7.0 miles northeast of the Deadhorse Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6005 Class E Airspace Extending Upward from 700 Feet or More Above the Surface of the Earth.

* * * * *

AAL AK E5 Deadhorse, AK [Revised]

Deadhorse, Deadhorse Airport, AK
(Lat. 70°11′41″ N., long. 148°27′55″ W.)

That airspace extending upward from 700 feet above the surface within a 7.0-mile radius of the Deadhorse Airport; and that airspace extending upward from 1,200 ft. above the surface within a 72-mile radius of the Deadhorse Airport.

* * * * *

Issued in Anchorage, AK, on March 20, 2008.

Michael A. Tarr,

Acting Manager, Alaska Flight Services Information Area Group.

[FR Doc. E8–6597 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1313

[Docket No. DEA–295P]

RIN 1117–AB07

Information on Foreign Chain of Distribution for Ephedrine, Pseudoephedrine, and Phenylpropanolamine

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Combat Methamphetamine Epidemic Act of 2005 (CMEA), which was enacted on March 9, 2006, requires DEA to collect from importers of ephedrine, pseudoephedrine, and phenylpropanolamine all information known to the importer on the foreign chain of distribution of the chemical from the manufacturer to the importer. DEA is proposing to amend its regulations to incorporate the requirement for this information into the import declaration.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before May 30, 2008.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–295'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be directly sent to DEA electronically by sending an electronic message to: *dea.diversion.policy@usdoj.gov*. Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the

http://www.regulations.gov Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file formats other than those specifically listed here.

Posting of Public Comments: Please note that all comments received are considered part of the public record and made available for public inspection online at *http://www.regulations.gov* and in the Drug Enforcement Administration's public docket. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all the personal identifying information you do not want posted online or made available in the public docket in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be posted online or made available in the public docket, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be posted online or made available in the public docket.

Personal identifying information and confidential business information identified and located as set forth above will be redacted and the comment, in redacted form, will be posted online and placed in the Drug Enforcement Administration's public docket file. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION CONTACT** paragraph.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington DC 20537 at (202) 307–7297.

SUPPLEMENTARY INFORMATION:

DEA's Legal Authority

DEA implements the Comprehensive Drug Abuse Prevention and Control Act of 1970, often referred to as the Controlled Substances Act (CSA) and the Controlled Substances Import and Export Act (21 U.S.C. 801–971), as amended. DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1399. These regulations are designed to ensure that there is a sufficient supply of controlled substances for legitimate medical, scientific, research, and industrial purposes and to deter the diversion of controlled substances to illegal purposes. The CSA mandates that DEA establish a closed system of control for manufacturing, distributing, and dispensing controlled substances. Any person who manufactures, distributes, dispenses, imports, exports, or conducts research or chemical analysis with controlled substances must register with DEA (unless exempt) and comply with the applicable requirements for the activity. The CSA as amended also requires DEA to regulate the manufacture, distribution, import, and export of chemicals that may be used to manufacture controlled substances illegally. Listed chemicals that are classified as List I chemicals are important to the manufacture of controlled substances. Those classified as List II chemicals may be used to manufacture controlled substances.

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177). The changes proposed here are needed to implement the statutory provisions. The statute is self-implementing; the provisions related to information to be collected at the importation of ephedrine, pseudoephedrine, and phenylpropanolamine became effective on March 9, 2006. The changes proposed in this rulemaking provide conforming amendments to make the language of the regulations consistent with that of the statute. DEA must implement the statute and is simply conforming its regulations to, and implementing, the statute.

Import Declaration Requirements

Under existing DEA regulations (21 CFR part 1313), importers of listed chemicals are required to provide DEA with advance notification of imports unless the importer has met the requirements as a regular importer of the listed chemical; for regular importers, the notification must be filed by the date of importation. In the importation declaration (DEA Form 486), the importer must provide information on the chemical (name, size and weight of the container, number of containers, total weight of chemical), importation (date, foreign port of shipment, United States port of entry) and the foreign supplier (name, address, contact information).

CMEA imposes several new requirements on imports of listed chemicals. CMEA amended 21 U.S.C. 971, ''Notification, suspension of shipment, and penalties with respect to importation and exportation of listed chemicals'', to require DEA to collect information regarding persons to whom the United States importer, exporter, broker, or trader transfers the listed chemical, actual quantities shipped, and the date the shipment occurred. If the person to whom the listed chemical is to be transferred is not a regular customer of the United States importer or exporter, then the importer or exporter must notify DEA no later than 15 days before the transaction is to take place. Further, if the person to whom the chemical is to be transferred changes subsequent to initial notification of DEA, or if the amount of the chemical to be transferred increases, the importer or exporter shall update the notice to DEA to identify the most recent prospective transferee or the most recent quantity or both (as the case may be) and may not transfer the listed chemical until after the expiration of the 15-day period beginning on the date on which the update is submitted to DEA, except that such 15-day restriction does not apply if the prospective transferee identified in the update is a regular customer. These changes apply to all listed chemicals. On April 9, 2007, DEA published an Interim Final Rule with Request for Comment codifying these provisions (72 FR 17401). Subsequently, due to requests from the regulated industry, DEA temporarily stayed certain provisions of that rule (72 FR 28601, May 22, 2007). That Interim Final Rule became effective June 8, 2007.

CMEA added a new paragraph (h) to 21 U.S.C. 971 that applies specifically to the importation of ephedrine, pseudoephedrine, and phenylpropanolamine. In paragraph (h)(1), the Act states that the import declaration ''shall include all information known to the importer on the chain of distribution of such chemical from the manufacturer to the importer.'' Paragraphs 971(h)(2) and (3) state that the Attorney General may ask foreign manufacturers and distributors

to provide information known to them on distribution of the chemical, including sales. If the foreign manufacturer or distributor refuses to cooperate, the Attorney General may issue an order prohibiting the importation of the three chemicals if the foreign manufacturer or distributor is part of the chain of distribution. Not later than 60 days prior to issuing the order, the Attorney General must publish in the **Federal Register** a notice of intent to issue the order. Imports handled by the foreign distributor may not be restricted during the 60-day period. In the Conference Report (H.R. 109–333), Congress stated that the ''provision will assist U.S. law enforcement agencies to better track where meth precursors come from, and how they get to the U.S. At present, very little information exists about the international 'chain of distribution' for these chemicals, hindering effective controls.''

DEA is proposing to add a new paragraph (d) to 21 CFR 1313.13, Contents of import declaration, to state that importers of ephedrine, pseudoephedrine, and phenylpropanolamine must provide information known to them on the chain of distribution from the manufacturer to the importer. DEA is also proposing to add a new 21 CFR 1313.42 to cover the provisions of paragraphs (h)(2) and (3) on orders to prohibit imports from foreign manufacturers and distributors who refuse to cooperate with requests for information.

Revision of DEA Form 486: Import/Export Declaration for List I and List II Chemicals

To comply with the changes made to the Controlled Substances Act by the Combat Methamphetamine Epidemic Act of 2005, DEA is proposing to establish a new DEA Form 486A to be used by persons importing ephedrine, pseudoephedrine, or phenylpropanolamine, or drug products containing ephedrine, pseudoephedrine, or phenylpropanolamine. This new form responds to the requirement regarding the foreign chain of distribution discussed above, as well as to requirements implemented regarding import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. In a separate rulemaking, ''Import and Production Quotas for Certain List I Chemicals'' [Docket No. DEA–293, RIN 1117–AB08] (72 FR 37439, July 10, 2007), DEA implemented the import quota provisions of CMEA. Importers of ephedrine, pseudoephedrine, and phenylpropanolamine will be required to provide information about their individual import quota on the DEA Form 486A so that DEA may determine whether the importer has enough quota remaining to import the quantity requested.

Thus, in addition to the fields currently present on the DEA Form 486, the DEA Form 486A contains the following fields:

- Name and address of foreign distributor (if applicable).
- Import quota, including: quota for current year; quota used to date for current year; and, amount of quota remaining.

Once the new DEA Form 486A is implemented, DEA will make both the DEA Form 486 and the DEA Form 486A fully interactive forms. That is, these forms would be able to be completed and submitted electronically. Currently, forms can be completed electronically, but must be printed and sent to DEA via facsimile. DEA notes that the availability of a fully interactive form has been long sought by the regulated industry.

Implementation of this Rule

Effective 30 days after publication of a Final Rule implementing these regulations in the **Federal Register**, all United States importers of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine would be required to use the new DEA Form 486A ''Importation of the List I Chemicals Ephedrine, Pseudoephedrine, and Phenylpropanolamine'' to notify DEA of their imports.

Regulatory Certifications

Regulatory Flexibility Act

The Acting Administrator hereby certifies that this rulemaking has been drafted in accordance with the provisions of the Regulatory Flexibility Act (5 U.S.C. 601–612). This rule is necessary to comply with statutory mandates which require that notices of importation for imports of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine provide to DEA all information known to the importer on the foreign chain of distribution of the chemical. As noted above, changes to the forms also respond to provisions regarding import quotas, requiring that importers note on the form the amount of quota issued and available for each chemical. Without these changes, DEA will be unable to comply with statutory mandates and will not be able to fully administer the system of import and production quotas mandated for ephedrine, pseudoephedrine, and phenylpropanolamine.

DEA notes that the statute requires importers to provide only information that is known to them; the burden associated with providing names on the foreign chain of distribution will be minimal. This rule does not impose any new costs. DEA notes that, prior to this rule, importers of ephedrine, pseudoephedrine, and phenylpropanolamine were required to complete a DEA Form 486 to import these List I chemicals. Only the information on the form has changed. Therefore, this rule will not have a significant economic impact on a substantial number of small entities.

Executive Order 12866

The Acting Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 1(b). It has been determined that this is ''a significant regulatory action.'' Therefore, this action has been reviewed by the Office of Management and Budget. As discussed above, this action is codifying statutory provisions and involves no agency discretion. This statutory change imposes minimal costs on importers; they simply have to file a form with DEA in advance of transactions that includes information that is known to them. They are not required to conduct research to obtain information. DEA notes that the requirement to complete the form is already present in DEA regulations. This rule merely requires that importers of these three List I chemicals provide information known to them regarding the foreign chain of distribution of the chemicals.

Paperwork Reduction Act

DEA is proposing to revise an existing information collection by establishing a new form for the reporting of imports of the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. Specifically, DEA is creating new DEA Form 486A, ''Import Declaration for Ephedrine, Pseudoephedrine, and Phenylpropanolamine''. This form permits the reporting of any information known to the United States importer regarding the foreign chain of distribution of the List I chemical(s).

Specifically, DEA estimates that 30 respondents will import ephedrine, pseudoephedrine, and phenylpropanolamine annually. These persons will conduct 350 individual importations, necessitating the submission of 350 forms. Because of the additional information required on the DEA Form 486A, DEA estimates that this form will take 20 minutes to

complete, as opposed to the DEA Form 486, which DEA estimates takes 15 minutes to complete. DEA notes here that the completion of the DEA Form 486A will be in lieu of the currently-required completion of the DEA Form 486. Therefore, while the number of responses remains constant, the hour burden increases due to the greater time associated with the DEA Form 486A. The net increase for this collection is 13 hours annually.

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

All comments, suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537.

Written comments and suggestions from the public and affected agencies concerning the collection of information are encouraged. Your comments on the information collection-related aspects of this rule should address one or more of the following four points:

(1) 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;

(2) 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;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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 Information Collection 1117–0023

(1) *Type of Information Collection:* Revision of an existing collection.

(2) *Title of the Form/Collection:* Import/Export Declaration for List I and List II Chemicals.

(3) Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:

Form Number: DEA Form 486 and DEA Form 486A. Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(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.

Abstract: Persons importing, exporting, and conducting international transactions with List I and List II chemicals must notify DEA of those transactions in advance of their occurrence, including information regarding the person(s) to whom the chemical will be transferred and the quantity to be transferred. Persons must also provide return declarations, confirming the date of the importation and transfer, and the amounts of the chemical transferred. For the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, importers must report all information known to them on the chain of distribution of the chemical from the manufacturer to the importer. This information is used to prevent shipments not intended for legitimate purposes.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:

	Number of respondents	Number of responses	Average time per response	Total (in hours)
Form 486 (export)	239	7,997	0.2 hour (12 minutes)	1,599.4
Form 486 (Export Return Declaration)	239	7,997	0.08 hour (5 minutes)	666.4
Form 486 (import)	230	2000	0.25 hour (15 minutes)	500
Form 486 (import return declaration)*	230	2200	0.08 hour (5 minutes)	183.3
Form 486A (import)	30	350	0.33 hour (20 minutes)	116.7
Form 486A (import return declaration)*	30	385	0.08 hour (5 minutes)	32.1
Form 486 (international transaction)	9	111	0.2 hour (12 minutes)	22.2
Form 486 (international transaction return declaration.	9	111	0.08 hour (5 minutes)	9.25
Quarterly reports for imports of acetone, 2-butanone, and toluene.	110	440	0.5 hour (30 minutes)	220
Total	239			3,349.35

*DEA assumes 10% of all imports will not be transferred in the first thirty days and will necessitate submission of a subsequent return declaration.

(6) An estimate of the total public burden (in hours) associated with the collection: DEA estimates that this collection will take 3,350 hours annually.

If additional information is required, contact Lynn Bryant, Department Clearance Officer, Information Management and Security Staff, Justice Management Division, Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street, NW., Washington, DC 20530.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more

(adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1313

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1313 is proposed to be amended as follows:

PART 1313—IMPORTATION AND EXPORTATION OF LIST I AND LIST II CHEMICALS

1. The authority citation for part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.13 is amended by adding paragraph (d) to read as follows:

§ 1313.13 Contents of import declaration.

* * * * *

(d) Any regulated person importing ephedrine, pseudoephedrine, or phenylpropanolamine must submit, on the import declaration, all information known to the importer on the chain of distribution of the chemical from the manufacturer to the importer. Ephedrine, pseudoephedrine, or phenylpropanolamine include each of the salts, optical isomers, and salts of optical isomers of the chemical.

3. Section 1313.42 is added to read as follows:

§ 1313.42 Prohibition of shipments from certain foreign sources.

(a) If the Administrator determines that a foreign manufacturer or distributor of ephedrine, pseudoephedrine, or phenylpropanolamine has refused to cooperate with a request by the Administrator for information known to the manufacturer or distributor on the distribution of the chemical, including sales, the Administrator may issue an order prohibiting the importation of the chemical in any case where the manufacturer or distributor is part of the chain of distribution.

(b) Not later than 60 days prior to issuing the order to prohibit importation, the Administrator shall publish in the **Federal Register** a notice of intent to issue the order. During the 60 day period, imports from the foreign manufacturer or distributor may not be restricted under this section.

Dated: March 14, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–6357 Filed 3–28–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–119518–07]

RIN 1545–BG92

Travel Expenses of State Legislators

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations relating to travel expenses of state legislators while away from home. The regulations affect eligible state legislators who make the election under section 162(h) of the Internal Revenue Code (Code). The regulations are necessary to clarify the amount of travel expenses that may be deducted by a state legislator who makes the election under section 162(h).

DATES: Written (paper or electronic) comments or a request for a public hearing must be received by June 30, 2008.

ADDRESSES: Send submissions to CC:PA:LPD:PR (REG–119518–07), Room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–119518–07), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Federal eRulemaking Portal at *http://www.regulations.gov* (IRS REG–119518–07).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, R. Matthew Kelley, (202) 622–7900; concerning submission of comments or a request for a hearing, Kelly Banks, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by May 30, 2008. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in § 1.162–24(e). This collection of information will help the IRS determine if a taxpayer may make an election under section 162(h). The collection of information is required to obtain a benefit.

The estimated burden is 30 minutes.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by the Office of Management and Budget.

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 return information are

confidential, as required by section 6103.

Background

This document contains proposed amendments to 26 CFR part 1 and 26 CFR part 301, relating to travel expenses of state legislators while away from home.

Section 162(a)(2) provides that a taxpayer generally is allowed a deduction for ordinary and necessary expenses paid or incurred during the taxable year in carrying on a trade or business, including traveling expenses while away from home.

Section 162(h) provides that an eligible individual who is a state legislator at any time during the taxable year may make an election under section 162(h) (an electing legislator). Under section 162(h)(4), the election is not available to any legislator whose place of residence within the legislative district represented by the legislator is 50 or fewer miles from the state capitol building.

As a result of making the election for a taxable year, under section 162(h)(1)(A) an electing legislator's place of residence within the district represented by the legislator is treated as the legislator's home. In addition, under section 162(h)(1)(B) an electing legislator is deemed to have expended for living expenses (in connection with the trade or business of being a legislator), on each legislative day of the electing legislator, the greater of the amount generally allowable for the day (i) to employees of the legislator's state for per diem while away from home, to the extent the amount does not exceed 110 percent of the amount described in (ii); or (ii) to employees of the executive branch of the Federal government for per diem while traveling away from home in the United States. Finally, under section 162(h)(1)(C) an electing legislator is deemed to be away from home in the pursuit of a trade or business on each legislative day.

Section 162(h)(2) defines a legislative day for an electing legislator as any day on which (A) the legislature is in session (including any day in which the legislature is not in session for a period of 4 consecutive days or less), or (B) the legislature is not in session but the physical presence of the electing legislator is formally recorded at a meeting of a committee of the legislature.

Section 301.9100–4T(a) of the Procedure and Administration Regulations provides that a legislator makes the election under section 162(h) by attaching a statement to the legislator's income tax return (or amended return) for the taxable year for which the election is effective. The statement must include the following information: (1) The taxpayer's name, address, and taxpayer identification number; (2) a statement that the taxpayer is making an election under section 162(h); and (3) information establishing that the taxpayer is entitled to make the election. A legislator must make the election by the due date for filing the return (including extensions). Under § 301.9100–4T(g), a legislator may revoke an election only with the consent of the Commissioner. Consent is requested by filing an application with the service center where the election was filed. The application must include the following information: (1) The taxpayer's name, address, and taxpayer identification number; (2) a statement that the taxpayer is revoking an election under section 162(h) for a specified year; and (3) a statement explaining why the taxpayer seeks to revoke the election.

Rev. Rul. 82–33 (1982–1 CB 28) (see § 601.601(d)(2)(ii)(*b*)) holds that (1) an electing legislator's tax home for all legislative travel, including travel between sessions, is the legislator's place of residence within the legislative district represented by the legislator; (2) the term ''living expenses'' for purposes of section 162(h) includes expenses for lodging, meals, laundry, and other incidental expenses but does not include expenses for travel fares, local transportation, or telephone calls; (3) a legislative day includes the days of any period for which the legislature is not in session for 4 consecutive days or less, without extension for Saturdays, Sundays, or holidays; (4) for purposes of section 162(h)(1)(B)(ii), the amount generally allowable to employees of the executive branch of the Federal government for per diem while traveling away from home in the United States is the per diem amount for the particular city in which the state capitol is located; and (5) any amount deductible by an electing legislator for deemed living expenses under section 162(h) is in addition to any other amount deductible under section 162(a) for other expenses incurred while traveling away from home.

An electing legislator's deduction under section 162(h) for deemed living expenses is reduced by the amount of any reimbursement received for the expenses that is not included in the legislator's gross income.

Section 1.62–1T(e)(4) provides rules regarding the allocation between meals and lodging of unreimbursed expenses of state legislators. Section 274(n) provides rules regarding the limitations on the amount allowable as a deduction for expenses for or allocable to meals.

Explanation of Provisions

The proposed regulations incorporate the holdings of Rev. Rul. 82–33, which will be obsoleted when the proposed regulations are issued as final regulations. The proposed regulations further provide that a taxpayer becomes a state legislator on the day the taxpayer is sworn into office and ceases to be a state legislator on the day following the day on which the taxpayer's term in office ends. The proposed regulations provide that the legislature of which an electing legislator is a member is in session when the members of the legislature are expected to attend and participate as an assembled body of the legislature, whether or not the electing legislator actually attends. The proposed regulations also provide that a legislator's legislative days include a day on which the legislator's attendance at a meeting of a committee of the legislature is formally recorded. A committee of the legislature is defined as a group that consists solely of members of the legislature charged with conducting business of the legislature. The proposed regulations further provide that a legislator's legislative days include any day that is not otherwise a legislative day if the legislator's attendance at a session of the legislature on that day is formally recorded. An example in the proposed regulations illustrates that if the members of the legislature are not expected to attend and participate as an assembled body on a day, then the legislature is not in session on that day; however, that day is a legislative day for those members whose actual attendance on that day is formally recorded.

The proposed regulations incorporate the current rules in § 301.9100–4T for making and revoking the election under section 162(h). The regulations propose to amend § 301.9100–4T by removing these rules from that section.

Effective/Applicability Date

The regulations are proposed to apply to expenses deemed expended under section 162(h) after the date the regulations are published as final regulations in the **Federal Register**.

Effect on Other Documents

When the proposed regulations are published as final regulations, Rev. Rul. 82–33 will be obsoleted.

Special Analyses

This notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866.

Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations and, because the regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, this notice of proposed rulemaking has been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Comments and Requests for a Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original with eight (8) copies) or electronic comments that are submitted timely to the IRS. Comments are requested on the clarity of the proposed regulations and how they can be made easier to understand. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person who timely submits written (including electronic) comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these regulations is R. Matthew Kelley of the Office of Associate Chief Counsel (Income Tax and Accounting). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are proposed to be amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.162–24 also issued under 26 U.S.C. 162(h). * * *

Par. 2. Section 1.162–24 is added to read as follows:

§ 1.162–24 Travel expenses of state legislators.

(a) *In general.* For purposes of section 162(a), in the case of any taxpayer who is a state legislator at any time during the taxable year and who makes an election under section 162(h) for the taxable year—

(1) The taxpayer's place of residence within the legislative district represented by the taxpayer is the taxpayer's home for that taxable year;

(2) The taxpayer is deemed to have expended for living expenses (in connection with the taxpayer's trade or business as a legislator) an amount equal to the sum of the amounts determined by multiplying each legislative day of the taxpayer during the taxable year by the greater of—

(i) The amount generally allowable with respect to that day to employees of the state of which the taxpayer is a legislator for per diem while away from home, to the extent the amount does not exceed 110 percent of the amount described in paragraph (a)(2)(ii) of this section; or

(ii) The Federal per diem with respect to that day for the taxpayer's state capital; and

(3) The taxpayer is deemed to be away from home in the pursuit of a trade or business on each legislative day.

(b) *Legislative day.* For purposes of section 162(h)(1) and this section, for any taxpayer who makes an election under section 162(h), a legislative day is any day on which the taxpayer is a state legislator and—

(1) The legislature is in session;

(2) The legislature is not in session for a period that is not longer than 4 consecutive days, without extension for Saturdays, Sundays, or holidays;

(3) The taxpayer's attendance at a meeting of a committee of the legislature is formally recorded; or

(4) The taxpayer's attendance at any session of the legislature that only a limited number of members are expected to attend (such as a ''pro forma'' session), on any day not described in paragraph (b)(1) or (b)(2) of this section, is formally recorded.

(c) *Fifty mile rule.* Section 162(h) and this section do not apply to any taxpayer who is a state legislator and whose place of residence within the legislative district represented by the taxpayer is 50 or fewer miles from the capitol building of the state. For purposes of this paragraph (c), the distance between the taxpayer's place of residence within the legislative district represented by the taxpayer and the capitol building of the state is the shortest of the more commonly traveled routes between the two points.

(d) *Definitions and special rules.* The following definitions apply for purposes of section 162(h) and this section.

(1) *State legislator.* A taxpayer becomes a state legislator on the day the taxpayer is sworn into office and ceases to be a state legislator on the day following the day on which the taxpayer's term in office ends.

(2) *Living expenses.* Living expenses include lodging, meals, and incidental expenses. *Incidental expenses* has the same meaning as in 41 CFR 300–3.1.

(3) *In session*—(i) *In general.* For purposes of this section, the legislature of which a taxpayer is a member is in session on any day if, at any time during that day, the members of the legislature are expected to attend and participate as an assembled body of the legislature.

(ii) *Examples.* The following examples illustrate the rules of this paragraph (d)(3):

Example 1. B is a member of the legislature of State X. On Day 1, the State X legislature is convened and the members of the legislature generally are expected to attend and participate. On Day 1, the State X legislature is in session within the meaning of paragraph (d)(3)(i) of this section. B does not attend the session of the State X legislature on Day 1. However, Day 1 is a legislative day for B for purposes of section 162(h)(2)(A) and paragraph (b)(1) of this section.

Example 2. C, D, and E are members of the legislature of State X. On Day 2, the State X legislature is convened for a limited session in which not all members of the legislature are expected to attend and participate. C and D are the only members who are called to, and do, attend the limited session on Day 2, and their attendance at the session is formally recorded. E is not called and does not attend. Day 2 is not a day described in paragraph (b)(2) of this section. On Day 2, the State X legislature is not in session within the meaning of paragraph (d)(3)(i) of this section. Day 2 is a legislative day as to C and D under section 162(h)(2)(B) and paragraph (b)(4) of this section. Day 2 is not a legislative day as to C and D under section 162(h)(2)(A) and paragraph (b)(1) of this section. Day 2 is not a legislative day as to E under sections 162(h)(2)(A) and (h)(2)(B) and paragraphs (b)(1) and (b)(4) of this section.

(4) *Committee of the legislature.* A committee of the legislature is any group consisting solely of legislators charged with conducting business of the legislature. Committees of the legislature include, but are not limited to, committees to which the legislature refers bills for consideration, committees that the legislature has authorized to conduct inquiries into

matters of public concern, and committees charged with the internal administration of the legislature. For purposes of this section, groups that are not considered committees of the legislature include, but are not limited to, groups that promote particular issues, raise campaign funds, or are caucuses of members of a political party.

(5) *Federal per diem.* The Federal per diem for any city and day is the maximum amount allowable to employees of the executive branch of the Federal government for living expenses while away from home in pursuit of a trade or business in that city on that day. See 5 U.S.C. 5702 and the regulations under that section.

(e) *Election*—(1) *Time for making election.* A taxpayer's election under section 162(h) must be made for each taxable year for which the election is to be in effect and must be made no later than the due date (including extensions) of the taxpayer's Federal income tax return for the taxable year.

(2) *Manner of making election.* A taxpayer makes an election under section 162(h) by attaching a statement to the taxpayer's income tax return for the taxable year for which the election is made. The statement must include—

(i) The taxpayer's name, address, and taxpayer identification number;

(ii) A statement that the taxpayer is making an election under section 162(h); and

(iii) Information establishing that the taxpayer is a state legislator entitled to make the election, for example, a statement identifying the taxpayer's state and legislative district and representing that the taxpayer's place of residence in the legislative district is not 50 or fewer miles from the state capitol building.

(3) *Revocation of election.* An election under section 162(h) may be revoked only with the consent of the Commissioner. An application for consent to revoke an election must be signed by the taxpayer and filed with the submission processing center with which the election was filed, and must include—

(i) The taxpayer's name, address, and taxpayer identification number;

(ii) A statement that the taxpayer is revoking an election under section 162(h) for a specified year; and

(iii) A statement explaining why the taxpayer seeks to revoke the election.

(f) *Effect of election on otherwise deductible expenses for travel away from home—(1) Legislative days*—(i) *Living expenses.* For any legislative day for which an election under section 162(h) and this section is in effect, the amount of an electing taxpayer's living expenses while away from home is the greater of the amount of the living expenses—

(A) Specified in paragraph (a)(2) of this section in connection with the trade or business of being a legislator; or

(B) Otherwise allowable under section 162(a)(2) in the pursuit of any other trade or business of the taxpayer.

(ii) *Other expenses.* For any legislative day for which an election under section 162(h) and this section is in effect, the amount of an electing taxpayer's expenses (other than living expenses) for travel away from home is the sum of the substantiated expenses, such as expenses for travel fares, telephone calls, and local transportation, that are otherwise deductible under section 162(a)(2) in the pursuit of any trade or business of the taxpayer.

(2) *Non-legislative days.* For any day that is not a legislative day, the amount of an electing taxpayer's expenses (including amounts for living expenses) for travel away from home is the sum of the substantiated expenses that are otherwise deductible under section 162(a)(2) in the pursuit of any trade or business of the taxpayer.

(g) *Cross references.* See § 1.62–1T(e)(4) for rules regarding allocation of unreimbursed expenses of state legislators and section 274(n) for limitations on the amount allowable as a deduction for expenses for or allocable to meals.

(h) *Effective/applicability date.* This section applies to expenses deemed expended under section 162(h) after the date these regulations are published as final regulations in the **Federal Register**.

PART 301—PROCEDURE AND ADMINISTRATION

Par. 3. The authority citation for part 301 continues to read as follows:

Authority: 26 U.S.C. 7805 * * *

§ 301.9100–4T [Amended]

Par. 4. Section 301.9100–4T is amended by removing from the table in paragraph (a)(1) section 127(a) and removing paragraph (a)(2)(iv).

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E8–6500 Filed 3–28–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Notice No. 81]

RIN 1513–AB45

Proposed Establishment of the Haw River Valley Viticultural Area (2007R–179P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau proposes to establish the 868-square mile ''Haw River Valley'' viticultural area in Alamance, Caswell, Chatham, Guilford, Orange, and Rockingham Counties, North Carolina. We designate viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase. We invite comments on this proposed addition to our regulations.

DATES: We must receive written comments on or before May 30, 2008.

ADDRESSES: You may send comments on this notice to one of the following addresses:

- *http://www.regulations.gov* (via the comment form for this notice posted on Regulations.gov, the Federal e-rulemaking portal); or
- Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044–4412.

See the Public Participation section of this notice for specific instructions and requirements for submitting comments, and for information on how to request a public hearing.

You may view copies of this notice and any comments we receive about this proposal at *http://www.regulations.gov*. A direct link to the appropriate Regulations.gov docket is available under Notice No. 81 on the TTB Web site at *http://www.ttb.gov/wine/wine_rulemaking.shtml*. You also may view copies of this notice and any comments we receive about this proposal by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. To make an appointment, call 202–927–2400.

FOR FURTHER INFORMATION CONTACT: N.A. Sutton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 925 Lakeville St., No. 158, Petaluma, CA 94952; phone 415–271–1254.

SUPPLEMENTARY INFORMATION:

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels, and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the regulations promulgated under the FAA Act.

Part 4 of the TTB regulations (27 CFR part 4) allows the establishment of definitive viticultural areas and the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) contains the list of approved viticultural areas.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region distinguishable by geographical features, the boundaries of which have been recognized and defined in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to its geographic origin. The establishment of viticultural areas allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of a viticultural area is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations outlines the procedure for proposing an American viticultural area and provides that any interested party may petition TTB to establish a grape-growing region as a viticultural area. Section 9.3(b) of the TTB regulations requires the petition to include—

- Evidence that the proposed viticultural area is locally and/or nationally known by the name specified in the petition;
- Historical or current evidence that supports setting the boundary of the proposed viticultural area as the petition specifies;
- Evidence relating to the geographic features, such as climate, soils, elevation, and physical features, that distinguish the proposed viticultural area from surrounding areas;
- A description of the specific boundary of the proposed viticultural area, based on features found on United States Geological Survey (USGS) maps; and
- A copy of the appropriate USGS map(s) with the proposed viticultural area's boundary prominently marked.

Haw River Valley Petition

Patricia McRitchie of McRitchie Associates, LLC, submitted a petition to establish the 868-square mile Haw River Valley viticultural area in North Carolina on behalf of all the local grape growers and winemakers.

The proposed Haw River Valley viticultural area is located in the Piedmont in north-central North Carolina. According to the USGS maps and the written boundary description submitted with the petition, the Haw River Valley region lies between the cities of Greensboro and Chapel Hill, and includes the southeastern-flowing Haw River and its accompanying watershed. The proposed Haw River Valley viticultural area lies to the east of the established Yadkin Valley viticultural area (27 CFR 9.174) and the proposed Swan Creek viticultural area (71 FR 53612). According to the petitioner, the proposed viticultural area encompasses approximately 868 square miles, which includes 60 acres of vineyards and 6 wineries. The petitioner submitted a map indicating that the 14 vineyards within the proposed viticultural area are geographically disbursed throughout the area.

The petitioner explains that the distinguishing features of the proposed Haw River Valley viticultural area include its geology, soils, elevation, and climate. Its inland location, between the Atlantic Ocean and the Appalachian Mountains, and its complex geological history combine to create a unique viticultural region. The Haw River watershed, which comprises 98 percent of the proposed viticultural area, was used to determine the proposed boundary line.

Name Evidence

According to the petitioner, the ''Haw'' name originated with the Sissipahaw Indians, Native Americans living in small villages along the Haw River. After the arrival of the first Europeans in the 16th century, the Sissipahaw Indians eventually abandoned their villages along the Haw River and joined other Native Americans in other parts of the North Carolina Piedmont.

The petitioner states that the ''Haw River'' and ''Haw River Valley'' names both have been used in reference to the region that this viticultural area petition describes. In the early 1700's John Lawson, an English naturalist and surveyor, wrote an account of his party crossing the ''famous Hau-River'' to get a safe distance from the Sissipahaw Indians. Also, in the ''Shuttle & Plow: A History of Alamance County, North Carolina'' (Alamance County Historical Association, 1999), Carole Troxler and William Vincent explain that the names ''Hawfields'' and ''Haw River Settlement'' reference the earliest colonial settlements in the Haw River Valley. Further, in ''Orange County, 1752–1952'' (The Journal of Southern History, May 1954), Hugh Lefler and Paul Wager reference the Haw River Valley.

According to evidence presented in the petition, the Haw River Valley name continues to be used to describe the region. The Burlington/Alamance County Convention Center and Visitors Bureau Web site (*http://www.burlington-area-nc.org/events.asp*) describes a September 9, 2006, Paddle[boat] dinner cruise that experiences the ''richness of the Haw River Valley.'' A flyer for the Haw River Festival for the Community describes a display of arrowheads and artifacts found in the Haw River Valley. The Haw River Valley Web site (*http://www.hawrivervalley.com/*) describes the area as a large, fertile region encompassing parts of Rockingham, Caswell, Guilford, Alamance, and Chatham Counties in North Carolina.

On November 23, 2006, the Greensboro News Record ran an article describing a strong storm depositing ''prodigious rain into the Haw River valley and effectively shutting down parts of the region.''

Boundary Evidence

According to the petitioner, the boundary of the proposed Haw River Valley viticultural area is based on nearly the entirety of the Haw River watershed's distinctive underlying geology and soils. The Haw River is approximately 110 miles long, and the proposed viticultural area includes that portion of the Haw River between Williamsburg and Griffins Crossroad, a town located approximately 2.5 miles northwest of Everett Jordan Lake. The Haw River headwaters start northwest of Greensboro, and the river travels east and south-southeast, gaining momentum in the Piedmont region. The river eventually flows into the Everett

Jordan Lake in Chatham County, joins the Deep River south of the Everett Jordan Lake dam, and then flows into the Cape Fear River.

The urban, nonagricultural Greensboro region lies close to, but outside of, the proposed northwestern portion of the boundary. Also, differing geology, soils, and elevations distinguish the Haw River watershed from the Dan River watershed to the north, the Inner Coastal Province to the east, the Sandhills to the south, and the western Piedmont Province to the west.

Distinguishing Features

According to the petitioner, the distinguishing features of the proposed Haw River Valley viticultural area include its geology, soils, elevation, and climate. The combination of the underlying geology of the Haw River Valley and its inland, nonmountainous geography influences the soils and the climate and creates a unique grape-growing region.

Geology

The petitioner states that Matthew Mayberry, of the Mayberry Land Company in Elkin, North Carolina, provided the geological data and documentation for the Haw River Valley viticultural area petition. Citing ''North Carolina: The Years Before Man,'' by Fred Beyer (Carolina Academic Press, Durham, North Carolina, 1991), Mr. Mayberry provided an interpretation of the geology in the Haw River Valley, as follows.

The Piedmont and Blue Ridge Provinces share a geologic history dating back to the formation of the continental landmasses. The mountain building of the region is attributed to plate tectonics, the spectrum of uplifting, and erosion. Long-term erosion has reduced the mountains to lower, more level terrains that gently slope toward the ocean. The Piedmont and Coastal Plain landforms are part of the erosional leveling process of the third global tectonic cycle.

The rock units in the Haw River Valley region date back approximately 700 million years. In contrast, the age of the rock units of the Yadkin Valley region, in the western part of the Piedmont Province, date back approximately 1.5 billion years.

The Haw River Valley region, including its rock units, is the geological result of volcanic metamorphism and igneous activity stemming from island arcs. Island arcs form when a continental plate overrides an oceanic plate, resulting in subduction zones that create volcanoes. In the northeastern part of the proposed viticultural area a caldera formed in an area of formerly intense volcanic activity. The caldera collapsed into a 36-by 9-mile ellipse-shaped area that igneous rock eventually filled.

The proposed Haw River Valley viticultural area lies in the Carolina Slate Belt, a result of tectonic movements of the North American and African continental plates. The slate belt trends to the northwest and disappears under the Carolina Coastal Plain, which extends southeast and eventually dips under the Atlantic Ocean.

Finally, according to Mr. Mayberry, the major rock types in the Haw River Valley include the following: Porpyritic Granite/Felsic Intrusive Complex, Felsic Gneiss, Mafic Volcanics, Felsic Volcanics, Intermediate Intrusive Rocks, Mica Gneiss, and Mica Schist (Muscovite and/or Biotite). The Haw River Valley igneous and metamorphic rocks, composed of magma, differ from those rocks formed from magma in the western Piedmont and Appalachian Mountains.

Soils

The petitioner states that James Lewis, soil scientist, Natural Resources Conservation Service, United States Department of Agriculture, provided the soils information for the Haw River Valley viticultural area petition. In his research, Mr. Lewis consulted the published soil surveys of Alamance, Caswell, Chatham, Guilford, Orange, and Rockingham Counties, North Carolina, and available updates to existing soil surveys.

According to Mr. Lewis, the soils of the proposed Haw River Valley viticultural area, compared to those of the surrounding regions, have unique and distinguishable characteristics. Most of the soils in the Haw River Valley are acidic and low in natural fertility.

The proposed Haw River Valley viticultural area is entirely in the udic soil moisture regime. (The udic moisture regime is common to soils of humid climates with well-distributed rainfall or with enough rain in summer that the amount of stored moisture plus rainfall is approximately equal to, or exceeds, the amount of evapotranspiration. In most years, at some time during the year water moves down through the soil.) Further, the proposed viticultural area lies dominantly in the thermic soil temperature regime, averaging 59 to 72 degrees F at a soil depth of 20 inches.

The soils in the proposed viticultural area formed primarily in residuum, or saprolite, weathered from igneous, intermediate, and mafic intrusive rocks and in felsic and intermediate volcanic rocks of the Carolina Slate Belt.

In the central portion of the proposed Haw River Valley viticultural area, the soils formed in residuum from mafic intrusive rocks. In these areas the soils have a clayey subsoil of mixed mineralogy and slightly better natural fertility than that of the soils to the east and south. The Mecklenburg soils are on nearly level and moderately steep uplands. These soils have moderately slow permeability. The Enon and Iredell soils are on uplands and some side slopes. These soils have a clayey subsoil and have a high or very high shrink-swell potential, respectively; because of these properties, they have poor internal drainage and perch water during wet periods.

In the western and northeastern portions of the proposed viticultural area, the soils formed mainly in igneous and intermediate intrusive rocks. In these areas the Cecil, Appling, Vance, Helena, and Sedgefield soils are dominant. Typically, these soils are deep and have a clayey subsoil. Also scattered throughout these areas are the Enon and Iredell soils formed in mafic, intrusive rocks.

In the northwesternmost portion of the proposed viticultural area, the soils formed in residuum derived from metamorphic rocks. In this area the Fairview, Clifford, Toast, and Rasalo soils on nearly level to steep uplands are dominant. Further, except for the Rasalo soils, these soils are very deep and well drained, and have a clayey subsoil, moderate permeability, and good internal structure. In the Rasalo soils, because of high shrinking and swelling in the clayey subsoil and slow permeability, the soils tend to perch water during wet periods.

In the eastern and southern portions of the Haw River Valley and in parts of the southwestern and northwestern portions, the soils formed primarily in residuum derived from felsic and intermediate volcanic rocks. In these areas the Georgeville and Herndon soils are very deep and well drained, and have a loamy surface layer, a clayey subsoil, moderate permeability, and good internal structure. These soils are on gently sloping to moderately steep uplands. Also in these areas are the Callison, Secrest, and Kirksey soils. These soils are moderately well drained and have a loamy surface layer and subsoil. These soils are on level flats and gently sloping upland ridges, in depressions, and around heads of drains. They vary in depth depending on the underlying soft and hard bedrock; consequently, they have poor

internal drainage and perch water during wet periods.

The soils weathered from rocks within the proposed Haw River Valley viticultural area have significant differences compared to the soils in the surrounding areas to the east, west, and south. However, they are similar to the soils in the surrounding north portion and in the northwesternmost portion of the proposed viticultural area.

East of the proposed Haw River Valley viticultural area, on the Inner Coastal Plain, the soils, predominantly Udults, have a thermic temperature regime, a udic moisture regime, a loamy or sandy surface layer, and a loamy or clayey subsoil. The soils are generally deep and well drained to poorly drained, and maintain adequate moisture during the viticultural growing season.

West of the proposed Haw River Valley viticultural area, most soils formed in saprolite weathered from igneous intrusive rocks and some gneisses and schists of the Charlotte Belt. However, some soils formed in residuum derived from intrusions of mafic rocks and have a clay subsoil of mixed mineralogy. The Gaston and Mecklenburg soils have moderate or moderately slow permeability and are moderately suitable for viticulture. The Enon and Irdell soils are also west of the proposed viticultural area.

According to ''Scientists Study Why More Storms Form in the Sandhills in the Summer,'' a news release dated July 5, 2001, from North Carolina State University, the soils are deep and sandy in the Sandhills region south of the proposed Haw River Valley viticultural area. Unlike the clay soils in the Piedmont, these soils, like the sandy loam of the Inner Coastal Plain, do not have much clay.

Elevation

The elevations in the proposed Haw River Valley viticultural area range from 350 feet at the southeastern boundary corner to over 800 feet at the northwestern boundary corner, according to elevation maps by John Boyer (Virginia Polytechnic Institute and State University, 2001) that the North Carolina Grape Council provided. The four physiographic regions of North Carolina are the eastern Outer Coastal Plain, the Inner Coastal Plain, the central Piedmont Province, and the western Blue Ridge Province, as shown on the Physiography of North Carolina map by M.A. Medina et al. (North Carolina Geological Survey, Division of Land Resources, 2004).

The Haw River Valley region lies in the Piedmont Province near the demarcation of the fall line with the Inner Coastal Plain, according to ''History and Environment of North Carolina's Piedmont Evolution of a Value-Added Society,'' by John Rogers (University of North Carolina, Department of Geology, 1999). Areas near the fall zone vary from 300 to 600 feet in elevation, in contrast with the approximately 1,500-foot elevation at the foot of the Blue Ridge Mountains, as shown on the Boyer maps.

The Piedmont Province consists of generally rolling, well rounded hills and ridges with a difference in elevation of a few hundred feet between the hills and valleys, according to the Boyer maps. The Inner Coastal Plain, which has stair-step planar terraces that dip gently toward the ocean, ranges from 25 to 600 feet in elevation, the petitioner explains.

Climate

The climatic features that distinguish the proposed Haw River Valley viticultural area are precipitation, air temperature, and growing season, according to the petitioner. The Haw River Valley has more moderate temperatures and greater precipitation than those in the surrounding areas outside the proposed boundary line. The climate within the Haw River Valley, which is generally similar throughout, varies from the surrounding regions outside the proposed viticultural area, according to data obtained from the Southeast Regional Climate Center (SRCC) and from horticultural information leaflets by Katharine Perry (North Carolina State University, revised December 1998).

The data from SRCC includes those from stations within and outside of the boundary line of the proposed Haw River Valley viticultural area, according to the petitioner. The table below lists the SRCC weather stations consulted and the direction and distance of the location of each weather station in relation to the Haw River Valley.

Weather station	Compass direction from Haw River Valley	Approximate distance from Haw River Valley
Brookneal, Virginia	North	84 miles.
Louisburg, North Carolina	East	52 miles.
Pinehurst, North Carolina	South	70 miles.
Mocksville, North Carolina	West	50 miles.

The air temperatures in the Haw River Valley region are generally warmer than those in the area to the north, cooler than those in the areas to the south and east, and similar to those in the area to the west on the Piedmont Province, the petitioner explains using SRCC data. The petitioner also provides, in the table below, the SRCC average annual high and low air temperatures, snow accumulation, and rainfall for the Haw River Valley and the areas outside the proposed boundary line.

Relation to the proposed Haw River Valley viticultural area	Average annual			
	High air temperature	Low air temperature	Snow accumulation	Rainfall
Inside the boundary line	69.8 °F	46.6 °F	5.9 in	45.27 in.
To the north	67 °F	42 °F	11.3 in	41.65 in.
To the east	71.4 °F	46 °F	4.1 in	45.98 in.
To the south	72.7 °F	49.2 °F	4.1 in	49.11 in.
To the west	70 °F	45.1 °F	9.9 in	44.57 in.

According to the petitioner, the annual frost-free growing season of the proposed Haw River Valley viticultural area runs from April 1 to November 1 and totals 214 days. The growing season is 2 to 4 weeks longer than that for the region to the west, and is similar to those for the regions to the immediate south and to the east of the proposed boundary line. The growing season length and frost-free dates fall within the parameters for successful viticulture of vinifera, hybrid, and Muscadine grapes, according to the ''Analysis for Viticultural Suitability in North Carolina,'' a map prepared by John Boyer (Virginia Polytechnic Institute and State University, 2001).

TTB Determination

TTB concludes that this petition to establish the 868-square-mile Haw River Valley viticultural area merits consideration and public comment as invited in this notice.

Boundary Description

See the narrative boundary description of the petitioned-for viticultural area in the proposed regulatory text published at the end of this notice.

Maps

The petitioner provided the required maps, and we list them below in the proposed regulatory text.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. If we establish this proposed viticultural area, its name, ''Haw River Valley,'' will be recognized as a name of viticultural significance under 27 CFR 4.39(i)(3). In addition, with the establishment of the Haw River Valley viticultural area, the name ''Haw River'' standing alone will be considered a term of viticultural significance because consumers and vintners could reasonably attribute the quality, reputation, or other characteristic of wine made from grapes grown in the proposed Haw River Valley viticultural area to the name Haw River itself. A name has viticultural significance when determined by a TTB officer (see 27 CFR 4.39(i)(3)). Therefore, the proposed part 9 regulatory text set forth in this document specifies both ''Haw River Valley'' and ''Haw River'' as terms of viticultural significance for purposes of part 4 of the TTB regulations.

If this proposed text is adopted as a final rule, wine bottlers using ''Haw River Valley'' or ''Haw River'' in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the viticultural area's full name or ''Haw River'' as an appellation of origin.

For a wine to be labeled with a viticultural area name or with a brand name that includes a viticultural area name or other term identified as being viticulturally significant in part 9 of the TTB regulations, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name or other term, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with the viticultural area name or other viticulturally significant term and that name or term appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the viticultural area name or other viticulturally significant term appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Accordingly, if a label uses the name ''Haw River Valley'' or ''Haw River'' for a wine that does not meet the 85 percent standard, the label will be subject to revocation upon the effective date of the approval of the Haw River Valley viticultural area.

Different rules apply if a wine has a brand name containing a viticultural area name or other term of viticultural significance that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

Public Participation

Comments Invited

We invite comments from interested members of the public on whether we should establish the proposed viticultural area. We are interested in receiving comments on the sufficiency and accuracy of the name, climatic, boundary and other required information submitted in support of the petition. In addition, we are interested in receiving comments on the proposal to identify ''Haw River'' as a term of viticultural significance. Please provide any available specific information in support of your comments.

Because of the potential impact of the establishment of the proposed Haw River Valley viticultural area on wine labels that include the words ''Haw River Valley'' or the words ''Haw River'' as discussed above under ''Impact on Current Wine Labels,'' we are particularly interested in comments regarding whether there will be a conflict between the proposed viticulturally significant terms and currently used brand names. If a commenter believes that a conflict will arise, the comment should describe the nature of that conflict, including any anticipated negative economic impact that approval of the proposed viticultural area will have on an existing viticultural enterprise. We are also interested in receiving suggestions for ways to avoid conflicts, for example by adopting a modified or different name for the viticultural area.

Submitting Comments

You may submit comments on this notice by using one of the following two methods:

- *Federal e-Rulemaking Portal:* You may electronically submit comments on this notice through Regulations.gov, the Federal e-rulemaking portal. A direct link to the Regulations.gov page containing this notice and its related comment submission form is available on the TTB Web site at *http://www.ttb.gov/wine/wine_rulemaking.shtml* under Notice No. 81. You may also reach this notice and its related comment form via the Regulatons.gov search page at *http://www.regulations.gov*. Supplemental files may be attached to comments submitted via Regulations.gov. For complete instructions on how to use Regulations.gov, visit the site and click on ''User Guide'' under ''How to Use this Site.''
- *Mail:* You may send written comments to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 14412, Washington, DC 20044–4412.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 81 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. We do not acknowledge receipt of comments, and we consider all comments as originals.

If you are commenting on behalf of an association, business, or other entity, your comment must include the entity's name as well as your name and position title. If you comment via *http://www.regulations.gov*, please enter the entity's name in the ''Organization'' blank of the comment form. If you comment via mail, please submit your entity's comment on letterhead.

You may also write to the Administrator before the comment closing date to ask for a public hearing. The Administrator reserves the right to

determine whether to hold a public hearing.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

Public Disclosure

On the Federal e-rulemaking portal, Regulations.gov, we will post, and you may view, copies of this notice and any electronic or mailed comments we receive about this proposal. A direct link to the Regulations.gov docket containing this notice and the posted comments received on it is available on the TTB Web site at *http://www.ttb.gov/wine/wine_rulemaking.shtml* under Notice No. 81. You may also reach the docket containing this notice and the posted comments received on it through the Regulatons.gov search page at *http://www.regulations.gov*. For instructions on how to use Regulations.gov, visit the site and click on ''User Guide'' under ''How to Use this Site.''

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including e-mail addresses. We may omit voluminous attachments or material that we consider unsuitable for posting.

You also may view copies of this notice and any electronic or mailed comments we receive about this proposal by appointment at the TTB Information Resource Center, 1310 G Street, NW., Washington, DC 20220. You may also obtain copies at 20 cents per 8.5 x 11-inch page. Contact our information specialist at the above address or by telephone at 202–927–2400 to schedule an appointment or to request copies of comments or other materials.

Regulatory Flexibility Act

We certify that this proposed regulation, if adopted, would not have a significant economic impact on a substantial number of small entities. The proposed regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of a viticultural area name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

This proposed rule is not a significant regulatory action as defined by Executive Order 12866. Therefore, it requires no regulatory assessment.

Drafting Information

N.A. Sutton of the Regulations and Rulings Division drafted this notice.

List of Subjects in 27 CFR Part 9

Wine.

Proposed Regulatory Amendment

For the reasons discussed in the preamble, we propose to amend title 27, chapter 1, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

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

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

2. Amend subpart C by adding § 9.__ to read as follows:

§ 9.__ Haw River Valley.

(a) *Name.* The name of the viticultural area described in this section is ''Haw River Valley''. For purposes of part 4 of this chapter, ''Haw River Valley'' and ''Haw River'' are terms of viticultural significance.

(b) *Approved maps.* The two United States Geological Survey 1:100,000-scale metric topographic maps used to determine the boundary of the Haw River Valley viticultural area are titled:

(1) Greensboro, North Carolina, 1984; and

(2) Chapel Hill, North Carolina, 1984.

(c) *Boundary.* The Haw River Valley viticultural area is located in all of Alamance County and portions of Caswell, Chatham, Guilford, Orange, and Rockingham Counties. The boundary of the Haw River Valley viticultural area is as described below:

(1) Begin at a point on the Greensboro map at the intersection of the Caswell and Orange Counties boundary line with Lynch Creek, southeast of Corbett and the Corbett Ridge, and then proceed in a straight line southeast 2 miles to the intersection of North Carolina State Highway 49 and an unnamed, light-duty road, known locally as McCulloch Road, located approximately 1 mile northeast of Carr, in west Orange County; then

(2) Proceed in a straight line south-southwest 11.9 miles, crossing over U.S. Interstate 85, to Buckhorn at Turkey Hill Creek in west Orange County; then

(3) Proceed in a straight line southeast 5.2 miles, crossing onto the Chapel Hill map, to its intersection with Dodsons Crossroad and an unnamed, light-duty road that runs generally north-northeast-south-southwest in west Orange County; then

(4) Proceed south-southwest on the unnamed, light-duty road 3.4 miles to its intersection with North Carolina State Highway 54, also known as Star Route 54, east of White Cross in west Orange County; then

(5) Proceed southeast in a straight line 14.1 miles, crossing over Terrells Mountain, Wilkinson Creek and several of its eastern tributaries, and U.S. Route 15–501, to its intersection with an unnamed road, known locally as Gilead Church Road, and U.S. Route 64 at Griffins Crossroads in Chatham County; then

(6) Proceed generally west along U.S. Route 64 approximately 20.7 miles to its intersection with U.S. Route 421 in Siler City, Chatham County; then

(7) Proceed generally northwest on U.S. Route 421 approximately 5.6 miles to its intersection with the Randolph County line, southeast of Staley; then

(8) Proceed straight north along the Randolph County line 7.4 miles to its intersection with the Guilford County line; then

(9) Proceed straight west along the Randolph County line 5.8 miles to its intersection with U.S. Route 421; then

(10) Proceed in a straight line north-northwest 20.5 miles, crossing onto the Greensboro map, to its intersection with U.S. Route 29 and North Carolina State Highway 150, between Browns Summit and Monticello in Guilford County; then

(11) Proceed generally east and north on North Carolina State Highway 150 approximately 4.3 miles to its intersection with North Carolina State Highway 87, east-northeast of Williamsburg in southeast Rockingham County; then

(12) Proceed in a straight line east-northeast 8.3 miles, crossing over the Caswell County line to a point at the intersection of the 236-meter elevation line, as marked on the map, and an unnamed road, known locally as Cherry Grove Road; then

(13) Proceed east and southeast along the unnamed road, known locally as Cherry Grove Road, 5 miles to its intersection with North Carolina State Highway 62 at Jericho in Caswell County; then

(14) Proceed generally southeast on North Carolina State Highway 62 approximately 1.8 miles to its intersection with an unnamed road, known locally as Bayne's Road at Anderson in Caswell County; then

(15) Proceed generally east on the unnamed road known locally as Bayne's Road 2 miles to its intersection with North Carolina State Highway 119 at Baynes in Caswell County; then

(16) Proceed generally south-southeast along North Carolina State Highway 119 approximately 1.7 miles to its intersection with the Caswell County line; then

(17) Proceed straight east along the Caswell County line 4.3 miles to the beginning point.

Signed: March 1, 2008.

John J. Manfreda,

Administrator.

[FR Doc. E8–6508 Filed 3–28–08; 8:45 am]

BILLING CODE 4810–31–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1611

Privacy Act Regulations

AGENCY: Equal Employment Opportunity Commission.

ACTION: Proposed rule.

SUMMARY: The Equal Employment Opportunity Commission is proposing to revise its regulations at 29 CFR Part 1611, which implement the Privacy Act of 1974, to exempt one of its systems of records from one of the Act's requirements.

DATES: Written comments on the proposed rule must be received on or before May 30, 2008. The Commission proposes to consider any comments received and thereafter adopt final regulations.

ADDRESSES: Written comments should be submitted to Stephen Llewellyn, Executive Officer, Equal Employment Opportunity Commission, 1801 L Street, NW., Washington, DC 20507. As a convenience to commentators, the Executive Secretariat will accept comments transmitted by facsimile (''FAX'') machine. The telephone number of the FAX receiver is (202) 663–4114. (This is not a toll-free number.) Only comments of six or fewer pages will be accepted via FAX transmittal. This limitation is necessary to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTD). (These are not toll-free telephone numbers.) You may also submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments. Copies of comments submitted by the public will be available to review at the Commission's library, Room 6502, 1801 L Street, NW., Washington, DC 20507 between the hours of 9:30 a.m. and 5 p.m. or can be reviewed at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas J. Schlageter, Assistant Legal Counsel, or Kathleen Oram, Senior Attorney, at (202) 663–4640 (voice) or (202) 663–7026 (TTY). Copies of this final rule are also available in the following alternate formats: large print, braille, audiotape and electronic file on computer disk. Requests for this notice in an alternative format should be made to EEOC's Publication Center at 1–800–669–3362 (voice) or 1–800–800–3302 (TTY).

SUPPLEMENTARY INFORMATION: The Equal Employment Opportunity Commission proposes to add a new section 1611.15 to its Privacy Act regulations to exempt records contained in EEOC–22, EEOC Personnel Security Files, from the accounting and disclosure provisions of the Privacy Act in accordance with section k(5) of the Act, but only to the extent that an accounting of disclosures or a disclosure itself identifies witnesses promised confidentiality as a condition of providing information during the course of a background investigation. The Commission also proposes to amend sections 1611.5(a)(5) and 1611.5(b) to conform them to the addition of the new exemption.

Regulatory Procedures

Executive Order 12866

Pursuant to Executive Order 12866, EEOC has determined that the regulation will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. Therefore, a detailed cost-benefit assessment of the regulation is not required.

Paperwork Reduction Act

This rule contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Regulatory Flexibility Act

The Commission, in accordance with the Regulatory Flexibility Act (5 U.S.C. 606(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This action concerns agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 29 CFR Part 1611

Privacy Act.

Dated: March 25, 2008.

For the Commission,

Naomi C. Earp,

Chair.

Accordingly, it is proposed to amend chapter XIV of title 29 of the Code of Federal Regulations as follows:

PART 1611—PRIVACY ACT REGULATIONS

1. The authority citation for part 1611 continues to read as follows:

Authority: 5 U.S.C. 552a.

2. In § 1611.5, revise paragraphs (a)(5) and (b) to read as follows:

§ 1611.5 Disclosure of requested information to individuals.

(a) * * *

(5) The Commission shall not deny any request under § 1611.3 concerning the existence of records about the requester in any system of records it maintains, or any request for access to such records, unless that system is exempted from the requirements of 5 U.S.C. 552a in §§ 1611.13, 1611.14, or 1611.15.

* * * * *

(b) Upon request, the appropriate Commission official shall make available an accounting of disclosures pursuant to 5 U.S.C. 552a(c)(3), unless that system is exempted from the

requirements of 5 U.S.C. 552a in §§ 1611.13, 1611.14, or 1611.15.

* * * * *

3. Section 1611.15 is added to read as follows:

§ 1611.15 Exemption—EEOC Personnel Security Files.

EEOC's system of records entitled EEOC Personnel Security Files contains records that document and support decisions regarding suitability, eligibility and fitness for service of applicants for EEOC employment and contract positions. The records include background investigation records. Pursuant to section (k)(5) of the Privacy Act, 5 U.S.C. 552a(k)(5), this system of records is exempt from the provisions of sections (c)(3) and (d)(1) of the Privacy Act, 5 U.S.C. 552a(c)(3) and (d)(1), but only to the extent that the accounting of disclosures or the disclosure of such material would reveal the identity of a source who furnished information to the government under an express promise that the identity of the source would be held in confidence.

[FR Doc. E8–6551 Filed 3–28–08; 8:45 am]

BILLING CODE 6570–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1625

RIN 3046–AA76

Disparate Impact Under the Age Discrimination in Employment Act

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Equal Employment Opportunity Commission (''EEOC'' or ''Commission'') is issuing this notice of proposed rulemaking (''NPRM'') to address issues related to the United States Supreme Court's decision in *Smith* v. *City of Jackson*. The Court ruled that disparate impact claims are cognizable under the Age Discrimination in Employment Act (''ADEA'') but that liability is precluded when the impact is attributable to a reasonable factor other than age. Current EEOC regulations interpret the ADEA as prohibiting an employment practice that has a disparate impact on individuals within the protected age group unless it is justified as a business necessity.

DATES: Comments must be received on or before May 30, 2008. The Commission will consider any comments received on or before the closing date and thereafter adopt final regulations. Comments received after the closing date will be considered to the extent practicable.

ADDRESSES: You may submit comments by any of the following methods:

- By mail to Stephen Llewellyn, Executive Officer, Executive Secretariat, Equal Employment Opportunity Commission, 1801 L Street, NW., Washington, DC 20507.
- By facsimile (''FAX'') machine to (202) 663–4114. (There is no toll free FAX number). Only comments of six or fewer pages will be accepted via FAX transmittal, in order to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTY). (These are not toll free numbers).
- By the Federal eRulemaking Portal: *http://www.regulations.gov.* After accessing this web site, follow its instructions for submitting comments.

Instructions: All comment submissions must include the agency name and docket number or the Regulatory Information Number (RIN) for this rulemaking. Comments need be submitted in only one of the above-listed formats, not all three. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information you provide. Copies of the received comments also will be available for inspection in the EEOC Library, FOIA Reading Room, by advanced appointment only, from 9 a.m. to 5 p.m., Monday through Friday except legal holidays, from May 30, 2008 until the Commission publishes the rule in final form. Persons who schedule an appointment in the EEOC Library, FOIA Reading Room, and need assistance to view the comments will be provided with appropriate aids upon request, such as readers or print magnifiers. To schedule an appointment to inspect the comments at the EEOC Library, FOIA Reading Room, contact the EEOC Library by calling (202) 663–4630 (voice) or (202) 663–4641 (TTY). (These are not toll free numbers).

FOR FURTHER INFORMATION CONTACT: Dianna B. Johnston, Assistant Legal Counsel, or Lyn J. McDermott, Senior Attorney-Advisor, at (202) 663–4638 (voice) or (202) 663–7026 (TTY). (These are not toll free numbers). This notice also is available in the following formats: large print, Braille, audio tape and electronic file on computer disk. Requests for this notice in an alternative format should be made to the Publications Information Center at 1–800–669–3362 (voice) or 1–800–800–3302 (TTY).

SUPPLEMENTARY INFORMATION: In *Smith* v. *City of Jackson*, 544 U.S. 228 (2005), the United States Supreme Court held that the ADEA authorizes recovery for disparate impact claims of discrimination. This holding validated the Commission's longstanding rule that disparate impact analysis applies in ADEA cases. The Court also held that the ''reasonable factors other than age'' (''RFOA'') test, rather than the business-necessity test, is the appropriate standard for determining the lawfulness of a practice that disproportionately affects older individuals. This ruling differs from the EEOC's position that an employment practice that had a disparate impact on individuals within the protected age group could not be a reasonable factor other than age unless it was justified as a business necessity. The Commission proposes to amend its regulation to reflect the Supreme Court's decision.

Smith v. City of Jackson

The *Smith* plaintiffs, senior police and public safety officers, alleged that the defendant City's pay plan had a disparate impact on older workers because it gave proportionately larger pay increases to newer officers than to more senior officers. Older officers, who tended to hold senior positions, on average received raises that represented a smaller percentage of their salaries than did the raises given to younger officers. The City explained that, after a survey of salaries in comparable communities, it raised the junior officers' salaries to make them competitive with those for comparable positions in the region. 544 U.S. at 241–42.

The Fifth Circuit Court of Appeals dismissed the plaintiffs' disparate impact claim on the ground that such claims ''are categorically unavailable under the ADEA.'' *Id.* at 231. The Supreme Court disagreed and ruled that plaintiffs may challenge facially neutral employment practices under the ADEA. *Id.* at 233–40. The Court also ruled, however, that the ''scope of disparate-impact liability under the ADEA is narrower than under Title VII'' of the Civil Rights Act of 1964, 42 U.S.C. 2000e *et seq.*[1] 544 U.S. at 240.

[1] Title VII prohibits employment discrimination based on race, color, religion, sex, and national origin. In *Griggs* v. *Duke Power Co.,* 401 U.S. 424 (1971), the Supreme Court first recognized the disparate impact theory of discrimination under Title VII. The Court held that Title VII prohibits not only intentional discrimination but also employment practices that, because they have a

Continued

In holding that disparate impact claims are cognizable under the ADEA, the Supreme Court relied in large part on the parallel prohibitory language and the common purposes of the ADEA and Title VII. *Id.* at 233–40. *Accord McKennon* v. *Nashville Banner Pub. Co.,* 513 U.S. 352, 358 (1995) (statutes share ''common substantive features'' and ''common purpose: 'the elimination of discrimination in the workplace''') (quoting *Oscar Meyer & Co.* v. *Evans,* 441 U.S. 750, 756 (1979)). The Court noted that, in passing the ADEA, Congress was concerned that application of facially neutral employment standards, such as a high school diploma requirement, may ''unfairly'' limit the employment opportunities of older individuals. 544 U.S. at 235 n.5 (quoting Report of the Sec'y of Labor, The Older American Worker: Age Discrimination in Employment 3 (1965), *reprinted in* U.S. EEOC, Leg. History of the ADEA 21 (1981)) (''Wirtz Report''). The Court observed that there is a ''remarkable similarity between the congressional goals'' of Title VII and ''those present in the Wirtz Report.'' 544 U.S. at 235 n.5.

At the same time, however, the Court identified two key textual differences that affect the relative scope of disparate impact liability under the two statutes. First, the ADEA contains the RFOA provision, which has no parallel in Title VII and precludes liability for actions ''otherwise prohibited'' by the statute ''where the differentiation is based on reasonable factors other than age.'' [2] Id. at 240. Second, in reaction to the decision in *Wards Cove Packing Co.* v. *Atonio,*[3] which ''narrowly construed the employer's exposure to liability on a disparate-impact theory,'' Congress amended Title VII but not the ADEA. 544 U.S. at 240 (citing the Civil Rights Act of 1991, sec. 2, 105 Stat. 1071). Accordingly, ''*Wards Cove*'s pre-1991 interpretation of Title VII's identical language remains applicable to the ADEA.'' 544 U.S. at 240.[4]

Applying its analysis, the Court rejected the *Smith* plaintiffs' disparate impact claims on the merits. The Court ruled that the plaintiffs failed to satisfy *Wards Cove's* requirement that they identify a ''specific test, requirement, or practice within the pay plan that has an adverse impact on older workers.'' *Id.* at 241.

In addition, focusing on the plan's purpose, design, and implementation, the Court found that the City's pay plan was based on reasonable factors other than age. The Court noted that the City grouped officers by seniority in five ranks and set wage ranges based on salaries in comparable communities. Most of the officers were in the three lowest ranks, where age did not affect officers' pay. In the two highest ranks, where all of the officers were over 40, raises were higher in terms of dollar amounts; they were lower only in terms of percentage of salary. The Court concluded that the plan, as designed and administered, ''was a decision based on a 'reasonable factor other than age' that responded to the City's legitimate goal of retaining police officers.'' *Id.* at 242.

Finally, the Court noted that, although ''there may have been other reasonable ways for the City to achieve its goals, the one selected was not unreasonable.'' Unlike Title VII's business necessity defense, which requires the employer to use the least discriminatory alternative, ''the reasonableness inquiry includes no such requirement.'' *Id.* at 243.

Revisions to Agency Regulations

The Commission proposes to revise current paragraph 1625.7(d) to state that an employment practice that has an adverse impact on individuals within the protected age group on the basis of older age is discriminatory unless the practice is justified by a ''reasonable factor other than age'' (RFOA). This revision reflects the Supreme Court's conclusion that disparate impact claims are cognizable under the ADEA and that the RFOA test, rather than the business-necessity test, is the appropriate standard for determining the lawfulness of a practice that disproportionately affects older individuals.

The proposed revision also states that the individual challenging the allegedly unlawful employment practice bears the burden of isolating and identifying the specific employment practice responsible for the adverse impact. As the Supreme Court stressed in *Smith,* ''it is not enough to simply allege that there is a disparate impact on workers, or point to a generalized policy that leads to such an impact. Rather, the employee is 'responsible for isolating and identifying the specific employment practices that are allegedly responsible for any observed statistical disparities.' ''[5]

The Commission proposes to revise current paragraph 1625.7(e) to state that, when the RFOA exception is raised, the employer has the burden of showing that a reasonable factor other than age exists factually. This section reiterates the Commission's longstanding position that the RFOA provision creates an affirmative defense that the employer must establish.[6]

Requiring the employer to bear the burden of proof is consistent with the language and structure of the ADEA. The RFOA provision is found in section 4(f)(1) of the ADEA, which states that ''[i]t shall not be unlawful for an employer * * * to take any action otherwise prohibited [by the ADEA] where age is a bona fide occupational qualification [''BFOQ''] reasonably

disparate impact on a group protected by Title VII, are ''fair in form but discriminatory in operation.'' *Id.* at 431.

[2] The Court found that the presence of the RFOA provision supported its conclusion that disparate impact claims are cognizable under the ADEA. 544 U.S. at 238–40. The RFOA provision ''plays its principal role'' in disparate impact cases, where it ''preclud[es] liability if the adverse impact was attributable to a nonage factor that was 'reasonable.' '' *Id.* at 239. Comparing the RFOA provision with the Equal Pay Act provision that precludes recovery when a pay differential is based on ''any other factor other than sex,'' 29 U.S.C. 206(d)(1), the Court found it ''instructive'' that ''Congress provided that employers could use only *reasonable* factors in defending a suit under the ADEA.'' 544 U.S at 239 n.11 (emphasis in the original).

[3] 490 U.S. 642 (1989).

[4] The ''identical'' language is in section 703(a)(2) of Title VII (42 U.S.C. 2000e–2(a)(2)) and section 4(a)(2) of the ADEA (29 U.S.C. 623(a)(2)), which make it unlawful for employers ''to limit, segregate, or classify'' individuals in a manner that would deprive or tend to deprive any individual of employment opportunities or otherwise adversely affect his status as an employee, because of such individual's [protected status].

The language of the two statutes significantly differs, however, with regard to the applicable defense. Unlike the ADEA, which provides a defense when the practice is based on a reasonable factor other than age (29 U.S.C. 623(f)(1)), Title VII provides a defense only when the practice is job related and consistent with business necessity (42 U.S.C. 2000e–2(k)(1)(A)).

[5] *Smith* v. *City of Jackson,* 544 U.S. 228, 241 (2005) (quoting *Wards Cove,* 490 U.S. at 656) (emphasis in *Smith*).

[6] Until recently, most courts treated RFOA as an affirmative defense. *See, e.g.*, *Enlow* v. *Salem-Keizer Yellow Cab Co., Inc.* 389 F.3d 802, 807–08 (9th Cir. 2004) (in the context of a disparate treatment claim, characterizing the RFOA as an affirmative defense and holding that it was unavailable where the challenged practice is based on age), *cert. denied,* 544 U.S. 974 (2005); *E.E.O.C.* v. *Johnson & Higgins, Inc.,* 91 F.3d 1529, 1541 (2d Cir. 1996) (same), *cert. denied,* 522 U.S. 808 (1997). However, the Second and Tenth Circuits have recently concluded that defendants bear only the burden of production, not the burden of persuasion, on the issue. *Meacham* v. *Knolls Atomic Power Lab.,* 461 F.3d 134, 141–43 (2d Cir. 2006), *cert. granted,* 76 U.S.L.W. 3391 (U.S. Jan. 18, 2008) (No. 06–1505); *Pippin* v. *Burlington Res. Oil & Gas Co.,* 440 F.3d 1186, 1200 (10th Cir. 2006). *But see Meacham,* 461 F3d at 147–53 (Pooler, J., dissenting) (RFOA is an affirmative defense). The court in *EEOC* v. *Allstate Ins. Co.,* 458 F. Supp. 2d 980 (E.D. Mo. 2006), *certification for interlocutory appeal on other grounds granted,* 2007 WL 38675 (E.D. Mo. Jan. 4, 2007), did not analyze the issue but followed the lead of *Pippin* and *Meacham* to conclude that the defendant did not bear the burden of proof. For the reasons explained in the text and accompanying footnotes, the Commission disagrees with *Meacham* and *Pippin* and concludes that the RFOA burden of proof rests with the employer.

necessary to the normal operation of the particular business, or where the differentiation is based on reasonable factors other than age.'' 29 U.S.C. 623(f)(1). Since the employer indisputably bears the burden of proving BFOQ,[7] the most natural construction of section 4(f)(1) as a whole is that the employer similarly bears the burden of proving RFOA. In addition, when Congress enacted the Older Workers Benefit Protection Act (''OWBPA'') amendments to the ADEA in 1990, it specifically stated that the employer bears the burden of proof on the RFOA affirmative defense in section 4(f)(1). S. Rep. No. 101–263, at 30 (1990), *as reprinted in* 1990 U.S.C.C.A.N. 1509, 1535 (noting that Congress was incorporating into section 4(f)(2) ''the language of [section] 4(f)(1) that is commonly understood to signify an affirmative defense''). This approach also is consistent with the allocation of burdens under the Equal Pay Act of 1963, 29 U.S.C. 206(d)(1), which precludes liability when the employer establishes that a pay differential is ''based on any other factor other than sex,'' 29 U.S.C. 206(d)(1)(iv).[8] The *Smith* Court did not need to discuss the burden of proof because the employer's actions were so eminently reasonable that it easily prevailed regardless of who bore the ultimate burden.

The Commission invites comments on these proposed changes from all interested parties. The Commission also invites comments on whether the regulations should address other matters concerning the application of the disparate impact theory of discrimination under the ADEA. In particular, the Commission would welcome comments on the following specific question:

1. Should the regulations provide more information on the meaning of ''reasonable factors other than age''? If so, what should the regulations say? For example, should the regulations refer to tort law standards such as negligence and reasonable standard of care when addressing the meaning of ''reasonable''? Should the regulations offer factors relevant to whether an employment practice is based on reasonable factors other than age? If so, what should those factors be?

[7] *See Smith,* 544 U.S. at 233 n.3 (2005) (referring to the BFOQ provision as ''an affirmative defense to liability'').

[8] *Corning Glass Works* v. *Brennan,* 417 U.S. 188, 196–97 (1974) (shifting the burden of proof to the employer ''is consistent with the general rule that the application of an exemption under the Fair Labor Standards Act is a matter of affirmative defense on which the employer has the burden of proof'').

Regulatory Procedures

Executive Order 12866

Pursuant to Executive Order 12866, EEOC has coordinated this proposed rule with the Office of Management and Budget. Under section 3(f)(1) of Executive Order 12866, EEOC has determined that the regulation will not have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State or local tribal governments or communities. Therefore, a detailed cost-benefit assessment of the regulation is not required.

Paperwork Reduction Act

This proposal contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

Regulatory Flexibility Act

The Commission certifies under 5 U.S.C. 605(b) that this proposed rule will not have a significant economic impact on a substantial number of small entities because it imposes no economic or reporting burdens on such firms and makes no change to employers' compliance obligations under the Act. Instead, the proposed rule brings the Commission's regulations into compliance with a recent Supreme Court interpretation of the Act. For this reason, a regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

List of Subjects in 29 CFR Part 1625

Advertising, Age, Employee benefit plans, Equal employment opportunity, Retirement.

Dated: March 25, 2008.

For the Commission.

Naomi C. Earp,

Chair.

For the reasons set forth in the preamble, the Equal Employment Opportunity Commission proposes to amend 29 CFR chapter XIV part 1625 as follows:

PART 1625—AGE DISCRIMINATION IN EMPLOYMENT ACT

1. The authority citation for part 1625 continues to read as follows:

Authority: 81 Stat. 602; 29 U.S.C. 621; 5 U.S.C. 301; Secretary's Order No. 10–68; Secretary's Order No. 11–68; Sec. 9, 81 Stat. 605; 29 U.S.C. 628; sec. 12, 29 U.S.C. 631, Pub. L. 99–592, 100 Stat. 3342; sec. 2, Reorg. Plan No. 1 of 1978, 43 FR 19807.

Subpart A—Interpretations

2. Revise paragraphs (d) and (e) of § 1625.7 to read as follows:

§ 1625.7 Differentiations based on reasonable factors other than age.

* * * * *

(d) Any employment practice that adversely affects individuals within the protected age group on the basis of older age is discriminatory unless the practice is justified by a ''reasonable factor other than age.'' An individual challenging the allegedly unlawful practice is responsible for isolating and identifying the specific employment practice that is allegedly responsible for any observed statistical disparities.

(e) Whenever the exception of ''a reasonable factor other than age'' is raised, the employer bears the burden of proving that the ''reasonable factor other than age'' exists factually.

* * * * *

[FR Doc. E8–6517 Filed 3–28–08; 8:45 am]

BILLING CODE 6570–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0065]

RIN 1625–AA00

Safety Zone: Stars and Stripes Fourth of July Fireworks Event, Nansemond River, Suffolk, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes establishing a safety zone on the Nansemond River in the vicinity of Suffolk, VA in support of the Stars and Stripes Fourth of July Fireworks event. This action is intended to restrict vessel traffic movement on the Nansemond River to protect mariners from the hazards associated with fireworks displays.

DATES: Comments and related material must reach the Coast Guard on or before April 30, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2008–0065 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call Lieutenant Junior Grade Chris Porter, Assistant Chief, Waterways Management Division, Sector Hampton Roads at (757) 668–5580. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–0065), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, click on ''Search for Dockets,'' and enter the docket number for this rulemaking (USCG–USCG–2008–0065) in the Docket ID box, and click enter. You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or the Commander, Sector Hampton Roads, Norfolk Federal Building, 200 Granby St., 7th Floor between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov.*

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

On July 4, 2008, the City of Suffolk, VA will sponsor a fireworks display on the Nansemond River in position 36° − 44′ −27.3″ N/076° −34′ −42″W (NAD 1983). Due to the need to protect mariners and spectators from the hazards associated with the fireworks display, access to the Nansemond River within 500 feet of the fireworks barge will be temporarily be restricted.

Discussion of Proposed Rule

The Coast Guard is establishing a safety zone on specified waters of the Nansemond River in the vicinity of Constant's Wharf in Suffolk, VA. This safety zone will encompass all navigable waters within 500 feet of the fireworks barge located in position 36° − 44′ −27.3″ N/076° −34′ −42″ W (NAD 1983). This regulated area will be established in the interest of public safety during the Stars and Stripes spectacular event and will be enforced from 5 p.m. to 10 p.m. on July 04, 2008. Access to the safety zone will be restricted during the specified date and times. Except for participants and vessels authorized by the Captain of the Port or his Representative, no person or vessel may enter or remain in the regulated area.

Regulatory Evaluation

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analysis based on 13 of these statutes or executive orders.

Executive Order 12866

This proposed 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. Although this regulation restricts access to the regulated area, the effect of this rule will not be significant because: (i) The safety zone will be in effect for a limited duration; and (ii) the Coast Guard will make notifications via maritime advisories so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed 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 proposed rule would not have a significant economic impact on a substantial number of small entities because the zone will only be in place for a limited duration and maritime advisories will be issued allowing the mariners to adjust their plans accordingly. However, this rule may affect the following entities, some of which may be small entities: the owners and operators of vessels intending to transit or anchor in that portion of the Nansemond River from 5 p.m. to 10 p.m. on July 4, 2008.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the proposed rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lieutenant Junior Grade Chris Porter, Assistant Chief, Waterways Management Division, Sector Hampton Roads at (757) 668–5584. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect 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 proposed 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 proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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. We invite your comments on how this proposed rule might impact tribal governments, even if that impact may not constitute a ''tribal implication'' under the Order.

Energy Effects

We have analyzed this proposed 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed 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 made a preliminary determination that this action is not likely to have a significant effect on the human environment. A preliminary ''Environmental Analysis Check List'' supporting this preliminary determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

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

Words of Issuance and Proposed Regulatory Text

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, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T05–008 to read as follows:

§ 165.T05–008 Safety Zone: Stars and Stripes Fourth of July Fireworks Event, Nansemond River, Suffolk, VA.

(a) *Location.* The following area is a safety zone: All waters of the Nansemond River, located within 500 feet of position 36° −44′ −27.3″ N/076° −34′ −42″ W in the vicinity of Constant's Wharf, Suffolk, VA. These coordinates are based upon (NAD 1983).

(b) *Definition:* Captain of the Port Representative: means any U.S. Coast Guard commissioned, warrant or petty officer who has been authorized by the Captain of the Port, Hampton Roads, Virginia to act on his behalf.

(c) *Regulation:*

(1) In accordance with the general regulations in 165.23 of this part, entry into this zone is prohibited unless authorized by the Captain of the Port, Hampton Roads or his designated representatives.

(2) The operator of any vessel in the immediate vicinity of this safety zone shall:

(i) Stop the vessel immediately upon being directed to do so by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(ii) Proceed as directed by any commissioned, warrant or petty officer on shore or on board a vessel that is displaying a U.S. Coast Guard Ensign.

(1) The Captain of the Port, Hampton Roads and the Sector Duty Officer at Sector Hampton Roads in Portsmouth, Virginia can be contacted at telephone Number (757) 668–5555 or (757) 484–8192.

(2) The Coast Guard Representatives enforcing the safety zone can be contacted on VHF–FM 13 and 16. (d) Effective Period: This regulation will be in effect from 5 p.m. to 10 p.m. on July 4, 2008.

Dated: March 14, 2008.

Patrick B. Trapp,

Captain, U.S. Coast Guard, Captain of the Port, Hampton Roads.

[FR Doc. E8–6474 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2008–0097]

RIN 1625–AA00

Safety Zone: Thames River, New London, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone on the federal channel of the Thames River surrounding the Amtrak Railroad Bridge in the Town of New London, Connecticut. This safety zone is necessary to protect vessels transiting in the area from hazards imposed by construction barges and equipment. The barges and equipment are being utilized to remove the old bascule bridge and install a new vertical lift span bridge over the Thames River. Entry into this zone will be prohibited unless authorized by the Captain of the Port, Long Island Sound.

DATES: Comments and related material must reach the Coast Guard on or before April 30, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2008–0097 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov*.

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001.

(3) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

(4) *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call LT D. J. Miller, Chief, Waterways Management, Coast Guard Sector Long Island Sound, 203–468–4596. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2008–0097), indicate the specific section of this document to which each comment applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time. Enter the docket number for this rulemaking (USCG–2008–0097) in the Search box, and click ''Go >>.'' You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or U.S. Coast Guard Sector Long Island Sound, 120 Woodward Ave, New Haven, Connecticut 06512 between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

Privacy Act

Anyone can 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov*.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

Currently, there is an Amtrak Railroad bascule bridge over the Thames River in the Town of New London, Connecticut. Amtrak decided to replace the 100 year old bascule bridge that crosses the Thames River with a new lift bridge. In 2005, the Coast Guard approved bridge construction and issued a permit for bridge construction for the Amtrak Railroad Bridge over the Thames River. Contractors began work constructing the two-lift span mechanism for the new bridge in early June 2005. To complete the construction on the bridge, barges need to block the navigable federal channel during the removal of the old bascule bridge and the installation of the new vertical lift span bridge. To ensure the continued safety of the boating community, the Coast Guard is establishing a safety zone in all navigable waters of the federal channel on the Thames River within 300 yards of the bridge. This proposed rule will effectively close the federal channel for the duration of the enforcement period; however, vessels that may safely navigate outside of the federal channel may continue to do so. This safety zone is necessary to protect the safety of the boating community who wish to utilize the federal channel on the Thames River in the vicinity of the Amtrak railroad bridge. Marine traffic may transit safely outside of the safety zone during the effective dates of the safety zone, allowing navigation in all other areas of the Thames River, except the portion delineated by this rule. Additionally, Coast Guard District One Bridge Branch will be issuing a Deviation to Bridge Operations for a period both before and after the removal of the span to facilitate the removal process.

Discussion of Proposed Rule

This regulation proposes to establish a temporary safety zone on the navigable federal channel of the Thames River within 300-yards of the Amtrak Railroad Bridge. This action is intended to prohibit vessel traffic in a portion of the federal channel on the Thames River in the Town of New London, Connecticut to provide for the safety of the boating community due to the hazards posed by significant construction equipment located in the waterway during the removal of the existing bascule bridge and installation of a new vertical lift span bridge. The safety zone will be needed for four consecutive days during the month of June 2008. Therefore, the safety zone would be in effect from 12:01 a.m. on June 14, 2008 until 11:59 p.m. on June 17, 2008. Notification for enforcement of the safety zone will be made via notice in the **Federal Register**, marine broadcasts and broadcast notice to mariners. Marine traffic that may safely do so, may transit outside of the safety zone during the enforcement period, allowing navigation on other portions of the Thames River no covered by this rule. Entry into this safety zone would be prohibited unless authorized by the Captain of the Port, Long Island Sound. Any violation of the safety zone described herein is punishable by, among others, civil and criminal penalties, in rem liability against the offending vessel, and license sanctions.

Regulatory Evaluation

This proposed 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.

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation is unnecessary. This regulation may have some impact on the public, but the potential impact would be minimized for the following reason: vessels may transit in all areas of the Thames River other than the area of the safety zone with minimal increased transit time and the safety zone will only be effective for a four-day period.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed 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 proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule may affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit in those portions of the Thames River in the Town of New London, Connecticut covered by the safety zone. For the reasons outlined in the Regulatory Evaluation section above, this rule will not have a significant impact on a substantial number of small entities.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

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 proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lieutenant Douglas Miller, Chief, Waterways Management at (203) 468–4596 or the Command Center at Coast Guard Sector Long Island Sound, CT, at (203) 468–4444. The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This proposed rule would call 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 proposed 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 proposed rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not effect 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 proposed 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 proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would 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 proposed 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.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed 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 made a preliminary determination that this action is not likely to have a significant effect on the human environment. A preliminary ''Environmental Analysis Check List'' supporting this preliminary determination is available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

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

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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 and 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Public Law 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

2. Add § 165.T01–0097 to read as follows:

§ 165.T01–0097 Safety Zone: Amtrak Railroad Bridge over Thames River Channel, Town of New London, CT.

(a) *Location*. The following area is a safety zone: All navigable waters of the federal channel on the Thames River in New London, CT, from surface to bottom, within 300 yards of the Amtrak Railroad Bridge.

(b) *Definitions*. The following definitions apply to this section: *Designated on-scene patrol personnel*, means any commissioned, warrant and petty officers of the U.S. Coast Guard operating Coast Guard vessels who has been authorized to act on the behalf of the Captain of the Port, Long Island Sound.

(c) *Regulations*. (1) The general regulations contained in 33 CFR § 165.23 apply.

(2) In accordance with the general regulations in § 165.23 of this part, entry into or movement within this zone is prohibited unless authorized by the Captain of the Port, Long Island Sound.

(3) All persons and vessels must comply with the Coast Guard Captain of the Port or the designated on-scene patrol personnel.

(4) Upon being hailed by a U.S. Coast Guard vessel by siren, radio, flashing light or other means, the operator of the vessel must proceed as directed.

(5) Persons and vessels may request permission to enter the zone on VHF–16 or via phone at (203) 468–4401.

(d) *Effective Period*. This rule is effective from 12:01 a.m. on June 14, 2008 to 11:59 p.m on June 17, 2008.

(e) *Enforcement Period*. This rule will be enforced for a 4 day period based on construction plans by Amtrak. Notification of enforcing the safety zone will be made via notice in the **Federal Register**, marine broadcasts and broadcast notice to mariners

Dated: March 10, 2008.

Daniel A. Ronan,

Captain, U.S. Coast Guard, Captain of the Port, Long Island Sound.

[FR Doc. E8–6472 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Parts 26 and 28

[Docket No. USCG–2003–16158]

RIN 1625–AA77

Commercial Fishing Industry Vessels

AGENCY: Coast Guard, DHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Coast Guard is developing a set of proposed amendments to its commercial fishing industry vessel regulations. The proposed changes would enhance maritime safety by adding new requirements for vessel stability and watertight integrity, stability training and assessments, vessel maintenance and self-examinations, immersion suits, crew preparedness, safety training, emergency preparation, safety and training personnel, safety equipment, and documentation. Miscellaneous conforming, clarifying, and other administrative changes are also contemplated.

DATES: Comments and related material must reach the Docket Management Facility on or before July 29, 2008.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2003–16158 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) *Online: http://www.regulations.gov.*

(2) *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

(3) *Fax:* 202–493–2251.

(4) *Hand delivery:* Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call M.M. Rosecrans, Chief, Fishing Vessel Safety Division (CG–5433), U.S. Coast Guard, telephone 202–372–1245, or e-mail *Michael.m.rosecrans@uscg.mil.* If you have questions on viewing or submitting material to the docket, call Ms. Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see DOT's ''Privacy Act'' paragraph below.

We are interested in the potential impacts from this proposed rule on small businesses and we request public comment on these potential impacts. If you think that this proposed rule would have a significant economic impact on you, your business, or your organization, please submit a comment to the Docket Management Facility at the address under **ADDRESSES**. In your comment, explain why, how, and to what degree you think this rule would have an economic impact on you.

A. Submitting Comments

If you submit a comment, please include your name and address, identify the docket number for this rulemaking (USCG–2003–16158), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

B. Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* at any time, click on ''Search for Dockets,'' and enter the docket number for this rulemaking (USCG–2003–16158) in the Docket ID box, and click enter. You may also visit the Docket Management Facility in room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

C. Privacy Act

Anyone can 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 the Department of Transportation's Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or you may visit *http://DocketsInfo.dot.gov.*

D. Public Meeting

The Coast Guard anticipates wide interest in this rulemaking and is considering how best to obtain early spoken comments from the public. If we determine a cost-effective way to receive spoken comments from all segments of the commercial fishing vessel industry and from the general public, we will announce it in a subsequent **Federal Register** notice.

II. Acronym Table

Acronym	Text
CFIVSAC	Commercial Fishing Industry Vessel Safety Advisory Committee.
CFR	Code of Federal Regulations.
CPR	Cardiopulmonary Resuscitation.
DOT	Department of Transportation.
EPIRB	Emergency Position Indicating Radio Beacon.
F/V	Fishing Vessel.
FRP	Fiberglass-reinforced Plastic.
IMO	International Maritime Organization.
NPRM	Notice of Proposed Rulemaking.
SNPRM ..	Supplemental Notice of Proposed Rulemaking.
U.S.C.	United States Code.

III. Note on the Regulatory Framework Affecting Commercial Fishing Industry Vessels

In the discussions that follow, we sometimes distinguish between documented and undocumented vessels. Under 46 U.S.C. chapter 121, a vessel of at least five net tons must meet the ownership tests and other criteria needed to obtain a certificate of documentation (Form CG–1270) with a fishery endorsement, before it can be employed in processing, storing, transporting (except in foreign commerce), planting, cultivating, catching, taking, or harvesting fish, shellfish, marine animals, pearls, shells, or marine vegetation in the navigable waters of the United States or its Exclusive Economic Zone. For Coast Guard regulations affecting the

documentation of fishing industry vessels, see 46 CFR part 67. Fishing industry vessels 100 feet or greater in length are also subject to Maritime Administration requirements found in 46 CFR part 356.

IV. Background and Purpose

Commercial fishing remains one of the most hazardous occupations in the United States. Congress addressed this problem by enacting the Commercial Fishing Industry Vessel Safety Act of 1988 (''the 1988 Act,'' Pub. L. 100–424, as subsequently amended; see generally, 46 U.S.C. chapter 45, ''Uninspected Commercial Fishing Industry Vessels''). The Act directed the Secretary of Transportation to provide safety requirements for fishing vessels, fish processing vessels, and fish tender vessels. It also established the Commercial Fishing Industry Vessel Safety Advisory Committee (CFIVSAC) to advise the Secretary on matters relating to the safe operation of commercial fishing vessels.

Coast Guard regulations under the 1988 Act were first issued on August 14, 1991 (56 FR 40364), and were further addressed in the following documents:

- August 3, 1992, interim rule (57 FR 34188) that amended the 1991 immersion suit requirements in 46 CFR 28.110, but advised the public that immersion suits would be the subject of further rulemaking;
- October 27, 1992, SNPRM (57 FR 48670) that proposed the adoption of stability regulations for vessels less than 79 feet in length;
- May 20, 1993, NPRM (58 FR 29502) that proposed further changes to immersion suit requirements;
- October 24, 1995, final rule (60 FR 54441) that adopted regulations for Aleutian Trade Act vessels;
- November 5, 1996, interim rule (61 FR 57268) that adopted safety equipment and vessel operating procedure regulations and deferred further action on the 1992 SNPRM's proposal to extend stability regulations to smaller vessels;
- September 4, 1997, final rule (62 FR 46672) that finalized the 1996 regulations with some changes; and
- July 15, 1998, notice (63 FR 38141) that announced the termination of the 1993 NPRM and the Coast Guard's plans for a subsequent rulemaking to address immersion suits, vessel stability, and other commercial fishing industry vessel issues.

These documents, as well as other background documents, are available in the docket. Each document may be downloaded.

In addition to past **Federal Register** notices, two recent studies indicated the need for further regulatory action. The first was the report of the Fishing Vessel Casualty Task Force appointed by the Coast Guard in 1999, following the loss of 11 commercial fishermen's lives in just three weeks. The Task Force report, ''Living to Fish, Dying to Fish'' (March 1999, see the docket), concluded that Coast Guard regulations issued under the 1988 Act had improved fishing vessel safety, but also identified several areas where further action is necessary. The Task Force recognized that some actions would be difficult to achieve; for instance, they concluded that an inspection program aimed at eliminating or reducing unsafe conditions would have the greatest beneficial impact on safety, but would be the most difficult measure to implement.

The second study was compiled by the Coast Guard and is titled ''Analysis of Fishing Vessel Casualties—A Review of Lost Fishing Vessels and Crew Fatalities, 1994–2004'' (''the 1994–2004 analysis''). This document is also available in the docket. Based upon the analysis, we concluded that flooding and capsizing are major causes of vessel loss and that casualties could be reduced by extending stability regulations to vessels less than 79 feet in length, improving crew preparedness, and by extending immersion suit requirements.

The tables that follow show data for vessel losses, fatalities, and cause of vessel losses from the 1994–2004 analysis. The data is included to clarify discussions elsewhere in this preamble. The numbers from these tables are used in the discussions that follow.

TABLE 1.—VESSEL LOSSES

Year	Number
1994	153
1995	117
1996	166
1997	138
1998	125
1999	123
2000	85
2001	133
2002	127
2003	114
2004	117
Total	1398

TABLE 2.—CAUSE OF VESSEL LOSS

Cause	Number
Flooding	493
Fire	282
Grounding	236
Capsizing	142
Collision	55
Allision	52
Unknown	42
Structural failure	35
Loss of vessel control	25
Weather	18
Explosion	9
Loss of electrical power	5
Overloading	1
Other	3
Total	1398

TABLE 3.—CAUSE OF FATALITIES

Casualty type	Fatalities
Vessel flooding, sinking, capsizing	328
Fall into water	154
Pulled overboard by gear	29
Diving accident	27
Dangerous atmosphere	18
Caught in winch	16
Smoke inhalation—vessel fire	10
Unknown injury type	10
Crushed by gear	10
Struck by line	7
Struck by moving object	7
Drowned clearing propeller	4
Caught in lines	3
Vessel collision	3
Other	15
Total	641

The major cause of fatalities between 1994 and 2004 can be traced to vessel losses. In the period reviewed, 1,398 vessels were lost and there were 641 fatalities. Of the 641 fatalities, 328 can be attributed to vessel losses (*i.e.*, flooding, sinking, and capsizing).

A. Past Recommendations

In addition to the two aforementioned studies, the Coast Guard reviewed all recommendations previously made regarding commercial fishing industry vessel safety. We examined recommendations from the National Transportation Safety Board, Marine Boards of Investigation, the Task Force report, and formal and informal marine casualty investigations. We then collected similar recommendations and determined the appropriate action to take for each group and individual recommendation.

Many recommendations addressed seeking authority to inspect commercial fishing industry vessels and to license mariners on board commercial fishing industry vessels to improve the condition of vessels and the competency

of mariners. The 1988 Act required the CFIVSAC to submit recommendations to Congress on inspection of vessels and licensing of mariners in the commercial fishing industry. The CFIVSAC recommended that Congress mandate vessel inspections and licensing of mariners. The Coast Guard requested additional authority to reclassify commercial fishing industry vessels as inspected vessels. This authority could provide for design and construction standards, mandatory inspections, and licensing of mariners on commercial fishing industry vessels similar to current requirements for cargo, passenger, and tank vessels. Congress has not granted the requested authority.

Wherever regulatory development authority already exists, we have analyzed each recommendation to determine the appropriate action. Some of the recommendations needed no action as regulations or policies already address the recommendation. Some recommendations form the basis of the potential regulatory changes discussed here. In certain cases, we would consider phasing in new requirements in order to reduce the economic burden on industry. Other safety recommendations are either inappropriate, overtaken by events, or otherwise untimely. The results of this review, entitled ''Review of Commercial Fishing Industry Vessel Safety Recommendations'', are available in the docket.

In the following pages, we discuss the principal changes we are considering. Many changes could include documentation requirements. Documentation gives owners and operating personnel a written record of regulatory compliance, reinforces the importance of that compliance, and facilitates quick compliance verification by the Coast Guard and other regulators.

V. Discussion of Regulatory Changes Under Consideration

A. Overview

Table 4 shows an overview of the new requirements we are considering, by vessel length. The potential new requirements are explained in more detail later in this document.

New stability and watertight integrity requirements, except for training, would apply only to vessels 50 to 79 feet because of the findings of the 1994–2004 analysis, the recommendations of the CFIVSAC, and because existing regulations apply to most vessels over 79 feet in length.

TABLE 4.—APPLICABILITY OF POTENTIAL NEW REQUIREMENTS BY VESSEL LENGTH

New requirement under consideration	All lengths	30′ > L < = 40′	40′ > L < = 50′	50′ > L < = 60′	60′ > L < = 70′	70′ > L < = 80′	L > 80′
Initial Stability Test				X	X	X	
Stability Review at Alteration				X	X	X	
Five-Year Periodic Stability Review				X	X	X	X
Shipbuilding Requirements				X	X	X	
Stability Training		X	X	X	X	X	X
Immersion Suits	X	X	X	X	X	X	X
Safety Training, Emergency Drills and Documentation		X	X	X	X	X	X
EPIRB		X	X	X	X	X	X
Survival Craft Stowage							X
Embarkation Station							X
High Water Alarms		X	X	X	X	X	X
Door Notice	X	X	X	X	X	X	X
Departure Reports				X	X	X	X

B. Vessel Stability and Watertight Integrity

The major new requirements we are considering for vessel stability and watertight integrity include:

- Stability requirements for vessels between 50 and 79 feet in length and certain loadlined vessels that are currently exempt from stability requirements;
- Stability training for masters and owners of vessels greater than 30 feet in length;
- Minimum criteria for stability training and training instructors;
- Repeating lightweight surveys (and in some circumstances, inclining tests) and updating stability instructions at least once every five years;
- Addition of new items to be addressed in stability instructions;
- Revision of certain stability calculations;
- Upgrading and highlighting of weathertight and watertight integrity requirements to prevent unintentional flooding;
- Emphasis on the owner's, as well as the master's, responsibility for vessel stability; and
- Notification to the Coast Guard prior to substantial vessel alteration or major conversion, recognizing that many stability and watertight integrity improvements can be made economically only during original construction or during a major modification.

1. General Discussion

Stability is the capacity of a vessel to return to an upright condition after being ''heeled'' or leaned over by external forces. Watertight integrity refers to a vessel's ability to withstand a static head of water without any leakage. Current Coast Guard regulations require stability calculations to be made, and stability instructions prepared, for newly constructed or substantially altered vessels of 79 feet or more in length. We are considering adding stability and watertight integrity requirements for fishing vessels between 50 and 79 feet in length. Stability and watertight integrity standards have been designed with 50- to 79-foot vessels in mind. Vessels of less than 50 feet in length might also benefit from such standards, but because standards for those vessels have not yet been designed, we are considering only 50-to 79-foot vessels at this time.

The 1988 Act mandates regulations for the operating stability of certain vessels. We originally proposed applying stability regulations to vessels of any length, but comments on our 1991 rulemaking expressed concern that the proposed standards drew upon International Maritime Organization (IMO) stability standards developed for vessels of 79 feet or more in length (''Torremolinos International Convention for the Safety of Fishing Vessels'', 1977) that would be inappropriate for smaller vessels. In light of those concerns, we set the 1991 rule's threshold at 79 feet, but we indicated our intention to revisit requirements for smaller vessels. In 1992, we proposed extending stability regulations to smaller vessels, but as previously noted that regulatory effort was deferred in 1996.

The 1999 Task Force report called for developing stability regulations for vessels greater than 50 feet in length (Recommendation 4.1). As previously mentioned, the 1994–2004 analysis identified flooding, sinking, and capsizing as the leading causes of vessel loss. Of the vessel losses, capsizing accounted for 142 vessel losses (10 percent of all vessel losses). Of the 328 fatalities, 115 can be attributed to capsizing and sudden sinkings where individuals had insufficient time to properly use survival equipment, including immersion suits. These statistics explain why the Coast Guard continues to be concerned with stability and watertight integrity issues within the commercial fishing industry.

In 1995, the CFIVSAC was asked to assist in developing stability standards for commercial fishing industry vessels less than 79 feet in length. In 1997, the CFIVSAC's stability subcommittee offered a set of recommended standards that would apply to commercial fishing industry vessels 50 feet or more in length. Those recommended standards are contained in the docket and form the basis of the stability requirements we are considering for vessels 50 to 79 feet in length.

The Task Force report called for changes in how stability is treated. Recommendations addressed developing instructions readily understood by masters (Recommendation 4.3) and programmatic enforcement of all requirements with a focus on dockside checks (Recommendation 3.2). In 1999, due to the high number of deaths in the Alaska/Bering Sea crab fisheries, the Coast Guard and the Alaska Department of Fish and Game began a program to analyze crab-vessel loading when stability instructions are provided on board the vessel prior to departure. Despite having stability information on board, overloading still occurred in some instances. Factors contributing to this, as confirmed in casualty investigations, are that the calculations often were not understood by operating personnel and stability information was often not updated after changes were made to the vessel, which invalidated the instructions provided.

2. Stability Training

Lack of situational awareness and understanding regarding stability principles and watertight integrity have been shown to contribute to or have been the primary reasons for a high percentage of vessel losses from sinking, flooding, and sudden capsizing. Analysis of recommendations made for improving commercial fishing industry vessel safety from Coast Guard investigating officers, the Task Force report, and other sources offer a number of recommendations for improving the competency of vessel masters relating to stability. Training in these principles may help prevent the cause of vessel losses. Therefore, we are considering requiring stability training for vessels 30 feet or more in length. We believe the 30-foot threshold covers all those vessels that are likely to operate in conditions where such training can be a critical safety factor.

The CFIVSAC has previously recommended mandatory stability training for masters of vessels. In July 2005, the CFIVSAC was asked to provide specific recommendations on who must have stability training and the composition of that training. The CFIVSAC recommended that the Coast Guard require masters and owners to receive a three-tiered regimen of stability instruction:

1. General principles of stability;
2. Risk factors specific to the region or fishery in which engaged; and
3. Vessel-specific training.

The requirements we are considering would be consistent with these recommendations.

The Coast Guard is inclined to adopt the CFIVSAC recommendation to require owners to receive training, since they provide operational guidance to the master in many instances. It is also the owner's responsibility to ensure the master is prepared for a voyage, including, but not limited to, understanding: the stability and watertight integrity risk factors; the stability instructions; and loading constraints and restrictions for the vessel.

The 1983 Marine Board of Investigation for the capsizing of the F/V ALTAIR and F/V AMERICUS stated that:

> There is convincing evidence that commercial fishermen in general lack an appreciation of principles of stability. This investigation demonstrated that there was a critical failure to utilize information (stability booklets) readily available for determining safe loading.

An example of lack of situational awareness regarding stability is the sinking of the F/V NORTHERN EDGE. The F/V NORTHERN EDGE blocked its freeing ports as a standard practice when dumping scallops on deck. In an instant, the vessel took water on deck that could not run off because of the blocked freeing ports. Water entered the vessel's interior through an open weathertight door that led to progressive flooding and sudden capsizing with the loss of five persons. Stability training would be intended to raise the situational awareness of masters, including the hazards presented by blocking freeing ports and leaving doors that may permit downflooding to remain open when not used for transit.

3. Stability Reassessment

The basis of all stability calculations is an accurate weight and location of the center of gravity in the lightweight condition. Any time there is uncertainty regarding the lightweight values, a reassessment of stability and/or a determination of the revised lightweight values is necessary.

A vessel in service for a period of time will experience weight changes. Some changes are easily determined such as the addition or removal of large equipment. In addition to weight changes that can be accurately determined from manufacturer's information, unaccounted weight changes occur. Unless carefully managed, weight changes tend to degrade the stability of a vessel by increasing the vessel's lightweight thereby decreasing the reserve buoyancy and raising the center of gravity, which decreases overall stability. Unfortunately, most vessels do not have a weight management system to account for the many large and small changes that occur; therefore, as a vessel ages, the margin of safety degenerates and a stability reassessment is needed. A stability review at least once every five years could be a reasonable interval for examining the vessel for the accumulated changes, both known and unknown.

We are considering requiring a lightweight survey to determine the amount of change to a vessel's lightweight. If changes can be accounted for accurately, the lightweight survey would be sufficient and the stability instructions could be updated based on that survey. Otherwise, an inclining test could be required to determine the lightweight and location of the center of gravity.

C. Vessel Maintenance and Self-Examination

We are considering requiring the owners of vessels that operate beyond the boundary line, with more than 16 persons on board, or that are fish-tender vessels in the Aleutian trade to conduct monthly self-examinations of their vessels according to criteria that we would provide. Masters would document these self-examinations.

The 1994–2004 analysis revealed that the majority (69 percent) of vessel losses can be attributed to hull and machinery failures. Predominantly, the losses

occurred while the vessels were not engaged in fishing operations. The most prevalent operation directly preceding a vessel loss (616) was transiting during non-fishing activities. The next most prevalent operation contributing to vessel loss was sinking while the vessel was moored (163).

The vessels experiencing the highest numbers of losses were wooden-hull vessels (548), steel-hull vessels (277), and fiberglass-reinforced plastic (FRP) hull vessels (261). Of the wooden-hull vessels lost, 265 (48 percent) were between 20 and 40 years old. For steel-hull vessels lost, 185 (66 percent) were between 20 and 40 years old. For FRP-hull vessels lost, 197 (75 percent) were in this age range.

Hull and machinery failures leading to vessel loss accounted for 25 percent of the 328 fatalities attributed to vessel flooding, sinking, or capsizing. Maintenance is an issue of major concern in reducing the likelihood of vessel losses and consequent fatalities. Because vessel loss is a major contributor to fatalities, reductions in vessel losses should lead to fewer fatalities.

The 1988 Act authorized the Coast Guard to develop regulations for equipment, maintenance, and use of equipment to minimize the risk of serious injury on documented fishing industry vessels that operate beyond the boundary line, with more than 16 individuals on board, or that are fish-tender vessels in the Aleutian trade. The 1988 Act also requires regulations for operational stability, as mentioned elsewhere in this document. In addition, the Coast Guard has developed regulations for fire protection, fire extinguishing, firefighting equipment, dewatering and bilge systems, fuel systems, and electrical systems. Each of these areas has a critical maintenance component. For instance, a watertight hull envelope, which is necessary for operational stability, can be compromised by loose planking, corroded or eroded hull plating, or wasted-through hull fittings, all of which can lead to breaches of a vessel's watertight integrity and stability degradation.

As previously discussed, the Coast Guard lacks authority for mandatory inspections of most commercial fishing industry vessels. Nonetheless, periodic examinations of a vessel and its equipment by personnel on board the vessel or other employees selected by the owner may accomplish safety improvements by reducing the number of vessel losses from machinery and hull failures.

Self-examinations would be the responsibility of the owner and the master. The owner would determine: (a) The level of detail for the examination; (b) the testing required as part of the examination process; and (c) the acceptance criteria for each item examined, if none is otherwise specified by regulation. The master would be the individual that either performs the examinations or supervises the examination process and documents acceptable completion of the examination. The master would be required to maintain a record of examinations.

Most vessel owners and masters are familiar enough with their vessels that they are already effectively performing these periodic examinations. For those owners and masters, these requirements would have little impact. For owners and masters that do not follow good marine practice and do not routinely check their vessel's condition, these requirements would mean spending the time to systematically examine the vessel and its equipment and document the examinations. Given the high number of vessels lost to mechanical and hull failures, improvements within vessel maintenance areas should reduce vessel losses and fatalities. A more formal process and documentation of examinations may lead to better maintenance.

As vessels become larger and more complex, the ability of the master to personally perform all examinations becomes increasingly difficult. It is common for larger vessels to have licensed engineers and mates on board to share the burden and responsibility with the master for performing examinations or to have specialized vendors and subcontractors perform some maintenance and examinations. These persons would be able to continue those processes as before with the exception of documenting their examinations.

D. Immersion Suits

The immersion suit requirements in 46 CFR 28.110 were originally issued in 1991. We amended the requirements in 1992 in response to public objections.

Documented commercial fishing industry vessels currently must carry immersion suits whenever operating seaward of the boundary line and beyond 32 degrees north or 32 degrees south latitude. Prior to the 1992 amendment, we also applied this requirement to documented vessels on any of the Great Lakes.

We are considering requiring vessels to carry immersion suits for their crew members whenever they operate in seasonally-cold waters. We would define ''seasonally cold'' much as we did in our 1993 NPRM.

All vessels, whether documented or not, must carry immersion suits while operating beyond-coastal cold waters; in Pacific coastal waters north of Point Reyes, CA; and on Lake Superior. Prior to the 1992 amendment, we also applied this requirement to all vessels operating in any cold-coastal waters or on any of the other Great Lakes. In issuing the 1992 amendment, we stated our intention to undertake further rulemaking under a recommendation of the CFIVSAC, which continued to support the 1991 scope of the requirement.

Our 1993 NPRM proposed extending immersion suit requirements to coastal and beyond-coastal waters that, regardless of latitude, are so cold at certain seasons that immersion suits can be important safety equipment. As previously noted, we terminated this proposal in 1998, with the intention of revisiting the immersion suit issue at a later time.

The 1994–2004 analysis of fishing vessel casualties identified water exposure as ''by far the most significant factor in personnel loss'' and pointed out that water exposure is involved in 80 percent of all fatalities. Two hundred and thirty-four (71 percent) fatalities from vessel losses occurred in west coast and northeastern waters that tend to be colder and more severe than elsewhere in the country. At the same time, Coast Guard data indicate ''fishermen survive nearly twice as often when survival equipment is used.'' The survival rate is even higher in the case of immersion suits: 61 percent for West Coast and northeastern incident victims who used the suits, compared with 27 percent for those who did not. Based on data from cold waters, we expect that requiring vessels to carry immersion suits if they are operating in cold waters would likely reduce casualties.

E. Crew Preparedness

We are considering the following crew preparedness requirements for vessels that operate beyond the boundary line, with more than 16 persons on board, or that are fish-tender vessels in the Aleutian trade:

- Recurring crew safety and survival training;
- Recurring drill requirements;
- Designation of a vessel safety officer;
- Presence of an on board drill conductor;
- Minimum training requirements for safety instructors, drill conductors, and

other individuals who are required to have safety training; and

• Cardiopulmonary resuscitation (CPR) and First Aid retraining every three years.

1. Training and Drills

The 1994–2004 analysis showed a marked increase in survivability for those familiar with lifesaving equipment, especially personal flotation devices. Of the 328 vessel-related fatalities due to sinking, flooding, and capsizing, only 48 (15 percent) had properly used personal flotation devices or immersion suits. Fatalities involving vessels that operate beyond the boundary line, with more than 16 persons on board, or that are fish-tender vessels in the Aleutian trade might be decreased by increasing the frequency with which realistic drills, involving all crew members, cover the proper use of lifesaving equipment.

The Marine Board of Investigation report into the 2001 sinking of the F/V ARCTIC ROSE, with the loss of 15 lives, recommended requiring recurring safety and survival training.

The need for this training is further demonstrated by the sinking of the F/V GULF KING 15. On December 11, 1997, the F/V GULF KING 15 burned and sank in the waters of the Gulf of Mexico, approximately 60 miles south of Freeport, Texas. The emergency position indicating radio beacon (EPIRB) failed to transmit a distress signal. All three crewmembers on board were able to abandon the vessel; however, they were unable to properly deploy the liferaft. They managed to cling to the uninflated liferaft for several hours. One of the crew drowned after letting go of the raft and the vessel master drowned while being rescued by another vessel. Had the EPIRB been operating properly, the crew would have had a better chance of surviving the casualty. Liferaft deployment and EPIRB operation are two of the topics that would be covered in the safety training we are considering.

A number of training organizations offer the type of training we have in mind, but it is not widespread enough for most of the commercial fishing industry. We think the initial investment for those desiring to provide this training is low and that the facilities needed for this training are generally available throughout the country.

We are considering requiring emergency drills after any personnel change involving persons to whom safety responsibilities are assigned. Most crews are small and rely heavily on teamwork and a shared understanding of responsibilities, equipment, and methodologies in an emergency. Having only one individual with safety responsibilities within a crew of eight or less can significantly affect the functioning of the team, because team members are highly interdependent during an emergency.

2. Vessel Safety Officer

We are considering requiring vessels that operate beyond the boundary line, with more than 16 persons on board, or that are fish-tender vessels in the Aleutian trade, to have a designated safety officer. The safety officer would report to the master, or if the master is the designated safety officer, to the owner. The safety officer would report on the condition or status of safety equipment, emergency instruction, emergency drills, and safety orientations, among other things. The purpose of having a designated safety officer is to reinforce the importance of safety on board fishing industry vessels. The larger the vessel, the more responsibility the master has. The master has primary responsibility for safety on board, but his or her many other responsibilities can detract from the master's focus on safety.

The designation of a safety officer would not relieve the master of responsibility for the safety of the vessel and crew. The safety officer could provide assistance to the master in safety responsibilities and be a constant reminder that safety should never be overlooked, forgotten, or subordinated to other vessel business.

3. On Board Drill Conductors

For vessels that operate beyond the boundary line, with more than 16 persons on board, or that are fish-tender vessels in the Aleutian trade, we are considering requiring an on board fishing vessel drill conductor to conduct safety orientations. This requirement would conform to recommendations of the Task Force report and the casualty investigation on the sinking of the fish processing vessel GALAXY. Each orientation would include survival equipment location and use, and any potential hazards affecting the vessel such as deck machinery, hazardous materials, or confined or unventilated spaces. Addressing these potential hazards would increase the overall safety awareness of the crewmembers in their work environment. The lessons initially communicated through safety orientations would be reinforced through monthly emergency drills.

Current regulations permit safety instruction and emergency drills to be conducted by any qualified person. A common practice is to have a professional trainer conduct the safety instruction and drills prior to the local fishing season; however, if a voyage lasts for an extended period of time or port calls are unpredictable, there may not be a professional trainer available for subsequent safety instruction and emergency drills. This potentially leaves the crew with nobody on board experienced in safety instruction and conducting emergency drills. Since on board instruction and drills are the primary means for the majority of those within the commercial fishing industry to become prepared for emergencies, this matter is too important to leave to chance.

In the past, the master was often qualified as a fishing vessel drill conductor, and this may remain the case. The master or a member of the crew who is trained as a fishing vessel drill conductor would be able to provide personal knowledge about the particulars, procedures, and equipment of that vessel. A second fishing vessel drill conductor would be required on board vessels with more than 16 individuals. This would alleviate the burden on the master and help ensure everyone gets trained in a timely manner. The Coast Guard does not believe more than two fishing vessel drill conductors are necessary on any particular vessel.

4. Requirements for Safety Instructors, Drill Conductors, and Other Safety Personnel

For vessels that operate beyond the boundary line, with more than 16 persons on board, or that are fish-tender vessels in the Aleutian trade, we are considering requiring minimum standards for the safety instructors, drill conductors, and for other personnel with specific safety responsibilities.

Fishing vessel safety instructors would need a valid Coast Guard letter of acceptance, renewable after five years. The letter of acceptance would verify that an instructor possesses necessary maritime and instructional experience, and is able to offer an eight-hour curriculum in various safety topics, using either a nationally recognized curriculum or one that the instructor submits for Coast Guard review.

Drill conductors and other individuals with specific safety responsibilities would need certification from a safety instructor attesting that they have satisfactorily completed the training that the safety instructor's letter of acceptance authorizes the safety instructor to give. Like letters of acceptance, these certificates would be valid for five years and could be

renewed after additional training. Fishing vessel drill conductors would also need to show that they can effectively communicate with all members of the crew despite any language barriers, either through translation or hands-on demonstration.

5. CPR and First Aid Training

We are considering expanding the existing requirements for CPR and First Aid training on vessels that operate beyond the boundary line, with more than 16 persons on board, or that are fish-tender vessels in the Aleutian trade. Currently, depending on the size of a vessel's crew, from one to four crew members must have certified training in CPR and First Aid. We are considering requiring refresher training every three years, per the recommendations and practice of the National Institute of Occupational Safety and Health, American National Red Cross, and American Heart Association. Training in first aid and CPR is readily available in most locations and is relatively inexpensive.

F. Safety Equipment

We are considering new measures, relating to the following safety equipment and affecting all commercial fishing industry vessels:

- Emergency position indicating radio beacons (EPIRBs);
- Survival craft;
- Embarkation stations;
- High water alarms; and
- Excess or outdated equipment.

1. EPIRBs

Current regulations require all commercial fishing vessels operating on the high seas or beyond three miles from the coastline of the Great Lakes to be equipped with EPIRBs, which can alert the worldwide search and rescue system and provide the exact location of a vessel in distress or immersed in water. By existing regulation (47 CFR 80.1061(f)), EPIRBs are supposed to be registered with the National Oceanic and Atmospheric Administration but this requirement is frequently overlooked, resulting in unregistered EPIRB activations and risk to Coast Guard search and rescue personnel. We are considering requiring that registration to be documented so that we can enforce the existing registration requirement.

2. Survival Craft

We are considering requiring all survival craft to be easily accessible, and launchable by just one crew member. This conforms to a recommendation of the GALAXY investigation. The means used to comply with this requirement would be left up to the individual vessel, and, for smaller devices, could include manual launching.

3. Embarkation Stations

We are considering new measures to upgrade the safety and usability of survival craft embarkation stations in the event the crew must abandon ship. Embarkation stations would need to be equipped with emergency lighting and boarding ladders, in conformity with a GALAXY investigation recommendation. After a phase-in period, this requirement would be extended to Aleutian Trade Act vessels.

4. High-Water Alarms

In line with a recommendation from the ARCTIC ROSE investigation, we are considering requiring the use of high-water alarms in enclosed fish sorting or processing spaces. Sudden flooding in these spaces can threaten a vessel's stability. By installing alarms that would sound both in the affected space and in the vessel's operating station regardless of the vessel's heel or trim, the crew would have more time to restore watertight integrity or prepare for abandonment of the vessel.

5. Excess or Outdated Equipment

Safety equipment exceeding regulatory minimums would need to be maintained and inspected like required equipment, or else clearly labeled and segregated for ''training use'' only. Outdated equipment, like expired distress flares, could be kept for training use, but also would need to be clearly labeled and segregated for that purpose.

G. Documentation

Compliance with most of the measures under consideration would be facilitated by new documentation requirements. Vessel owners or masters would need to document stability training and assessments, vessel self-examinations, safety and survival training, and the use and maintenance of immersion suits and other safety equipment. Before leaving on a fishing trip, a vessel's master would need to file a departure report with the owner, attesting to the vessel's stability condition. Operating personnel would have a written record of compliance with the requirements. Written documentation would provide owners not operating as the vessel master with one means of ensuring that safety is not overlooked, and it would give them a record of operating personnel's activities. Written documentation of safety activities also allows the Coast Guard and other regulatory enforcement agencies to more quickly verify compliance with the safety requirements. This leads to more thorough examinations and less time spent verifying compliance with safety requirements. This is especially beneficial when compliance is checked while vessels are engaged in fishing activities.

Questions

Public response to the following questions will help the Coast Guard develop a more complete and carefully considered rulemaking. The questions are not all-inclusive, and any supplemental information is welcome. In responding to each question, please explain the reasons for each answer. We encourage you to let us know your specific concerns with respect to each/any of the requirements under consideration.

1. Given the statistics on vessel losses in Tables 2 and 3, what issues related to stability and watertight integrity should the Coast Guard consider addressing in regulations?

2. Table 2 shows that vessel flooding results in the most vessel losses, and Table 3 shows that flooding and sinking account for a significant portion of fatalities. What areas should be addressed to reduce vessel flooding losses and fatalities?

3. What routine measures are used to prevent unintentional flooding?

4. How often is your vessel examined by a marine surveyor and under what circumstances? Is documentation of the survey provided?

5. Table 3 shows that fire is a significant cause of vessel losses. What areas should the Coast Guard consider addressing to reduce the number of fire-related vessel losses (including, but not limited to: construction standards, detection and extinguishing equipment, fire fighting equipment, and firefighting training)?

6. What means are used to limit the danger of fires and the consequence of fires?

7. Table 2 shows that a significant number of vessel losses are related to allisions, collisions, and groundings; how should the Coast Guard address these causes of vessel losses?

8. What impact has safety training had in improving safety within the commercial fishing industry? Do you have recommendations concerning safety training?

9. What impact has crew drills had in improving safety within the commercial fishing industry? Do you have recommendations concerning crew drills?

10. If training were required would it be accomplished during off-season times?

11. How would additional training impact one's ability to fish?

12. If stability standards for vessels between 50 feet and 79 feet in length are considered, what standards should apply, and to which vessels should the standards apply?

13. How does a crew become experienced in safety procedures?

14. Should entry level crewmembers be expected to have a minimum level of familiarity with safety procedures?

15. How and when is stability guidance used? If stability guidance is available but not used, please explain why.

16. How are operating personnel made aware of stability and watertight integrity guidance?

17. How often should stability guidance be reviewed, updated, or validated?

18. How are modifications to a vessel or its gear accounted for relative to the vessel's maximum load, watertight integrity, and other stability considerations?

19. How adequate are current requirements for personal protection and survival equipment?

20. How do crew members become familiar with vessel safety and survival equipment?

21. How are safety risks aboard your vessel(s) identified and minimized?

22. If you are a small business, what economic impact on you, your business, or your organization would the rules we are considering have? In your comments please explain why, how, and to what degree such rules would have an economic impact.

23. Have you experienced—or are you aware of—any situations where any of the measures under consideration saved lives, or prevented/reduced harm/damage to vessels?

24. Are there areas not addressed that would benefit safety within the commercial fishing industry?

25. What are the costs of each requirement we are considering? Are there comparable alternative solutions to each requirement under consideration that may be more cost effective?

26. What are the direct and indirect costs of each requirement we are considering? For example, labor costs, training costs, and hourly wages of fishermen (or alternative measures of valuing their time if they are not salaried)? The costs of vessel losses, including equipment, lost catches, and any other opportunity costs?

27. Can any of the requirements we are considering be completed off-season? If so, which ones? For those that cannot, how much time would be taken away from productive fishing time to complete the requirement? How would this affect revenue, i.e., fish catches?

28. What would be the impact on the domestic fishing industry, if any, of each requirement we are considering? Would there be a differential impact by size of vessel or region?

29. What would be the economic impact of each requirement we are considering on States, local, and tribal governments?

30. What other requirements, if any, should the Coast Guard be considering?

Dated: March 21, 2008.

Brian M. Salerno,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Marine Safety, Security and Stewardship.

[FR Doc. E8–6477 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–15–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 25 and 74

[WT Docket No. 02–55; ET Docket Nos. 00–258 and 95–18; FCC 08–73]

Improving Public Safety Communications in the 800 MHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The Commission proposes to eliminate, as of January 1, 2009, the requirement that Broadcast Auxiliary Service (BAS) licensees in the thirty largest markets and fixed BAS links in all markets be transitioned before the Mobile Satellite Service (MSS) operators can begin offering service. The Commission also seeks comment on how to mitigate interference between new MSS entrants and incumbent BAS licensees who have not completed relocation before the MSS entrants begin offering service. In addition, the Commission seeks comment on allowing MSS operators to begin providing service in those markets where BAS incumbents have been transitioned.

DATES: Comments must be filed on or before April 30, 2008, and reply comments must be filed on or before May 30, 2008.

ADDRESSES: You may submit comments, identified by [WT Docket No. 02–55, ET Docket No. 00–258 and ET Docket No. 95–18], by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web Site: http://www.fcc.gov/cgb/ecfs/.* Follow the instructions for submitting comments.
- *E-mail:* [Optional: Include the E-mail address only if you plan to accept comments from the general public]. Include the docket number(s) in the subject line of the message.
- *Mail:* [Optional: Include the mailing address for paper, disk or CD-ROM submissions needed/requested by your Bureau or Office. Do not include the Office of the Secretary's mailing address here.]
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by e-mail: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Nicholas Oros, Office of Engineering and Technology, (202) 418–0636, e-mail: *Nicholas.Oros@fcc.gov*, TTY (202) 418–2989.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Further Notice of Proposed Rule Making,* WT Docket No. 02–55, ET Docket No. 00–258, ET Docket No. 95–18, FCC 08–73, adopted March 5, 2008, and released March 5, 2008. The full text of this document 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 complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY–B402, Washington, DC 20554. The full text may also be downloaded at: *http://www.fcc.gov.*

Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. Comments may be filed using: (1) The Commission's Electronic Comment Filing System (ECFS), (2) the Federal Government's eRulemaking Portal, or (3) by filing paper copies. *See Electronic Filing of Documents in Rulemaking Proceedings*, 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by

accessing the ECFS: *http://www.fcc.gov/cgb/ecfs/* or the Federal eRulemaking Portal: *http://www.regulations.gov*. Filers should follow the instructions provided on the Web site for submitting comments.

- For ECFS filers, if multiple docket or rulemaking numbers appear in the caption of this proceeding, filers must transmit one electronic copy of the comments for each docket or rulemaking number referenced in the caption. In completing the transmittal screen, filers should include their full name, U.S. Postal Service mailing address, and the applicable docket or rulemaking number. Parties may also submit an electronic comment by Internet e-mail. To get filing instructions, filers should send an e-mail to *ecfs@fcc.gov*, and include the following words in the body of the message, ''get form.'' A sample form and directions will be sent in response.
- *Paper Filers:* Parties who choose to file by paper must file an original and four copies of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although we continue to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

- The Commission's contractor will receive hand-delivered or messenger-delivered paper filings for the Commission's Secretary at 236 Massachusetts Avenue, NE., Suite 110, Washington, DC 20002. The filing hours at this location are 8 a.m. to 7 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes must be disposed of *before* entering the building.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.
- U.S. Postal Service first-class, Express, and Priority mail should be addressed to 445 12th Street, SW., Washington, DC 20554.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Summary of Further Notice of Proposed Rulemaking

1. The Further Notice of Proposed Rulemaking, tentatively concludes to eliminate, starting on January 1, 2009, the rule that 2 GHz Mobile Satellite Service (MSS) systems may not begin operation until the relocation of the Broadcast Auxiliary Service (BAS) in the thirty largest markets and fixed BAS links in all markets is complete (top 30 market rule). In addition, the Commission seeks comment on the potential for interference that may occur if the 2 GHz MSS entrants begin operations prior to relocation of the BAS incumbents as well as means that interference may be avoided or corrected. The Commission also seeks comment on allowing MSS operators to begin providing service in those markets where BAS incumbents have been relocated, even if the top 30 market rule is not eliminated.

2. The 2 GHz BAS licensees are being relocated from 1990–2110 MHz to 2025–2110 MHz so as to provide spectrum for new services such as MSS. MSS operations in the 2 GHz MSS band will consist of both satellite uplink and ancillary terrestrial component (ATC) operations. Because these MSS facilities are licensed in the same spectrum as existing BAS operations, the Commission has had to adopt policies, such as the top 30 market rule, that take into account the likelihood of MSS and BAS interference. If MSS begins operation before BAS operations are relocated, MSS ''would have to accept interference from the remaining BAS users until they are relocated.'' Such interference could be caused by BAS transmitters to both ATC base stations and satellite receivers. MSS operations also would have to avoid causing interference from MSS handset transmitters (satellite and ATC) to BAS receivers that are not yet relocated. Under the current rules, BAS licensees maintain primary status in the 1990–2025 MHz band until they are relocated by a new entrant; they decline relocation by a new entrant; or the BAS relocation rules sunset on December 13, 2013.

3. The Commission has tentatively concluded to eliminate the top 30 market rule as of January 1, 2009. This change would allow the 2 GHz MSS operators to begin offering nationwide service, both satellite and ATC, once the Commission has determined that they have met their operational milestones and even if the BAS relocation is not completed. Even in the absence of the top 30 market rule, MSS would be primary in those TV markets where BAS relocation is completed but secondary in those TV markets where BAS is not yet relocated. However, if the Commission were to retain the top 30 market rule and BAS relocation were to follow the plan submitted by Sprint Nextel *et al.*, on December 6, 2007, the 2 GHz MSS operators would not be able to offer service until September 2009, well beyond the dates by which MSS operators ICO and TerreStar are required as a condition of their licenses to have operational satellite systems. The Commission seeks comment on this tentative conclusion to eliminate the top 30 market rule. It also seeks comment on whether it should modify other requirements to facilitate MSS entry into the 2 GHz MSS band.

4. In addition to the top 30 market rule, MSS operations cannot begin until all fixed BAS links in all markets are relocated. Fixed BAS links, unlike mobile BAS operations that can often be switched to other available BAS channels, can't easily change frequencies which may make it more challenging to avoid interference. Because MSS operations, including ATC, could begin nationwide before the BAS relocation has been completed in many markets, interference between the services could occur. Because only those fixed links in the MSS band (2000–2020 MHz) could potentially receive co-channel interference, the Commission seeks comment on requiring only fixed BAS links in the MSS band in all markets to be relocated before MSS can begin operations. If the Commission decides not to adopt this modified requirement for relocating fixed BAS links prior to MSS beginning operations in the MSS band, it seeks comment on maintaining the current interference requirement in order to minimize service disruptions, *i.e.*, require that MSS not cause interference to BAS in markets where BAS has not yet relocated, and MSS would have to accept interference caused by BAS in markets where BAS has not yet relocated.

5. Even if the Commission were to eliminate the top 30 market rule by Jan. 1, 2009, it does not propose to alter the current rule that BAS licensees maintain primary status in the 1990–2025 MHz band until they are relocated by a new entrant; they decline relocation by a new entrant; or the BAS relocation rules sunset on December 13, 2013. The Commission seeks comment on whether it should maintain this requirement or alter it in some way.

6. The MSS operators may be able to share spectrum with BAS licensees that

are not relocated if the 2 GHz MSS operators were to begin offering nationwide service by January 1, 2009. Sharing may be possible through coordination between the MSS operators and BAS licensees or BAS may be able to operate with reduced bandwidth using digital equipment where possible. The Commission seeks comment on the likelihood and extent of interference between MSS and BAS. It also seeks comment on how, if MSS was secondary to BAS in a market, MSS could avoid or correct interference that might occur.

7. In order to develop a complete record on approaches other than the top 30 market rule that would allow 2 GHz MSS operators to begin operations in the MSS band by January 1, 2009, the Commission also seeks comment on a market-by-market approach for MSS entry. Under a market-by-market approach, MSS could begin providing service, both satellite and ATC, in a market once all BAS operations, including fixed BAS links there have been relocated, rather than wait until BAS in the top 30 markets and all fixed BAS links in all markets are relocated. MSS deployment would be incremental and tied to BAS relocation, rather than a nationwide cut-over at a specific date. This approach may be feasible because ICO's and TerreStar's satellites are designed with multiple spot beams that can operate independently of each other. Each spot beam can concentrate the signals from the satellite to an area on the ground with a radius of several hundred miles. Although the footprint of a spot beam may not exactly match a TV market, many of the BAS operations are being relocated in market clusters according to the Sprint Nextel *et al.*, plan. The result is that BAS relocation will be occurring in large regional areas of the country, which should allow the satellites' spot beams to provide service in many places while effectively avoiding BAS operations that are not yet relocated. The market-by-market approach also would facilitate the MSS operators' ability to conduct market trials of their satellite and ATC networks in different areas of the country as BAS operations are relocated but before the top 30 markets are relocated. Although a market-by-market approach would reduce the likelihood of interference between MSS and BAS, interference between the two services would not be completely avoided. Because ATC stations could not be operational in a market until BAS there was relocated, co-channel interference from BAS transmitters to ATC base station receivers and from MSS handsets (operating with ATC base stations) to BAS receivers will be avoided. However, because the spot beam footprint may not match exactly the BAS market areas, co-channel interference from BAS transmitters to satellite receivers and from MSS handsets (transmitting to MSS satellites) to BAS receivers still may occur, although it is unlikely. The Commission seeks comment on the likelihood and extent of interference between MSS and BAS if it were to adopt a market-by-market approach.

Initial Regulatory Flexibility Analysis

9. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[1] the Commission has prepared this present 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 *Further Notice of Proposed Rule Making* (FNPRM). 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 in the FNPRM. The Commission will send a copy of this FNPRM, including this IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA).[2] In addition, the NPRM and IRFA (or summaries thereof) will be published in the **Federal Register**.[3]

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

10. In the *Further Notice of Proposed Rulemaking*, the Commission seeks comment on a tentative conclusion to modify the requirement that BAS licensees in the thirty largest markets be transitioned before the two 2 GHz Mobile-Satellite Service (MSS) operators (ICO and TerreStar) can begin offering service. Because the transition of the 2 GHz BAS licensees may be completed beyond the dates by which the 2 GHz MSS systems are expected to be operational, the Commission explores alternative ways of balancing the needs of incumbent Broadcast Auxiliary Services (BAS) licensees to provide service without suffering harmful interference and the introduction of new MSS operations in a timely manner.

11. In the *Further Notice of Proposed Rulemaking*, the Commission request comments on a tentative conclusion to eliminate, as of January 1, 2009, the rule requiring that BAS in the top 30 markets by population and all fixed BAS links be transitioned before 2 GHz MSS operators may begin offering service. In addition, the Commission seeks comment on whether and how to modify the requirement that fixed BAS links in all markets be relocated before MSS operations can commence. It also seeks comment on whether it should maintain the requirement that BAS licensees maintain primary status in the 1990–2025 MHz band until they are relocated; they decline relocation by a new entrant; or the BAS relocation rules sunset on December 13, 2013. Furthermore, the Commission seeks comment on what would be the extent and likelihood of interference between MSS and BAS, if MSS operators enter the band before the completion of the BAS transition. The Commission seeks comment on how, if MSS was secondary to BAS in a market, MSS could avoid or correct any interference that might occur. Finally, the Commission seeks comment on using a market-by-market approach for MSS entry to the band as an alternative to modifying the top 30 market rule. Under a market-by-market approach, MSS could begin providing service, both satellite and ATC, in a market once all BAS operations have been relocated, rather than wait until the top 30 market rule is satisfied.

B. Legal Basis

12. The proposed action is taken pursuant to Sections 4(i) and (j) of the Communications Act of 1934, as amended, 47 CFR 154(i) and (j), and Section 1.3 of the Commission's Rules.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

13. 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 proposed rules, if adopted.[4] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.''[5] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.[6] A small

[1] *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), Public Law No. 104–121, Title II, 110 Stat. 847 (1996).

[2] *See* 5 U.S.C. 603(a).

[3] *Id.*

[4] 5 U.S.C. 603(b)(3).

[5] 5 U.S.C. 601(6).

[6] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small business concern'' in 15 U.S.C. 632). Pursuant to the RFA, the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or

business concern is one which: (1) Is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[7]

14. The proposed rule modifications may affect the interest of BAS, LTTS, and CARS licensees (which we have been referring to throughout this document generically as ''BAS''). BAS services involve a variety of transmitters, generally used to relay broadcast programming to the public (through translator and booster stations) or within the program distribution chain (from a remote news gathering unit to the studio). The CARS service includes transmitters generally used to relay cable programming within cable television system distribution systems. The Commission has not developed a definition of small entities applicable to Broadcast Auxiliary Service, Local Television Transmission Service or Cable Television Relay Service. Therefore, the applicable definition of small entity is the definition under the Small Business Administration (SBA) rules applicable to radiotelephone companies.

15. *BAS.* This service uses a variety of transmitters to relay broadcast programming to the public (through translator and booster stations) or within the program distribution chain (from a remote news gathering unit back to the stations). There are approximately 712 TV BAS licensees in the 1990–2110 MHz band, and these licensees will ultimately be required to use only the 2020–2110 MHz portion of that band. It is unclear how many of these will be affected by our new rules.

16. The Commission has not developed a definition of small entities specific to BAS licensees. The U.S. Small Business Administration (SBA) has developed small business size standards, as follows: For TV BAS, we use the size standard for Television Broadcasting, which consists of all such companies having annual receipts of no more than $12.0 million.[8] According to Census Bureau data for 1997, there were 906 Television Broadcasting firms, total that operated for the entire year.[9] Of this total, 734 firms had annual receipts of $9,999,999.00 or less and an additional 71 had receipts of $10 million to $24,999,999.00.[10] Thus, under this standard, the majority of firms can be considered small.

17. *CARS.* There are nine CARS mobile licensees in the 1990–2110 MHz band, and these licensees will ultimately be required to use only the 2020–2110 MHz portion of that band. It is unclear how many of these will be affected by our new rules. The SBA has developed a small business size standard for Cable and other Program Distribution, which consists of all such companies having annual receipts of no more than $12.5 million.[11] According to Census Bureau data for 1997, there were 1,311 firms within the industry category Cable and Other Program Distribution, total, that operated for the entire year.[12] Of this total, 1,180 firms had annual receipts of $9,999,999.00 or less, and an additional 52 firms had receipts of $10 million to $24,999,999.00.[13] Thus, under this standard, the majority of firms can be considered small.

18. *LTTS.* There are 34 LTTS licensees in the 1990–2110 MHz band, and these licensees will ultimately be required to use only the 2020–2110 MHz portion of that band. It is unclear how many of these will be affected by our new rules. The Commission has not yet defined a small business with respect to local television transmission services. For purposes of this IRFA, we will use the SBA's definition applicable to Cellular and Other Wireless Telecommunications—*i.e.*, an entity with no more than 1,500 persons.[14] According to Census Bureau data for 1997, there were 977 firms in this category, total, that operated for the entire year.[15] Of this total, 965 firms had employment of 999 or fewer employees, and an additional 12 firms had employment of 1,000 employees or more.[16] Thus, under this size standard, the majority of firms can be considered small.

19. *MSS.* The appropriate SBA size standard for mobile satellite service is for the category of ''Other Telecommunications.'' This category ''comprises establishments primarily engaged in (1) providing specialized telecommunications applications, such as satellite tracking, communications telemetry, and radar station operations; or (2) providing satellite terminal stations and associated facilities operationally connected with one or more terrestrial communications systems and capable of transmitting telecommunications to or receiving telecommunications from satellite systems.'' [17] Under this category, such a business is small if it has $13.5 million or less in average annual receipts.[18] For this category, Census Bureau data for 2002 show that there were a total of 332 firms that operated for the entire year.[19] Of this total, 303 firms had annual receipts of under $10 million and 15 firms had annual receipts of $10 million to $24,999,999.[20] Consequently, we estimate that the majority of Other Telecommunications firms are small entities that might be affected by our action. The proposed rule changes would affect two 2 GHz MSS operators. While the Commission does not believe these two MSS operators to be small due to the high costs associated with launching their service, it has nonetheless included them in this analysis.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

20. The interest of BAS licensees would be affected by the proposed rule changes by either subjecting them to the threat of increased interference from MSS or by making their licenses secondary to MSS in a portion of the spectrum. The potential harm to BAS will depend on the particular changes made to the rule. If MSS is allowed to enter the band on a market-by-market basis only where BAS has been transitioned, BAS would likely suffer little or no interference. If MSS is allowed to enter the band before BAS has been transitioned, but is required to cause no interference to BAS, then BAS would also likely suffer little or no interference. However, if BAS licensees are made secondary when MSS enters the band, those BAS licensees who have not been relocated could suffer interference. If such interference does occur, the BAS licensee may be able to

more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.'' 5 U.S.C. 601(3).

[7] Small Business Act, 15 U.S.C. 632 (1996).

[8] 13 CFR 121.201, NAICS code 515120.

[9] U.S. Census Bureau, 1997 Economic Census, Subject Series: Information, ''Receipts Size of Firms Subject to Federal Income Tax: 1997,'' Table 4, NAICS code 515120 (issued Oct. 2000).

[10] *Id.* The census data do not provide a more precise estimate.

[11] *Id.* at NAICS code 515120.

[12] *Id.*

[13] *Id.* The census data do not provide a more precise estimate.

[14] 13 CFR 121.201, NAICS code 517212.

[15] U.S. Census Bureau, 1997 Economic Census, Subject Series: Information, ''Employment Size of Firms Subject to Federal Income Tax: 1997,'' Table 5, NAICS code 517212 (issued Oct. 2000).

[16] *Id.* The census data do not provide a more precise estimate of the number of firms that have employment of 1,500 or fewer employees; the largest category provided is ''Firms with 1,000 employees or more.''

[17] U.S. Census Bureau, 2002 NAICS Definitions, ''517910 Other Telecommunications''; *http://www.census.gov/epcd/naics02/def/NDEF517.HTM.*

[18] 13 CFR 121.201, NAICS codes 517410.

[19] U.S. Census Bureau, 2002 Economic Census, Subject Series: Information, ''Establishment and Firm Size (Including Legal Form of Organization),'' Table 4, NAICS code 517910 (issued Nov. 2005).

[20] *Id.* An additional 14 firms had annual receipts of $25 million or more.

avoid the interference by operating on another BAS channel. Moreover, this interference would be temporary because all the BAS licensees are scheduled to relocate by September 7, 2009 to spectrum that does not conflict with MSS.

21. The proposed rule changes would also affect the interest of the two 2 GHz MSS operators, TerreStar and ICO. Under the current rules TerreStar and ICO cannot begin operations in this band until after the top 30 markets have been relocated. Consequently, modifying the top 30 market rule to allow them to enter the band sooner will provide the 2 GHz MSS operators with a benefit and not a burden.

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

22. Our primary concern in this proceeding continues to be balancing the needs of incumbent BAS licensees to provide service without suffering harmful interference and the introduction of new MSS in a timely manner. If the Sprint Nextel *et al.*, plan for BAS relocation is successfully implemented, ICO's and TerreStar's ability to begin operation in the 2 GHz MSS band could be delayed until September 2009 under the current rules. On the other hand, if BAS relocation of the top 30 markets and fixed BAS links in all markets is completed earlier than is now anticipated but before all BAS markets are relocated, interference between MSS, including ATC, and BAS is likely to occur in those markets not yet relocated. In the latter case, MSS would have to accept interference from the remaining BAS users until they are relocated. It seeks comment on whether to maintain this non-interference requirement. The Commission also seeks comment on whether it should modify other requirements for MSS entry into the 2 GHz MSS band.

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

23. None.

Ordering Clauses

24. The *Further Notice of Proposed Rule Making is adopted.* This authority is taken pursuant to Sections 4(i) and (j) of the Communications Act of 1934, as amended, 47 CFR 154(i) and (j), and Section 1.3 of the Commission's Rules.

25. The Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of the *Further Notice of Proposed Rulemaking,* including the Initial Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. E8–6494 Filed 3–28–08; 8:45 am]

BILLING CODE 6712–01–P

NATIONAL TRANSPORTATION SAFETY BOARD

49 CFR Part 830

Notification and Reporting of Aircraft Accidents or Incidents and Overdue Aircraft, and Preservation of Aircraft Wreckage, Mail, Cargo, and Records

AGENCY: National Transportation Safety Board (NTSB).

ACTION: Notice of proposed rulemaking.

SUMMARY: The NTSB is proposing to amend its regulations concerning notification and reporting requirements with regard to aircraft accidents or incidents. The existing version of the definitions section does not address unmanned aircraft accidents; therefore, the NTSB proposes to update the definitions section in order to define ''unmanned aircraft accident.''

DATES: Submit comments on or before June 30, 2008.

ADDRESSES: You may send written comments using any of the following methods:

1. *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.

2. *Mail:* Mail comments concerning this proposed rule to Dana Schulze, AS–lO, National Transportation Safety Board, 490 L'Enfant Plaza, SW., Washington, DC 20594–2000.

3. *Fax:* (202) 314–6319, Attention: Dana Schulze.

4. *Hand Delivery:* 6th Floor, 490 L'Enfant Plaza, SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Dana Schulze, Office of Aviation Safety, (202) 314–6323.

SUPPLEMENTARY INFORMATION:

Statutory and Regulatory Evaluation

This rule proposes to add a definition of ''unmanned aircraft accident'' alongside the existing definition of ''aircraft accident,'' to include a requirement to report unmanned aircraft accidents under the notification requirements of 49 CFR 830.5(a), which requires immediate notification of any aircraft accident, as defined at 49 CFR 830.2. The NTSB also seeks to add a reference to this new definition in the existing definition of ''aircraft accident.'' These additions will enhance aviation safety by providing the NTSB with notification of events in which persons are injured or the aircraft sustains substantial damage. Such reports will enable the NTSB to conduct investigations, influence corrective actions, and propose safety recommendations with regard to unmanned aircraft in a timely manner. In addition, these reports will assist the NTSB with safety studies and analysis of any trends in aviation transportation that could affect aviation safety.

The NTSB has considered whether this rule is a ''significant regulatory action'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and has determined that this rule does not meet the definition of ''significant regulatory action.'' In particular, the rule will not: have an annual effect on the economy of $100 million or more or adversely affect the economy; create a serious inconsistency or interfere with an action that another agency has taken or plans to take; materially alter the budgetary impact of any grants, entitlements, or the like; or raise novel legal or policy issues. As such, Executive Order 12866 does not require the NTSB to complete an assessment of the potential costs and benefits under section 6(a)(3) of that Order.

Likewise, the NTSB has analyzed this rule under the Unfunded Mandates Reform Act, 2 U.S.C. 1501–1571. The NTSB acknowledges that this proposed reporting requirement may affect state, local, and tribal entities because those entities may utilize unmanned aircraft for a variety of purposes. However, the NTSB maintains that requiring such entities to report to the NTSB transportation accidents arising from the operation of unmanned aircraft will not result in any expenditure by any private sector organization or entity that would exceed $100 million. As such, the NTSB asserts that the Unfunded Mandates Reform Act does not prevent the NTSB's enactment of this proposed regulation. Likewise, the NTSB has analyzed this proposed rule as required by the National Environmental Policy Act, 42 U.S.C. 4321–4347, and has determined that this proposed regulation does not necessitate further analysis under the provisions of the National Environmental Policy Act.

In addition, the NTSB has considered whether this rule would have a significant economic impact on a substantial number of small entities,

under the Regulatory Flexibility Act (5 U.S.C. 601–612). The NTSB 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. Indeed, the changes to part 830 that the NTSB proposes herein will only result in a potential increase in the number of reports that small entities must submit to the NTSB; the NTSB does not anticipate that submitting such reports will have a significant economic impact on small entities. Moreover, in accordance with 5 U.S.C. 605(b), the NTSB has submitted this certification to the Chief Counsel for Advocacy at the Small Business Administration.

This rule proposes no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) but will require that the public notify the NTSB of more events. As such, the NTSB has submitted this NPRM to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act. The NTSB will continue to use Form No. 6120.1 to receive notification of events that are reportable under 49 CFR Part 830. OMB last approved the use of Form No. 6120.1 on June 30, 2006, and this approval will expire on June 30, 2009 (OMB Control No. 3147–0001). The NTSB estimates that the number of respondents for the submission of this notification using the aforementioned form will increase by a very modest amount: approximately five additional reports per year. As such, after this rule becomes effective, the NTSB anticipates receiving reports on Form No. 6120.1 from approximately 2,205 respondents per year; this estimate includes approximately 2,200 reports on Form 6120.1 that the NTSB receives from all notification requirements in 49 CFR Part 830, as well as approximately five additional reports that the NTSB expects to receive each year due to the new definition that is the subject of this NPRM. All other information regarding the use of Form No. 6120.1 will remain the same. The public may submit comments regarding the collection of this information to the OMB desk officer for the NTSB.

The NTSB recognizes that Congress's intent in promulgating the Paperwork Reduction Act was to reduce the burden on individuals and ensure that the information collected would not be duplicative of other federal information collections. The NTSB notes that some individuals or entities from which the NTSB must receive notification of an event under part 830 may also be required to report the event to the Federal Aviation Administration (FAA). However, this reporting is currently not required under FAA regulations but is required in individual agreements authorizing the operation of unmanned aircraft. See 72 FR 6689 (Feb. 13, 2007). Therefore, any duplicative reporting that may occur will be uncommon, as it will be limited to individual agreements into which the FAA has entered with specific operators or parties and will occur infrequently at the NTSB, given the NTSB's estimate that it will receive approximately five additional reports per year. In any event, the NTSB asserts that such duplicative reporting, while minimal, is necessary for the NTSB to fulfill its statutory mission of improving safety. The NTSB's response to unmanned aircraft accidents could include immediately dispatching an investigator to the location of the damaged aircraft to evaluate the circumstances of the accident and observe various components of the aircraft, or other locations where perishable information exists or requires collection for the investigation. Such a response would not be possible if the operator only reported the event to the FAA. The NTSB also notes that it has experienced impediments to some investigations, such as an inability to recover and examine critical parts, when the NTSB belatedly received notification of the event. Overall, the NTSB does not anticipate that duplicative reporting will be commonplace, and, to the extent that duplicate reports occur, the NTSB asserts that such reports are necessary and will not cause an undue burden on the public.

Moreover, the NTSB does not anticipate that this rule will have a substantial, direct effect on State or local governments or preempt state law; as such, this rule does not have implications for federalism under Executive Order 13132, Federalism. This rule also complies with all 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. In addition, the NTSB has evaluated this rule under: Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights; Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks; Executive Order 13175, Consultation and Coordination with Indian Tribal Governments; Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use; and the National Technology Transfer and Advancement Act, 15 U.S.C. 272 note. The NTSB has concluded that this rule does not contravene any of the requirements set forth in these Executive Orders or statutes, nor does this rule prompt further consideration with regard to such requirements. With regard to these aforementioned legal considerations, the NTSB notes that this proposed requirement is an extension of its existing requirements for the reporting of manned aircraft accidents; as such, the NTSB's analyses of the aforementioned statutes and Executive Orders is analogous to its considerations with regard to notification of other aircraft accidents in which a person is on board the aircraft.

Discussion of Proposed Addition to Section 830.2

The NTSB proposes to add the definition of ''Unmanned aircraft accident'' by adding the following text: ''Unmanned aircraft accident means an occurrence associated with the operation of a public or civil unmanned aircraft that takes place between the time that the aircraft is activated with the purpose of flight and the time that the aircraft is deactivated at the conclusion of its mission, in which any person suffers death or serious injury, or in which the aircraft receives substantial damage.'' The NTSB also proposes to add a brief reference at the end of the existing definition of ''aircraft accident'' in section 830.2, which will state: ''For purposes of this part, the definition of 'aircraft accident' includes 'unmanned aircraft accident,' as defined herein.''

Interpretation of Proposed Definition

The NTSB's reference to ''substantial damage'' in the proposed definition is appropriate given that substantial damage includes ''damage or failure to an aircraft that adversely affects the structural strength, performance, or flight characteristics of the aircraft, and would normally require major repair or replacement of the affected component.'' The NTSB does not propose altering the definition of ''substantial damage'' and will apply the full definition, including all exclusions that the definition contains, to the proposed addition of unmanned aircraft accidents. Likewise, the NTSB does not intend to alter its definition of the term, ''serious injury,'' which is also defined in section 830.2. Overall, the NTSB notes that this proposed addition does not contravene, alter, or in any way affect any of the other terms that section 830.2 defines.

The NTSB's proposed addition to the existing definition of ''aircraft accident,'' to include a reference to unmanned aircraft accidents, will

ensure that the reporting requirement within section 830.5 unambiguously applies to aircraft accidents in which manned and unmanned aircraft are involved. Except with regard to the NTSB's proposed addition of this reference via a short sentence at the end of the definition of ''aircraft accident,'' this reference does not change the existing interpretation or applicability of ''aircraft accident.''

Moreover, the NTSB's use of the term ''aircraft'' is similarly appropriate given that this reference does not contradict or supersede the existing definition of ''aircraft'' at 14 CFR 1.1 (which defines ''aircraft'' as ''a device that is used or intended to be used for flight in the air''). Similarly, the NTSB intends its reference to the term ''unmanned aircraft'' to be consistent with the FAA's definition of ''unmanned aircraft'' at 72 FR 6689 (Feb. 13, 2007), wherein the FAA defines an ''unmanned aircraft'' as ''a device that is used, or is intended to be used, for flight in the air with no onboard pilot.'' Further, the NTSB intends for this proposed rule to apply to the category of unmanned aircraft used as public aircraft or civil aircraft, not those used as model aircraft; hence, the NTSB has included the terms ''civil'' and ''public'' within this definition and incorporates the existing definitions of those terms in section 830.2 as applicable to this definition. Moreover, the incorporation of these terms is consistent with the FAA's categorization of unmanned aircraft, as described at 72 FR 6689, 6690 (Feb. 13, 2007) (explaining three unique ways in which an operator may obtain authority to operate three types of unmanned aircraft, which include public, civil, and model aircraft), and conforms to the statutory directive that Congress issued to the NTSB, at 49 U.S.C. 1131(a)(1)(A) and 1132(a) (directing the NTSB to investigate civil and public aircraft accidents). In summary, the text of the NTSB's proposed definition does not affect and is not inconsistent with any of the definitions that the FAA has promulgated; as such, the NTSB does not anticipate that this definition will create ambiguity.

Effect of Proposed Definition on Transportation Safety

The Independent Safety Board Act of 1974 (codified, as amended, at 49 U.S.C. 1101–1155) directs the NTSB to investigate the facts, conditions, and circumstances relating to transportation accidents and to recommend steps to reduce or eliminate such accidents. The NTSB also has the authority to conduct special studies and investigations on matters pertaining to safety and for the prevention of accidents. The NTSB anticipates that this proposed amendment will enhance aviation safety by providing the NTSB with direct and timely notification of events that involve safety concerns regarding unmanned aircraft. Such notification will consequently enable the NTSB to conduct investigations, through which the NTSB can influence or enable necessary corrective actions in a timely manner. Such corrective actions function to prevent future transportation accidents and improve safety. The NTSB also anticipates that this regulatory amendment will assist the NTSB in improving safety via the agency's safety recommendation process, under 49 U.S.C. 1116, 1131, and 1136.

The NTSB notes that congress has directed the NTSB to carry out special studies and investigations concerning transportation safety and evaluate the effectiveness of transportation safety consciousness of other departments, agencies, and instrumentalities in the interest of improving transportation safety. See 49 U.S.C. 1116(b). In addition, Congress has recognized the NTSB's process of issuing safety recommendations as one that has successfully prevented potential transportation accidents. See H.R. Rep. No. 103–239(I) at 1 (1993), which emphasizes the importance of the NTSB's safety recommendations and states that such recommendations ''have saved countless human lives.'' In addition to performing these duties, the NTSB significantly influences transportation safety in conducting its aviation accident investigations. Often, organizations, such as state or local agencies; other Federal agencies; foreign governments; and private entities from the aviation industry, will implement changes during the course of an NTSB investigation to improve safety and prevent future accidents. Consequently, the NTSB is effective in improving safety in a variety of ways; the NTSB anticipates that the proposed notification requirement will assist the NTSB in improving safety via the NTSB's investigative process, safety recommendations, and identification of safety concerns.

For example, the NTSB investigated the April 25, 2006, crash of an unmanned aircraft system (UAS) that the United States Customs and Border Protection (CBP) agency was operating near Nogales, Arizona. The NTSB found that several factors related to pilot training and proficiency in dealing with emergency situations contributed to the accident. In addition to these findings, the NTSB identified several other safety deficiencies regarding the UAS equipment design and maintenance, the CBP's operational contingency plans, and the safety risk management process used to ensure safety while operating the aircraft in the United States National Airspace System (NAS) The investigation also revealed a number of safety issues related to the FAA's air traffic management of the unmanned aircraft and the FAA's practice of monitoring unmanned aircraft operations under the current system of authorization. As a result of these findings, the CBP took action to improve certain aspects of its UAS equipment design and operation. Likewise, the FAA also took action to reconsider its current means of monitoring UAS operations in the NAS. Although these actions addressed some of the investigation's safety findings, the NTSB remained concerned about other potential safety deficiencies and the risk they presented for a possible midair collision between an unmanned aircraft and a human-piloted aircraft or a possible collision involving an unmanned aircraft and persons or property on the ground; the NTSB also remained concerned that these deficiencies may not be adequately addressed by current UAS operating procedures. As a result, the NTSB issued 22 safety recommendations to address the specific findings and concerns identified in the CBP accident investigation, as well as to improve the safety of other unmanned aircraft operations in the NAS. See Safety Recommendations A–07–065 through A–07–086, available at *http://www.ntsb.gov*.

In the course of conducting the CEP investigation, the NTSB also became aware that the framework of safety standards and regulations related to the design, operation, and continuing airworthiness of unmanned aircraft systems for use in the NAS is insufficient when compared to that of manned aircraft and that the development of these regulations and standards is a new and evolving area of civil aviation. Given this assessment, combined with the knowledge that numerous public use and civil entities are already currently operating their unmanned aircraft in the NAS today under specific approval from the FAA, the NTSB determined that it should receive notification of accidents involving unmanned aircraft. The NTSB anticipates that it will investigate these occurrences and make determinations and issue safety recommendations that other entities will use to develop safety improvements. Such a purpose is

consistent with Congress's intent in creating the NTSB and supplying the NTSB with its broad investigative authority. The NTSB also notes that the investigation of such occurrences will provide critical data and lessons learned that can assist regulators and industry in the development of safety regulations and standards and the monitoring of their effectiveness in improving the safety of unmanned aircraft operations in the NAS.

The NTSB has carefully considered the safety concerns that unmanned aircraft accidents could present. The NTSB notes that Congress's intention in creating the NTSB and providing it with broad authority with regard to investigating transportation accidents indicates a general purpose of preventing transportation accidents, because such accidents can cause death or physical harm. In recognizing this statutory purpose, the NTSB proposes to amend section 830.2 by including a definition of unmanned aircraft accidents, in accordance with the proposed language, below.

List of Subjects in 49 CFR Part 830

Aircraft accidents, Aircraft incidents, Aviation safety, Overdue aircraft notification and reporting, Reporting and recordkeeping requirements.

For the reasons discussed in the preamble, the NTSB proposes to amend 49 CFR Part 830 as follows:

PART 830—NOTIFICATION AND REPORTING OF AIRCRAFT ACCIDENTS OR INCIDENTS AND OVERDUE AIRCRAFT, AND PRESERVATION OF AIRCRAFT WRECKAGE, MAIL, CARGO, AND RECORDS

1. The authority citation for 49 CFR part 830 is revised to read as follows:

Authority: Independent Safety Board Act of 1974, as amended (49 U.S.C. 1101—1155); Federal Aviation Act of 1958, Pub. L. No. 85–726, 72 Stat. 731 (codified as amended at 49 U.S.C. 40101).

2. Amend § 830.2 as follows:

A. Add a new sentence at the end of the definition of ''Aircraft accident'' to read as set forth below; and

B. Add a definition of ''Unmanned aircraft accident'' in alphabetical order to read as follows:

§ 830.2 Definitions.

* * * * *

Aircraft accident * * * For purposes of this part, the definition of ''aircraft accident'' includes ''unmanned aircraft accident,'' as defined herein.

* * * * *

Unmanned aircraft accident means an occurrence associated with the operation of a public or civil unmanned aircraft that takes place between the time that the aircraft is activated with the purpose of flight and the time that the aircraft is deactivated at the conclusion of its mission, in which any person suffers death or serious injury, or in which the aircraft receives substantial damage.

Dated: March 24, 2008.

Vicky D'Onofrio,

Federal Register Liaison Officer.

[FR Doc. E8–6393 Filed 3–28–08; 8:45 am]

BILLING CODE 7533–01–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

RIN 0648–AV34

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Amendment 30A

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

ACTION: Notice of availability of Amendment 30A to the Reef Fish Fishery Management Plan; request for comments.

SUMMARY: NMFS announces the Gulf of Mexico Fishery Management Council (Council) has submitted Amendment 30A to the Fishery Management Plan (FMP) for the Reef Fish Resources of the Gulf of Mexico for review, approval, and implementation by NMFS. Amendment 30A proposes actions to end overfishing of greater amberjack and gray triggerfish and to rebuild these stocks to sustainable levels.

DATES: Written comments must be received no later than 5 p.m., eastern time, on May 30, 2008.

ADDRESSES: You may submit comments, identified by ''0648–AV34'' by any of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal e-Rulemaking Portal *http://www.regulations.gov*.
- Fax: 727–824–5308; Attention: Peter Hood.
- Mail: Peter Hood, Southeast Regional Office, NMFS, 263 13th Avenue South, St. Petersburg, FL 33701.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

Copies of Amendment 30A, which include a supplemental environmental impact statement, an initial regulatory flexibility analysis, and a regulatory impact review may be obtained from the Gulf of Mexico Fishery Management Council, 2203 North Lois Avenue, Suite 1100, Tampa, FL 33607; telephone 813–348–1630; fax 813–348–1711; e-mail *gulfcouncil@gulfcouncil.org*; or may be downloaded from the Council's website at *http://www.gulfcouncil.org/*.

FOR FURTHER INFORMATION CONTACT: Peter Hood, telephone 727–824–5305; fax 727–824–5308; e-mail *peter.hood@noaa.gov*.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each Regional Fishery Management Council to submit any fishery management plan or amendment to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, upon receiving a plan or amendment, publish an announcement in the **Federal Register** notifying the public that the plan or amendment is available for review and comment.

Background

The reauthorized Magnuson-Stevens Act of 2006 requires regional fishery management councils to establish annual catch limits (ACLs) for each stock or stock complex and accountability measures (AMs) to ensure these ACLs are not exceeded. Amendment 30A addresses these requirements for greater amberjack and gray triggerfish.

Greater amberjack have been under a rebuilding plan since 2003. However, a new stock assessment completed in 2006 concluded that the stock is not recovering as projected. It remains overfished and NMFS recently determined overfishing is recurring. Amendment 30A is necessary to end overfishing and adjust total allowable catch (TAC) and management measures to bring the greater amberjack rebuilding

plan back on course for stock recovery within the original 10-year time frame. To achieve this goal, TAC must be reduced by 32 percent to rebuild the stock by 2012.

For greater amberjack, Amendment 30A considers actions to constrain harvest to a TAC of 1.9 million lb (863,636 kg). Measures to constrain recreational harvest include a quota (which would also function as an ACL) of 1,368,000 lb (620,514 kg), increasing the minimum size limit to 30 inches (76 cm) fork length (FL), and prohibiting the bag limit for captain and crew of for-hire vessels. These measures are expected to reduce recreational landings by 26 percent. For the commercial fishery, Amendment 30A would establish a commercial quota (which would function as an ACL) of 503,000 lb (228,157 kg), thus reducing the commercial harvest by 38 percent.

The amendment proposes an allocation for greater amberjack of 73 percent for the recreational sector and 27 percent for the commercial sector. These allocations were derived from long-term average landings from 1981–2004.

To ensure the greater amberjack stock recovers, AMs are proposed. These AMs are intended to ensure landings do not exceed the TAC allowed by the rebuilding plan. The amendment authorizes the Assistant Administrator for Fisheries, NOAA, (AA) to shorten fishing seasons by sector within the current fishing year, or in the subsequent year, if landings are exceeded or are projected to be exceeded.

NMFS has determined gray triggerfish are undergoing overfishing based on the 2006 stock assessment. Based on status determination criteria proposed by the Council in Amendment 30A, the gray triggerfish stock would be considered overfished. Amendment 30A is necessary to establish management measures to end overfishing of gray triggerfish and would establish a rebuilding plan.

The proposed gray triggerfish rebuilding plan in Amendment 30A uses a constant fishing mortality strategy that optimizes yield while allowing the stock to rebuild by the end of 2012. Under the proposed rebuilding plan, TAC would be set at 500,000 lb (226,796 kg). In lieu of a recreational quota, Amendment 30A proposes to establish ACLs for the recreational sector of 394,000 lb (178,715 kg) for 2008, 426,000 lb (193,230 kg) for 2009, and 457,000 lb (207,291 kg) for 2010 and subsequent fishing years, until revised based on a subsequent stock assessment and appropriate rulemaking. Increasing the recreational minimum size limit for gray triggerfish to 14 inches (36 cm) FL is intended to constrain harvest to a level less than the ACL. This action is expected to reduce recreational landings by 60 percent, and achieve a 45 percent reduction in recreational harvest, necessary to rebuild the gray triggerfish stock. For the commercial fishery, actions in Amendment 30A would increase the commercial size limit to 14 inches (36 cm) FL and establish a commercial quota, which is less than the proposed commercial ACL. For 2008, the quota would be 80,000 lb (36,287 kg), 93,000 lb (42,184 kg) for 2009, and 106,000 lb (48,081 kg) for 2010. The commercial quota would remain at the 2010 level until revised based on a subsequent stock assessment and appropriate rulemaking. These measures are expected to reduce the commercial harvest by 61 percent in 2008, and improve the probability of achieving the 49 percent reduction in commercial harvest necessary for the stock to rebuild.

To ensure the stock recovers, AMs are proposed in Amendment 30A which give the AA the authority to shorten recreational and commercial fishing seasons. For the recreational fishery, AMs would provide the AA authority to shorten the fishing year in the following year if multi-year running average landings exceed the recreational ACL, with the exception of 2008, the first year of the rebuilding plan. The first year would use only 2008 landings as the basis of whether the following year would need to be shortened. For the commercial fishery, the proposed AMs would give the AA the authority to shorten the fishing season within the fishing year, or in the following year, if multi-year running average landings exceed, or are projected to exceed, the commercial ACLs. The exception to this would be for 2008, the first year of the rebuilding plan, which would use only 2008 landings. For both the recreational and commercial fisheries, ACLs are based on the yield from the fishing mortality rate associated with optimum yield. These yield levels are higher than the harvest allowed under the proposed management actions.

Amendment 30A would also define status determination criteria for gray triggerfish, as required by the Magnuson-Stevens Act. Currently, only a maximum fishing mortality threshold has been defined for gray triggerfish equal to the fishing mortality rate associated with harvesting the maximum sustainable yield (F_{MSY}). Amendment 30A would define the minimum stock size threshold as (1–M)*B_{MSY} where M is the natural mortality rate and B_{MSY} is the stock size capable of supporting maximum sustainable yield on a continuing basis. The optimum yield would be defined as the yield associated with 0.75*F_{MSY}.

A proposed rule that would implement measures outlined in Amendment 30A has been received from the Council. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable law. If that determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

Consideration of Public Comments

Comments received by May 30, 2008, whether specifically directed to the amendment or the proposed rule, will be considered by NMFS in its decision to approve, disapprove, or partially approve the amendment. Comments received after that date will not be considered by NMFS in this decision. All comments received by NMFS on the amendment or the proposed rule during their respective comment periods will be addressed in the final rule.

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

Dated: March 25, 2008.

Alan D. Risenhoover

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

[FR Doc. E8–6523 Filed 3–28–08; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 680

[Docket No. 080129098–8101–01]

RIN 0648–AW45

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Crab Rationalization Program

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations implementing Amendment 26 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (FMP). These proposed

regulations would amend the Bering Sea/Aleutian Islands Crab Rationalization Program. Amendment 26 would amend the FMP to exempt permanently quota share issued to crew members, and the annual harvest privileges derived from that quota share, from requirements for delivery to specific processors, delivery within specific geographic regions, and participation in an arbitration system to resolve price disputes. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act, the FMP, and other applicable law.

DATES: Comments must be received no later than May 15, 2008.

ADDRESSES: Send comments to Sue Salveson, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region, NMFS, Attn: Ellen Sebastian. You may submit comments, identified by RIN 0648–AW45, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal website at *http://www.regulations.gov*.
- Mail: P. O. Box 21668, Juneau, AK 99802.
- Fax: (907) 586–7557.
- Hand delivery to the Federal Building: 709 West 9th Street, Room 420A, Juneau, AK.

All comments received are a part of the public record and will generally be posted to *http://www.regulations.gov* without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

NMFS will accept anonymous comments. Attachments to electronic comments will be accepted in Microsoft Word, Excel, WordPerfect, or Adobe portable document file (pdf) formats only.

Copies of Amendment 26, the Regulatory Impact Review (RIR)/Initial Regulatory Flexibility Analysis (IRFA) prepared for this action, and the Environmental Impact Statement (EIS) prepared for the Crab Rationalization Program may be obtained from the NMFS Alaska Region at the address above or from the Alaska Region website at *http://www.fakr.noaa.gov/sustainablefisheries.htm*.

FOR FURTHER INFORMATION CONTACT: Glenn Merrill, 907–586–7228, *glenn.merrill@noaa.gov*.

SUPPLEMENTARY INFORMATION: The king and Tanner crab fisheries in the exclusive economic zone of the Bering Sea and Aleutian Islands (BSAI) are managed under the FMP. The FMP was prepared by the North Pacific Fishery Management Council (Council) under the Magnuson-Stevens Fishery Conservation and Management Act as amended by the Consolidated Appropriations Act of 2004 (Public Law 108–199, section 801). Amendments 18 and 19 to the FMP implemented the BSAI Crab Rationalization Program (Program). Regulations implementing Amendments 18 and 19 were published on March 2, 2005 (70 FR 10174) and are located at 50 CFR part 680.

Crab Rationalization Program Overview

Under the Program, NMFS issued four types of quota share (QS) to persons based on their qualifying harvest histories in the BSAI crab fisheries during a specific period of time defined under the Program. The first two types of QS were issued to holders of license limitation program (LLP) licenses endorsed for a crab fishery. Catcher/processor LLP license holders were issued catcher/processor vessel owner (CPO) QS based on the catch history of catcher processors using an LLP license, and catcher vessel LLP license holders were issued catcher vessel owner (CVO) QS based on the catch history of catcher vessels using an LLP license. Under the Program, 97 percent of the QS was initially issued as CVO and CPO QS. The remaining 3 percent of the QS was initially issued to vessel captains and crew as ''C shares,'' based on their harvest histories as crew members onboard crab fishing vessels. Captains and crew onboard catcher/processor vessels were issued catcher/processor crew (CPC) QS; and captains and crew onboard catcher vessels were issued catcher vessel crew (CVC) QS.

Each year, the QS issued to a person yields an amount of individual fishing quota (IFQ), which is a permit that provides an exclusive harvest privilege for a specific amount of raw crab pounds, in a specific crab fishery, in a given season. The size of each annual IFQ allocation is based on the amount of QS held by a person in relation to the total QS pool in a crab fishery. As an example, a person holding QS equal to one percent of the QS pool in a crab fishery would receive IFQ to harvest 1 percent of the annual total allowable catch (TAC) in that crab fishery. NMFS can issue the resulting IFQ to the QS holder directly, or to a crab harvesting cooperative comprised of multiple QS holders. Crab harvesting cooperatives have been used extensively by QS holders to allow them to receive a larger IFQ pool and coordinate deliveries and price negotiations among numerous vessels. Most QS holders, including CVC and CPC QS holders, have joined cooperatives in the first two years of the Program, and are likely to continue to do so because of the economic and administrative benefits of consolidating their IFQ.

The IFQ derived from CPO and CPC QS may be harvested and processed at sea and is not required to be delivered to a specific onshore processor or stationary floating crab processor, or within a specific geographic region. However, the IFQ derived from CVO QS is subject to (1) delivery requirements to a specific onshore processor or stationary floating crab processor, (2) delivery within specific geographic regions, also known as regionalization, and (3) requirements to participate in an arbitration system. The IFQ derived from CVC QS must be delivered to onshore or stationary floating crab processors, but is currently exempt from delivery requirements to specific processors, regionalization requirements, and requirements to participate in the arbitration system. However, under the existing regulations, CVC QS and the resulting IFQ will be subject to the same delivery, regionalization, and arbitration system requirements as CVO QS/IFQ after June 30, 2008.

When the Program was adopted in 2004, the Council recommended regularly scheduled reviews of the Program 18 months, three years, and five years after its implementation to assess specific issues. Beginning in February 2007, Council staff began preparation of the 18-month review. Among other issues examined during this review, Council staff provided a summary of the key issues and concerns relevant to applying delivery, regionalization, and arbitration system requirements to CVC QS/IFQ holders. Members of the public noted that applying these requirements to CVC QS/IFQ holders after June 30, 2008, would limit their ability to address logistical complications, not provide flexibility for CVC IFQ holders to deliver to alternative markets if desired, substantially increase the costs of operation, and not provide substantial additional stability to processors and communities. Based on these concerns, in April 2007, the Council tasked staff to prepare an analysis that would review the implications of permanently exempting CVC QS/IFQ from delivery, regionalization, and arbitration system requirements. The Council deliberated over the issue at subsequent meetings, and in December 2007, recommended

permanently exempting CVC QS/IFQ from all three of these Program requirements.

Effects of the Proposed Action

The following sections describe the Council's rationale for delaying the application of delivery, regionalization, and the arbitration system requirements to CVC QS/IFQ until June 30, 2008, the effect of applying those requirements to CVC QS/IFQ after June 30, 2008, and the rationale provided by the Council for recommending a permanent exemption for CVC QS/IFQ from these requirements.

Processor delivery requirements. Existing processor delivery regulations recognize the historic participation of processors and communities dependent on crab processing in the BSAI crab fisheries by requiring that a portion of the annual TAC be delivered to specific onshore or stationary floating crab processors. A detailed description of the rationale for linking harvesters and processors in this manner is described in detail in the EIS prepared for the Program and the RIR/IRFA prepared for this proposed action (see **ADDRESSES**).

After considering a range of alternatives, the Council recommended and NMFS implemented regulations that require 90 percent of the IFQ derived from CVO and CVC QS be delivered to onshore processors. This requirement ensures a linkage between harvesters who historically delivered onshore and specific processors. The Program established this linkage by issuing processor quota shares (PQS) to processors with historic participation in crab processing during a specific period. PQS yields individual processor quota (IPQ) on an annual basis that represents a privilege to receive a certain amount of crab harvested. Currently, 90 percent of the IFQ derived from CVO QS holders is issued as Class A IFQ. NMFS issues one pound of IPQ for each pound of Class A IFQ, creating a one-to-one correspondence between Class A IFQ and IPQ. The remaining 10 percent of the annual CVO IFQ are issued as Class B IFQ, which may be delivered to any processor and are not required to be delivered to a processor with unused IPQ.

The Council also recommended that because CVC QS was generated based on deliveries to onshore or stationary floating crab processors, it also should be issued as 90 percent Class A IFQ and 10 percent Class B IFQ. In addition to the Class A and B IFQ issuance requirements for CVC IFQ, the Council recommended and the Program implements limits on the ability of CVC QS holders to transfer, or lease, their CVC IFQ to other persons. This limitation was intended to ensure that CVC QS holders who received their QS by participating as captains and crew on crab vessels continued to be active participants onboard vessels in order to receive the benefits of their CVC IFQ. The Council recognized that logistical complications and confusion likely would arise early in the Program as a result of the interaction of the requirement that limits the ability to lease CVC IFQ and the requirement that 90 percent of that CVC IFQ would be issued as Class A IFQ and would be subject to processor delivery. The Council recognized that these complications could be exacerbated with the anticipated fleet contraction occurring under the Program.

To facilitate CVC QS/IFQ holders and reduce the complex process of matching of Class A IFQ to specific processors with IPQ, the Program exempted CVC IFQ from issuance as Class A/B IFQ and the prohibitions on CVC IFQ leasing for the first three crab fishing years. The Council indicated that this three year period, which expires on June 30, 2008 (see 50 CFR 680.41(e) and 50 CFR 680.42(b)(6) and (c)(5)) should provide CVC QS/IFQ holders time to adapt to the Program before phasing in these additional restrictions. Further, the Council recommended that the appropriateness of applying Class A and B IFQ restrictions should be reviewed 18 months after the implementation of the Program. The Council anticipated that applying these restrictions to CVC QS may not be necessary to achieve the goals of providing additional stability to the processing sector and communities, and could impose additional costs and complexity on CVC QS/IFQ holders. The Council recognized that the effect on processor and community stability could be minimal given the small allocation of CVC QS (i.e., not greater than three percent of the total QS pool in any fishery) and that only 90 percent of the resulting CVC IFQ would be subject to issuance as Class A IFQ and be subject to delivery to specific processors holding IPQ.

The RIR/IRFA prepared for this proposed action by Council and NMFS staff indicates that the application of Class A IFQ delivery requirements to CVC IFQ would logistically complicate use of those shares (see **ADDRESSES**). In the first two years of the Program, many harvesters have asserted that logistical demands in the crab fisheries are greatly increased when coordinating landings of Class A IFQ under the delivery and regional landing requirements. Specifically, individual CVC IFQ holders who are not participating in a crab harvesting cooperative would be forced to compete for delivery with holders of CVO IFQ shares to specific processors holding IPQ. CVO IFQ holders are likely to be in a much better negotiating position with respect to processors because of their relatively large share holdings (i.e., vessel owner shares are allocated 97 percent of the QS pool). Given the relatively large number of CVC IFQ holders compared to CVO IFQ holders, this would require extensive efforts and create additional complications to coordinate the time critical linkages with a processor's IPQ before fishing begins. Public testimony received during the Council's deliberations noted these concerns and asserted that the potential advantages to processors and communities by establishing these delivery requirements were outweighed by the additional costs that CVC QS/IFQ holders would incur. Public testimony from processors and communities with processing facilities did not dispute this assertion and supported permanently exempting CVC QS from the requirements that it be issued as Class A and B IFQ.

Permanently extending the exemption of the Class A/B IFQ delivery requirements to CVC QS/IFQ holders would not be anticipated to have adverse effects on other participants given the limited number of these shares relative to CVO, CPO, and CPC QS/IFQ. Adding the Class A IFQ to CVC IFQ, which is less than three percent of the total annual IFQ issued, would not have an appreciable effect on processor stability or substantially benefit specific communities with processing facilities. This is further supported by the fact that CVC QS/IFQ has been exempt from the Class A IFQ delivery requirement for the first three years of the Program and no negative effects were indicated in the RIR/IRFA. Public testimony provided during Council review of this issue did not indicate that there would be negative effects on processors or communities as a result of a permanent exemption from Class A/B designation for CVC IFQ.

Additionally, based on a review of recent harvest patterns provided in the draft RIR/IRFA, it appears as though CVC IFQ delivery patterns are similar to those of Class A IFQ. These patterns could change in the future so that CVC IFQ would be more likely to be delivered independently of Class A IFQ to other markets; however, given the relatively small percentage of the total landings that are assigned to CVC IFQ onboard a vessel, it is unlikely to expect delivery patterns for CVC IFQ to differ from the delivery patterns currently observed. Furthermore, even if the

delivery patterns of CVC IFQ did change in the future, it is not clear that a shift in such a relatively small amount of IFQ would have an appreciable effect on overall processor operations or deliveries to specific communities.

Regionalization. In addition to processor share landing requirements, Class A IFQ and IPQ are subject to regional landing requirements. Those shares must be landed and processed in specified geographic regions. Those regions are described in the EIS prepared for the Program and the RIR/IRFA prepared for this action (see **ADDRESSES**). The Class A IFQ regional delivery requirements vary depending on the specific crab fishery but generally ensure that a portion of the catch is delivered within areas that have communities that are active in crab processing. For most crab fisheries, there are two regions. One region is typically considered the more remote region. The requirement to land within the more remote region provides some assurance that the small number of processors and communities historically active within that region will continue to receive catch that could otherwise be diverted to the less remote region thereby disadvantaging the more remote region relative to those other processors or communities.

If CVC IFQ were subject to a Class A/B IFQ designation, then 90 percent of the CVC IFQ would be defined as Class A IFQ and therefore subject to regionalization. Because the Program exempted CVC IFQ from a Class A/B IFQ designation through June 30, 2008, to reduce the initial complexities of matching shares and for the other reasons mentioned in the previous section, CVC IFQ also was exempted from regionalization.

If CVC QS/IFQ were subject to the Class A/B IFQ designation, the Class A CVC IFQ would be subject to regionalization, and a greater proportion of the catch would have to be landed in specific geographic regions. The amount of additional pounds that would be subject to regionalization and landed within each region would vary. The net effect of regionalizing CVC IFQ is that less than three percent of the total IFQ issued in a crab fishery would be subject to regionalization. This is because three percent of the IFQ may be issued as CVC or CPC IFQ. A portion of the three percent of the IFQ issued as CVC and CPC IFQ in a crab fishery would be comprised of CVC IFQ. The relative amount of CPC and CVC IFQ issued varies among the crab fisheries and is described in the RIR/IRFA prepared for this proposed action (see **ADDRESSES**). Only 90 percent of the IFQ issued as CVC IFQ would be issued as Class A IFQ that is subject to regionalization.

It is difficult to predict whether applying regional delivery requirements to CVC IFQ would have an impact on existing delivery patterns within a given region for a specific crab fishery. Based on data in the RIR/IRFA from the first two years of the Program, CVC IFQ has had delivery patterns very similar to CVO Class A IFQ for a variety of reasons. These include economic inefficiencies when establishing markets for CVC IFQ separate from CVO Class A IFQ given the relatively small amounts of CVC IFQ, the need to use CVC IFQ to accommodate unique situations such as icing conditions and the loss of a floating processor during the early part of the *C. opilio* fishery in 2006, and the operational inefficiencies that can result when attempting to make deliveries of CVC IFQ distinct from CVO IFQ.

Given the high level of crab cooperative membership among all QS holders (including CVC QS holders), it is likely that most CVC QS holders will continue to cooperate with CVO QS holders and pool their IFQ in a cooperative. This coordinated management makes it likely that CVC IFQ assigned to a cooperative would be delivered in coordination with CVO Class A IFQ assigned to a cooperative. It is possible that permanently exempting CVC IFQ from regionalization could encourage cooperatives to combine their CVC IFQ with CVO Class B IFQ for delivery to markets outside of the region designated for the CVO Class A IFQ. However, it is not possible to predict whether such a shift in delivery patterns will occur. Given the fact that CVC IFQ is currently exempt from regionalization, and CVC IFQ is delivered in conjunction with CVO Class A IFQ currently, it is not clear if a continuing exemption from regionalization requirements would have any noticeable effect on the overall delivery of CVC IFQ within a given region. However, permanently exempting CVC IFQ from regionalization requirements could provide opportunities to CVC IFQ holders to use additional markets that would be foreclosed if those shares are subject to regionalization.

Arbitration System. To aid participants in resolving price and delivery disputes that may arise among Class A IFQ and IPQ holders, the Council developed an arbitration system. Regulations require that Class A IFQ and IPQ holders join private arbitration organizations. These arbitration organizations, in turn, must enter into contracts that define the procedure for resolving price disputes. The arbitration system serves several functions to resolve price and delivery disputes including establishing a mechanism for the orderly matching of Class A IFQ with IPQ, developing a market report and non-binding price formula to inform price negotiations, and providing a binding arbitration procedure to resolve impasses in negotiations. A more complete description of the arbitration system is provided in the RIR/IRFA prepared for this action and the EIS prepared for the Program (see **ADDRESSES**).

Since the arbitration system applies only to Class A IFQ, the existing exemption of CVC IFQ from Class A/B IFQ designation effectively exempts CVC IFQ from the arbitration system. If the Class A/B IFQ designation is applied to CVC QS, then participation in the arbitration system would be mandatory for CVC QS/IFQ holders. Participation in the arbitration system costs money and can require involvement in complex negotiations should disputes need to be resolved through binding arbitration.

Arbitration organization fees are borne by its members. Currently, the arbitration organization for harvesters charges each member $500. Whether a discounted rate would be offered to CVC QS/IFQ holders because of their relatively small share holdings is not known and would need to be determined by the arbitration organization. It is possible that costs could decline over time as the administrative aspects of the arbitration system become more established. Other general costs for the arbitration system, including hiring arbitrators and preparing the market report and non-binding price formula, are split evenly between the harvesting and the processing sectors. Based on experience from the first two years of the Program, it is likely that administrative costs of the arbitration program will remain less than one-half cent per pound of delivered product in the future.

In addition to the administrative aspects of the arbitration system, CVC QS/IFQ holders may also have costs related to their participation in a binding arbitration proceeding. These costs can be incurred either individually or through collective action with other Class A IFQ holders who are in a cooperative with the CVC QS holder. Individual participation by CVC QS holders who are not members of a cooperative would be costly and likely would be ineffective because of the administrative complexity and substantive challenges of participation in a binding arbitration. Collective participation allows the pooling of resources and information, thereby

reducing the individual burden of participation in a binding arbitration. Many fishermen believe that professional representation is necessary to guide negotiations due to the complexity of the system and the expense of gathering market information needed for effective negotiation. Harvester cooperatives have coordinated binding arbitration negotiations through an inter-cooperative agreement, the Inter-Cooperative Exchange, which has helped distribute these costs. Whether CVC QS holders would be charged for participation in the Inter-Cooperative Exchange at the same level as holders of CVO or CPO QS, or at a discounted rate, is not known, and would be at the discretion of the harvesters participating in the binding arbitration.

At a minimum, applying arbitration system requirements to CVC QS/IFQ holders would increase their costs of operation. Depending on the relative size of their quota holdings, these additional costs could represent a substantial portion of the value derived from their quota. In the extreme, these additional costs could outweigh the value derived from the quota and make it unprofitable to participate in the fishery. It is not possible to predict the number of persons who might be in such a position due to the potential variability in arbitration costs, exvessel values, and quota share holdings applicable to each person.

Summary. The Council recommended, and this proposed rule would implement, a permanent exemption to delivery, regionalization, and arbitration system requirements for CVC QS/IFQ holders. As described in greater detail in the previous section and the RIR/IRFA prepared for this action, this proposed rule would permanently extend the existing exemption to avoid the additional costs and complexity that will result to CVC QS/IFQ holders and the very limited benefits that may accrue to some processors and communities if the delivery, regionalization, and arbitration system requirements were applied to CVC QS/IFQ.

NMFS is proposing to modify the Program regulations to remove all instances that either require or refer to CVC IFQ being redesignated as Class A/B IFQ after June 30, 2008. These references occur in regulatory text at 50 CFR 680.2, 680.20, 680.21, 680.40, and 680.42.

Classification

The Assistant Administrator for Fisheries, NOAA, has determined that this proposed rule is consistent with Amendment 26, the Magnuson-Stevens Fishery Conservation and Management Act, and other applicable laws, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

An IRFA was prepared that describes the impact this proposed rule would have on small entities. Copies of the RIR/IRFA prepared for this proposed rule are available from NMFS (see **ADDRESSES**). The RIR/IRFA prepared for this proposed rule incorporates by reference an extensive RIR/IRFA prepared for Amendments 18 and 19 to the FMP that detailed the impacts of the Program on small entities.

The IRFA for this proposed action describes the action; describes in detail the reasons why this action is being proposed; describes the objectives and legal basis for the proposed rule; describes and estimates the number of small entities to which the proposed rule would apply; describes any projected reporting, record keeping, or other compliance requirements of the proposed rule; identifies any overlapping, duplicative, or conflicting Federal rules; and describes any significant alternatives to the proposed rule that accomplish the stated objectives of the Magnuson-Stevens Act and any other applicable statutes, and that would minimize any significant adverse economic impact of the proposed rule on small entities.

The description of the proposed action, its purpose, and its legal basis are described in the preamble and are not repeated here. All of the directly regulated entities under this proposed rule are individuals. Only individuals can hold CVC QS/IFQ, and only regulations applicable to CVC QS/IFQ would be modified by this action. The IRFA estimates that currently 219 individuals hold CVC QS/IFQ and would be directly regulated by the proposed action. The IRFA notes that estimates of the number of small CVC QS/IFQ holders under the Program are complicated by limited share holder information, but, conservatively, the IRFA estimates that all of the individuals would be considered small entities. The standard used by the U.S. Small Business Administration to define a small entity involved in fish harvesting is described in the IRFA (see **ADDRESSES**).

The proposed rule would not change or require additional existing reporting, recordkeeping, and other compliance requirements. The analysis uncovered no Federal rules that would conflict with, overlap, or be duplicated by the alternatives under consideration.

All of the directly regulated individuals would be expected to benefit from this action relative to the status quo alternative because it would relieve these individuals from requirements that would increase their costs of operation. Among the two alternatives considered, status quo and the proposed action, the proposed action would be the alternative that would minimize adverse economic impacts on the individuals that are directly regulated. Only one alternative to the status quo was deemed appropriate because the proposed action is to permanently extend the exemption from delivery, regionalization, and arbitration system requirements for CVC QS/IFQ holders. Additionally, there is no information available to indicate that exempting CVC QS/IFQ holders from delivery, regionalization, and arbitration system requirements for a longer fixed period of time (e.g., until June 30, 2011, or June 30, 2014) would have any different effects on the benefits or costs for communities, processors, or CVC QS/IFQ holders that would not occur under the status quo or the permanent exemption alternative. Because the net effect of such an alternative would not differ from the two alternatives under consideration other than to change the date when the delivery, regionalization, and arbitration system requirements would apply, such an approach was briefly considered but not analyzed as a distinct alternative. As described in the preamble to this proposed action, it is not possible to exempt CVC QS/IFQ holders from only one of the three requirements because delivery, regionalization, and arbitration system requirements are integrated and no additional alternatives were needed to analyze the proposed action that would exempt CVC QS/IFQ holders from only one or two of the requirements.

Although the alternatives under consideration in this action would have distributional and efficiency impacts for individual participants, such as reducing some operational costs for CVC QS/IFQ holders, in no case are these impacts in the aggregate expected to be substantial. Although neither of the alternatives has substantial negative impacts on small entities, preferred Alternative 2 minimizes the potential negative impacts that could arise under Alternative 1, the status quo alternative. Differences in efficiency that could arise are likely to affect most participants in a minor way having an overall insubstantial impact. As a consequence, neither alternative is expected to have any significant economic or socioeconomic impacts. Nevertheless,

Alternative 2 is preferable because it reduces costs of operations for small entities to a limited degree.

List of Subjects in 50 CFR Part 680

Alaska, Fisheries.

Dated: March 26, 2008.

Samuel D. Rauch III

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 680 is proposed to be amended as follows:

PART 680—SHELLFISH FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

1. The authority citation for 50 CFR part 680 is revised to read as follows:

Authority: 16 U.S.C. 1862; Pub. L. 109–241; Pub. L. 109–479.

2. In § 680.2, the definitions of ''Arbitration IFQ'', and ''Arbitration QS'' are revised to read as follows:

§ 680.2 Definitions.

* * * * *

Arbitration IFQ means:

(1) Class A catcher vessel owner (CVO) IFQ held by a person who is not a holder of PQS or IPQ and who is not affiliated with any holder of PQS or IPQ, and

(2) IFQ held by an FCMA cooperative.

Arbitration QS means CVO QS held by a person who is not a holder of PQS or IPQ and is not affiliated with any holder of PQS or IPQ.

* * * * *

3. In § 680.20, paragraphs (a)(1), (b)(1)(i), the introductory text to paragraph (c), and paragraph (e)(7) are revised to read as follows:

§ 680.20 Arbitration System.

(a) * * *

(1) Arbitration System. All CVO QS, Arbitration IFQ, Class A IFQ holders, PQS and IPQ holders must enter the contracts as prescribed in this section that establish the Arbitration System. Certain parts of the Arbitration System are voluntary for some parties, as specified in this section. All contract provisions will be enforced by parties to those contracts.

* * * * *

(b) * * *

(1) * * *

(i) Holders of CVO QS,

* * * * *

(c) *Preseason requirements for joining an Arbitration Organization.* All holders of CVO QS, PQS, Arbitration IFQ, Class A IFQ affiliated with a PQS or IPQ holder, and IPQ must join and maintain a membership in an Arbitration Organization as specified in paragraph (d) of this section. All holders of QS, PQS, IFQ, or IPQ identified in the preceding sentence must join an Arbitration Organization at the following times:

* * * * *

(e) * * *

(7) *IFQ and IPQ Issuance and Selection of the Market Analyst, Formula Arbitrator, and Contract Arbitrator(s).* NMFS will not issue CVO IFQ and IPQ for a crab QS fishery until Arbitration Organizations establish by mutual agreement contracts with a Market Analyst, Formula Arbitrator, and Contract Arbitrators for that fishery and notify NMFS.

* * * * *

4. In § 680.21, paragraph (a)(1)(iii)(B) is revised to read as follows:

§ 680.21 Crab harvesting cooperatives.

* * * * *

(a) * * *

(1) * * *

(iii) * * *

(B) Upon joining a crab harvesting cooperative for a CR fishery, NMFS will convert all of a QS holder's QS holdings for that CR fishery to crab harvesting cooperative IFQ.

* * * * *

5. In § 680.40, paragraphs (b)(1)(ii), (b)(2)(i)(B), (b)(2)(ii)(C), (c)(2)(v)(J), (c)(4) introductory text, (h)(2)(i), (h)(2)(ii), and (h)(6)(ii) are revised to read as follows:

§ 680.40 Quota Share (QS), Processor QS (PQS), Individual Fishing Quota (IFQ), and Individual Processor Quota (IPQ) issuance.

* * * * *

(b) * * *

(1) * * *

(ii) *Catcher Vessel Crew (CVC) QS* shall be initially issued to qualified persons defined in paragraph (b)(3) of this section based on legal landings of unprocessed crab.

* * * * *

(2) * * *

(i) * * *

(B) *South QS* if the legal landings that gave rise to the QS for a crab QS fishery were not landed in the North Region, and all CVO QS allocated to the WAI crab QS fishery; or

* * * * *

(ii) * * *

(C) CVC QS;

* * * * *

(c) * * *

(2) * * *

(v) * * *

(J) The percentage calculated in paragraph (c)(2)(v)(I) of this section may be adjusted according to the provisions at paragraphs (c)(3) and (c)(4) of this section. The amount calculated in paragraph (c)(2)(v)(H) of this section is multiplied by the percentage for each region. These regional QS designations do not apply to CVC QS.

* * * * *

(4) *Regional designation of Western Aleutian Islands golden king crab.* Fifty percent of the CVO QS that is issued in the WAG crab QS fishery will be initially issued with a West regional designation. The West regional designation applies to QS for delivery west of 174° W. longitude. The remaining 50 percent of the CVO QS initially issued for this fishery is not subject to regional designation (Undesignated QS). A person (p) who would receive QS based on the legal landings in only one region will receive QS with only that regional designation. A person who would receive QS with more than one regional designation for that crab QS fishery would have his or her QS holdings regionally adjusted on a pro rata basis as follows:

* * * * *

(h) * * *

(2) * * *

(i) QS shall yield Class A or Class B IFQ if:

(A) Initially assigned to the CVO QS sector; or

(B) Transferred to the CVO QS sector from the CPO QS sector.

(ii) The Class A/B IFQ TAC is the portion of the TAC assigned as Class A/B IFQ under paragraphs (h)(2)(i)(A) and (B) of this section.

* * * * *

(6) * * *

(ii) CVC IFQ is not subject to regional designation.

* * * * *

6. In § 680.42, paragraph (b)(6) is revised to read as follows:

§ 680.42 Limitations on use of QS, PQS, IFQ, and IPQ.

* * * * *

(b) * * *

(6) Any person harvesting crab under a Class B IFQ, CPO IFQ, CVC IFQ, or CPC IFQ permit may deliver that crab to any RCR.

* * * * *

[FR Doc. E8–6584 Filed 3–28–08; 8:45 am]

BILLING CODE 3510–22–S

Notices

Federal Register
Vol. 73, No. 62
Monday, March 31, 2008

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

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: International Trade Administration (ITA).

Title: Annual Report from Foreign-Trade Zones.

Form Number(s): ITA–359P.

OMB Control Number: 0625–0109.

Type of Request: Regular submission.

Burden Hours: 14,674.

Number of Respondents: 163.

Average Hours per Response: 38 to 211 hours (depending on size and structure of the foreign-trade zone).

Needs and Uses: The Foreign-Trade Zone Annual Report is the vehicle by which Foreign-Trade Zone (FTZ) grantees report annually to the Foreign-Trade Zones Board, pursuant to the requirements of the Foreign Trade Zones Act (19 U.S.C. 81a–81u). The annual reports submitted by grantees are the only complete source of compiled information on FTZ's. The data and information contained in the reports relates to international trade activity in FTZ's. The reports are used by the Congress and the Department to determine the economic effect of the FTZ program. The reports are also used by the FTZ Board and other trade policy officials to determine whether zone activity is consistent with U.S. international trade policy, and whether it is in the public interest. The public uses the information regarding FTZ's activities to evaluate their effect on industry sectors. The information contained in annual reports helps zone grantees in their marketing efforts.

Affected Public: State, local, or tribal governments; not-for-profit institutions.

Frequency: Annually.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: David Rostker, (202) 395–3897.

Copies of the above information collection proposal can be obtained by calling or writing Diana Hynek, Departmental Paperwork Clearance Officer, (202) 482–0266, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to David Rostker, OMB Desk Officer, Fax number (202) 395–7285 or via the Internet at *David_Rostker@omb.eop.gov*.

Dated: March 25, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–6486 Filed 3–28–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Proposed Information Collection; Comment Request; U.S. Commercial Service Brand Analysis and Strategy Survey

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, 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.

DATES: Written comments must be submitted on or before May 30, 2008.

ADDRESSES: Direct all written comments to Diana Hynek, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6625, 14th and Constitution Avenue, NW., Washington, DC 20230 (or via the Internet at *dHynek@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Jennifer Kirsch; Phone: 202–482–5449; Fax: 202–482–5362; E-mail: *Jennifer.Kirsch@mail.doc.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

Expanding U.S. exports is a national priority essential to improving U.S. trade performance. The Department of Commerce (DOC) International Trade Administration (ITA) U.S. Commercial Service (CS) serves as the key U.S. government agency responsible for promoting exports of goods and services from the United States, particularly by small- and medium-sized enterprises, and assisting U.S. exporters in their dealings with foreign governments. The Government Performance and Results Act of 1993 and the President's Management Agenda Fiscal Year 2002 mandate CS to improve program performance and achieve better results for the American people. In accordance with these mandates, the CS needs to address the weaknesses and opportunities for improvement identified by the Office of Management and Budget's 2003 Program Assessment Rating Tool (PART). To address these weaknesses and opportunities, to remain relevant to the marketplace, and to meet the objective of ''broadening and deepening'' the U.S. exporter base, the CS must increase its market penetration. To increase market penetration, U.S. companies have to (1) know about the CS and then (2) choose to work with the CS. Currently, there is no research available about CS awareness or purchasing behavior. The customer satisfaction and net promoter metrics that the CS have are only tied to existing customers and do not provide insights on how to increase market penetration and how to appeal to prospective customers. Implementing four new metrics: awareness, consideration, transaction, and loyalty, will provide the CS with the data it needs to provide a baseline for the CS brand and benchmark the CS against other organizations.

The CS has contracted with The Research Associates (TRA) to conduct surveys to understand awareness levels of the CS among U.S. companies and purchasing behaviors of U.S.

companies. By understanding the attitudes and behaviors of U.S. companies regarding awareness and purchasing behaviors, the CS can increase awareness of the CS among customers and prospective customers; influence non-customers to consider working with the CS, encourage customers and prospective customers to buy from the CS, and create loyalty among these customers.

II. Method of Collection

Firms will be recruited via the telephone using lists obtained from third party vendors. Data collection will be conducted via a telephone survey and/or e-mail survey.

III. Data

OMB Control Number: None.
Form Number(s): None.
Type of Review: Regular submission.
Affected Public: Business or other for-profit organizations.
Estimated Number of Respondents: 400.
Estimated Time per Response: 15 minutes.
Estimated Total Annual Burden Hours: 100.
Estimated Total Annual Cost to Public: $0.

IV. Request for Comments

Comments are invited 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 (including hours and cost) of the proposed collection of information; (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 through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: March 25, 2008.

Gwellnar Banks,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. E8–6487 Filed 3–28–08; 8:45 am]

BILLING CODE 3510–FP–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews, Request for Revocation in Part, and Deferral of Administrative Review

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

SUMMARY: The Department of Commerce (the Department) has received requests to conduct administrative reviews of various antidumping and countervailing duty orders and findings with February anniversary dates. In accordance with the Department's regulations, we are initiating those administrative reviews. The Department received a request to revoke one antidumping duty order in part. The Department also received requests to defer the initiation of an administrative review for one antidumping duty order.

EFFECTIVE DATE: March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Sheila E. Forbes, Office of AD/CVD Operations, Customs Unit, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482–4697.

SUPPLEMENTARY INFORMATION:

Background

The Department has received timely requests, in accordance with 19 CFR 351.213(b)(2004), for administrative reviews of various antidumping and countervailing duty orders and findings with February anniversary dates. With respect to the antidumping duty orders on Frozen Warmwater Shrimp from Brazil, Ecuador, India, Thailand, the People's Republic of China and the Socialist Republic of Vietnam, the initiation of the antidumping duty administrative review for these cases will be published in a separate initiation notice. The Department received a timely request to revoke in part the antidumping duty order on Stainless Steel Flanges from India with respect to one exporter. The Department also received requests in accordance with 19 CFR 351.213(c) to defer for one year the initiation of the February 1, 2007 through January 31, 2008, antidumping duty administrative review and to continue the deferral of the February 1, 2005 through January 31, 2006, antidumping duty administrative review of the antidumping duty order on Low Enriched Uranium from France.[1]

Initiation of Reviews

In accordance with section 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following antidumping and countervailing duty orders and findings. We intend to issue the final results of these reviews not later than February 28, 2009. Also, in accordance with 19 CFR 351.213(c) we are deferring for one year the initiation of the February 1, 2007 through January 31, 2008 administrative review of the antidumping duty order on Low Enriched Uranium from France (A–427–818) with respect to one producer/exporter.

	Period to be reviewed
Antidumping Duty Proceedings	
Brazil:	
Stainless Steel Bar, A–351–825	2/1/07–1/31/08
Villares Metals S.A.	
Frozen Warmwater Shrimp,[2] A–351–838	2/1/07–1/31/08
Ecuador: Frozen Warmwater Shrimp,[3] A–331–802	2/1/07–8/14/07
India: Stainless Steel Bar, A–533–810	2/1/07–1/31/08
Ambica Steels Limited	
Venus Wire Industries, Pvt. Ltd.	
Forged Stainless Steel Flanges, A–533–809	2/1/07–1/31/08
Echjay Forgings Pvt. Ltd.	

[1] On April 5, 2006, in response to requests, the Department deferred the initiation of the 2005/2006 antidumping duty administrative review on imports of low enriched uranium from France. *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Deferral of Administrative Reviews,* 71 FR 17077 (April 5, 2006). This review is being deferred for another year based on submissions filed by all parties on February 22, 2008 and February 25, 2008.

	Period to be reviewed
Hotmetal Forge (India) Pvt. Ltd. Pradeep Metals Ltd. Frozen Warmwater Shrimp,[4] A–533–840	2/1/07–1/31/08
Republic of Korea: Certain Cut-to-Length Carbon-Quality Steel Plate, A–580–836 Dongkuk Steel Mill Co., Ltd.	2/1/07–1/31/08
Thailand: Frozen Warmwater Shrimp,[5] A–549–822	2/1/07–1/31/08
The People's Republic of China: Axes/Adzes [6] A–570–803 Truper Herramientas S.A. de C.V.	2/1/07–1/31/08
Bars/Wedges,* A–570–803 Truper Herramientas S.A. de C.V.	2/1/07–1/31/08
Frozen Warmwater Shrimp,[7] A–570–893	2/1/07–1/31/08
Hammers/Sledges,* A–570–803 Truper Herramientas S.A. de C.V.	2/1/07–1/31/08
Picks/Mattocks,* A–570–803 Truper Herramientas S.A. de C.V.	2/1/07–1/31/08
Certain Preserved Mushrooms,[8] A–570–851 Fujian Yu Xing Fruit and Vegetable Foodstuff Development Co.	2/1/07–1/31/08
Socialist Republic of Vietnam: Frozen Warmwater Shrimp,[9] A–552–802	2/1/07–1/31/08
Countervailing Duty Proceedings	
Republic of Korea: Certain Cut-to-Length Carbon-Quality Steel Plate, C–580–837 Dongkuk Steel Mill Co., Ltd.	1/1/07–12/31/07
Suspension Agreements	
None.	
Deferral of Initiation of Adminstrative Review	
France: Low Enriched Uranium, A–427–818 Eurodif S.A./AREVA NC (formerly COGEMA).	2/1/07–1/31/08

[2] The initiation of the administrative review for the above referenced case will be published in a separate initiation notice.
[3] The initiation of the administrative review for the above referenced case will be published in a separate initiation notice.
[4] The initiation of the administrative review for the above referenced case will be published in a separate initiation notice.
[5] The initiation of the administrative review for the above referenced case will be published in a separate initiation notice.
[6] (*) If the the above-named company does not qualify for a separate rate, all other exporters of Heavy Forged Hand Tools from the People's Republic of China who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.
[7] The initiation of the administrative review for the above referenced case will be published in a separate initiation notice.
[8] If the above-named company does not qualify for a separate rate, all other exporters of certain preserved mushrooms from the People's Republic of China who have not qualified for a separate rate are deemed to be covered by this review as part of the single PRC entity of which the named exporters are a part.
[9] The initiation of the administrative review for the above referenced case will be published in a separate initiation notice.

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an antidumping duty order under section 351.211 or a determination under section 351.218(f)(4) to continue an order or suspended investigation (after sunset review), the Secretary, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine, consistent with *FAG Italia* v.*United States,* 291 F.3d 806 (Fed. Cir. 2002), as appropriate, whether antidumping duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Interested parties must submit applications for disclosure under administrative protective orders in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures* (73 FR 3634). Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.*, the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

These initiations and this notice are in accordance with section 751(a) of the Tariff Act of 1930, as amended (19 U.S.C. 1675(a)), and 19 CFR 351.221(c)(1)(i).

Dated: March 26, 2008.

Stephen J. Claeys,

Deputy Assistant Secretary for Import Administration.

[FR Doc. E8–6564 Filed 3–28–08; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Environmental Technologies Trade Advisory Committee (ETTAC)

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of open meeting.

DATES: April 18, 2008.

TIMES: 9 a.m. to 3 p.m.

ADDRESSES: Department of Commerce, 14th and Constitution, NW., Washington DC 20230, Room 4813.

SUMMARY: The Environmental Technologies Trade Advisory Committee (ETTAC) will hold a plenary meeting on April 18, 2008 at the U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, in Room 4813. The ETTAC will discuss updated negotiations in the World Trade Organization's environmental goods and services trade liberalization, trade issues concerning China, drafting of a recommendation paper, among other administrative committee priority items. The meeting is open to the public and time will be permitted for public comment.

Written comments concerning ETTAC affairs are welcome anytime before or after the meeting. Minutes will be available within 30 days of this meeting.

The ETTAC is mandated by Public Law 103–392. It was created to advise the U.S. government on environmental trade policies and programs, and to help it to focus its resources on increasing the exports of the U.S. environmental industry. ETTAC operates as an advisory committee to the Secretary of Commerce and the Trade Promotion Coordinating Committee (TPCC). ETTAC was originally chartered in May of 1994. It was most recently re-chartered until September 2008.

For further information phone Ellen Bohon, Office of Energy and Environmental Technologies Industries (OEEI), International Trade Administration, U.S. Department of Commerce at (202) 482–0359. This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to OEEI at (202) 482–5225.

Dated: March 19, 2008.

Patricia M. Sefcik,

Acting Director, Office of Energy and Environmental Industries.

[FR Doc. E8–6466 Filed 3–28–08; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–820]

Stainless Steel Bar from France: Preliminary Results of Antidumping Duty Administrative Review

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

SUMMARY: In response to a timely request by Ascometal, S.A. (Ascometal), the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on stainless steel bar (SSB) from France with respect to Ascometal. The period of review (POR) is March 1, 2006, through February 28, 2007.

We preliminarily determine that Ascometal did not sell SSB below normal value (NV) during the POR. Interested parties are invited to comment on the preliminary results. If the preliminary results are adopted in our final results of administrative review, we will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries.

EFFECTIVE DATE: March 31, 2008.

FOR FURTHER INFORMATION CONTACT: David Goldberger or Terre Keaton Stefanova, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW, Washington, DC 20230; telephone: (202) 482–4136 or (202) 482–1280, respectively.

SUPPLEMENTARY INFORMATION:

Background

On March 7, 2002, the Department of Commerce (the Department) published in the **Federal Register** an antidumping duty order on SSB from France. *See Antidumping Duty Order: Stainless Steel Bar from France*, 67 FR 10385 (March 7, 2002). On March 2, 2007, the Department published in the **Federal Register** a notice of ''Opportunity To Request Administrative Review'' of the antidumping duty order on SSB from France for the POR. *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review*, 72 FR 9505 (March 2, 2007). On March 30 and April 2, 2007, Ugitech, S.A. (Ugitech) and Ascometal submitted timely letters requesting that the Department conduct an administrative review of their sales of SSB made during the POR, pursuant to section 751 of the Tariff Act of 1930, as amended (the Act). On April 27, 2007, the Department published a notice of initiation of an administrative review with respect to Ascometal and Ugitech. *See Initiation of Antidumping and Countervailing Duty Reviews*, 72 FR 20986 (April 27, 2007). On April 30, 2007, we issued antidumping duty questionnaires to both companies.

On May 24, 2007, Ugitech timely withdrew its request for an administrative review. The Department published the rescission of the administrative review with respect to Ugitech on June 15, 2007. *See Stainless Steel Bar from France: Notice of Partial Rescission of Antidumping Duty Administrative Review*, 72 FR 33202 (June 15, 2007).

Ascometal submitted responses to sections A, B, and C of the Department's questionnaire in June 2007. We issued a supplemental questionnaire in July 2007, and received a response to this questionnaire later that month. Ascometal provided additional information in response to Department requests during November 2007.

On June 27, 2007, the petitioners[1] requested that the Department initiate a sales-below-cost investigation of Ascometal. On August 8, 2007, we initiated this investigation. *See* Memorandum to James Maeder, Director, Office 2, AD/CVD Operations, entitled ''Petitioners' Allegation of Sales Below the Cost of Production for Ascometal S.A.,'' dated August 8, 2007 (COP Initiation Memo). On August 9, 2007, we instructed Ascometal to respond to section D of the Department's questionnaire. On September 10, 2007, we granted Ascometal's request to report its cost of production (COP) based on the period January 1, 2006, through December 31, 2006, rather than the POR. Ascometal submitted its response to section D of the questionnaire on September 28, 2007. On October 12, 2007, we issued a supplemental section D questionnaire to Ascometal, to which Ascometal submitted its response on November 2, 2007.

On November 2, 2007, we extended the time limit for the preliminary results in this review until March 31, 2008. *See Notice of Extension of Time Limit for Preliminary Results in Antidumping Duty Administrative Review: Stainless Steel Bar From France*, 72 FR 62209 (November 2, 2007).

We conducted a verification of Ascometal's reported U.S. sales data in December 2007, and issued our verification report on February 5, 2008. In response to our February 6, 2008, request, Ascometal submitted a revised U.S. sales database reflecting certain verification corrections and findings on February 15, 2008.

Scope of the Order

For purposes of this order, the term ''stainless steel bar'' includes articles of

[1] The petitioners include the following companies: Carpenter Technology Corporation; Crucible Specialty Metals Division, Crucible Materials Corporation; and Electroalloy Corporation, a Division of G.O. Carlson, Inc.

stainless steel in straight lengths that have been either hot-rolled, forged, turned, cold-drawn, cold-rolled or otherwise cold-finished, or ground, having a uniform solid cross section along their whole length in the shape of circles, segments of circles, ovals, rectangles (including squares), triangles, hexagons, octagons, or other convex polygons. SSB includes cold-finished stainless steel bars that are turned or ground in straight lengths, whether produced from hot-rolled bar or from straightened and cut rod or wire, and reinforcing bars that have indentations, ribs, grooves, or other deformations produced during the rolling process.

Except as specified above, the term does not include stainless steel semi-finished products, cut length flat-rolled products (*i.e.*, cut length rolled products which if less than 4.75 mm in thickness have a width measuring at least 10 times the thickness, or if 4.75 mm or more in thickness having a width which exceeds 150 mm and measures at least twice the thickness), products that have been cut from stainless steel sheet, strip or plate, wire (*i.e.*, cold-formed products in coils, of any uniform solid cross section along their whole length, which do not conform to the definition of flat-rolled products), and angles, shapes and sections.

The SSB subject to this order is currently classifiable under subheadings 7222.11.00.05, 7222.11.00.50, 7222.19.00.05, 7222.19.00.50, 7222.20.00.05, 7222.20.00.45, 7222.20.00.75, and 7222.30.00.00 of the *Harmonized Tariff Schedule of the United States* (HTSUS). Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Fair Value Comparisons

To determine whether sales of SSB by Ascometal to the United States were made at less than NV, we compared constructed export price (CEP) to the NV, as described in the ''Constructed Export Price'' and ''Normal Value'' sections of this notice.

Pursuant to section 777A(d)(2) of the Act, we compared the CEPs of individual U.S. transactions to the weighted-average NV of the foreign like product where there were sales made in the ordinary course of trade, as discussed in the ''Cost of Production Analysis'' section below.

Product Comparisons

In accordance with section 771(16) of the Act, we considered all products produced by Ascometal covered by the description in the ''Scope of the Order'' section, above, to be foreign like products for purposes of determining appropriate product comparisons to U.S. sales. Pursuant to 19 CFR 351.414(e)(2), we compared U.S. sales to sales made in the home market within the contemporaneous window period, which extends from three months prior to the month of the U.S. sale until two months after the sale. Where there were no sales of identical merchandise in the comparison market made in the ordinary course of trade to compare to U.S. sales, we compared U.S. sales to sales of the most similar foreign like product made in the ordinary course of trade. In making the product comparisons, we matched foreign like products based on the physical characteristics reported by Ascometal in the following order: general type of finish, grade, remelting process, type of final finishing operation, shape, and size range.

Constructed Export Price

We calculated CEP in accordance with section 772(b) of the Act because the subject merchandise was sold in the United States by Ascometal's affiliate, Lucchini USA Inc. (LUSA), to unaffiliated purchasers.

We based CEP on the delivered prices to unaffiliated purchasers in the United States. We made deductions from the starting price for movement expenses in accordance with section 772(c)(2)(A) of the Act. These expenses included, where appropriate, foreign inland freight, foreign brokerage and handling, ocean freight, transport insurance, U.S. inland freight expenses, U.S. customs duties and fees (including harbor maintenance fees and merchandise processing fees), and port unloading and sorting charges. In accordance with section 772(d)(1) of the Act, we deducted those selling expenses associated with economic activities occurring in the United States, including direct selling expenses (credit expenses, warranty expenses, and credit insurance expenses), indirect selling expenses, and inventory carrying costs.

Ascometal did not report a shipment date and the credit expense for one U.S. sale. As facts available under section 776(a)(1) of the Act, we calculated the imputed credit expense for this sale by using the reported date of sale as the date of shipment and applying the credit expense calculation methodology reported in Ascometal's questionnaire response. For further discussion, *see* ''Preliminary Results Notes and Margin Calculation for Ascometal, S.A.,'' Memorandum to the File dated concurrently with this notice.

Normal Value

A. Home Market Viability

In order to determine whether there was a sufficient volume of sales in the home market to serve as a viable basis for calculating NV, we compared the volume of home market sales of the foreign like product to the volume of U.S. sales of the subject merchandise, in accordance with section 773(a)(1)(C) of the Act.

Because Ascometal's aggregate volume of home market sales of the foreign like product was greater than five percent of its aggregate volume of U.S. sales of the subject merchandise, we determined that its home market was viable. Therefore, we used home market sales as the basis for NV in accordance with section 773(a)(1)(B) of the Act.

B. Level of Trade

Section 773(a)(1)(B)(i) of the Act states that, to the extent practicable, the Department will calculate NV based on sales at the same level of trade (LOT) as the export price (EP) or CEP. Sales are made at different LOTs if they are made at different marketing stages (or their equivalent). *See* 19 CFR 351.412(c)(2). Substantial differences in selling activities are a necessary, but not sufficient, condition for determining that there is a difference in the stages of marketing. *See id. See also Notice of Final Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate From South Africa*, 62 FR 61731, 61732 (November 19, 1997) (*Plate from South Africa*). In order to determine whether the comparison sales are at different stages in the marketing process than the U.S. sales, we review the distribution system in each market (i.e., the chain of distribution), including selling functions, class of customer (customer category), and the level of selling expenses for each type of sale.

Pursuant to section 773(a)(1)(B)(i) of the Act, in identifying LOTs for EP and comparison market sales (*i.e.*, NV based on either home market or third country prices), we consider the starting prices before any adjustments. Where NV is based on constructed value (CV), we determine the NV LOT based on the LOT of the sales from which we derive selling expenses, general and administrative expenses, and profit for CV, where possible. *See* 19 CFR 351.412(c). For CEP sales, we consider only the selling activities reflected in the price after the deduction of expenses and profit under section 772(d) of the Act. *See id.; Micron Technology, Inc. v. United States*, 243 F. 3d 1301, 1314–15 (Fed. Cir. 2001). When the Department

is unable to match U.S. sales to sales of the foreign like product in the comparison market at the same LOT as the EP or CEP, the Department may compare the U.S. sale to sales at a different LOT in the comparison market. In comparing EP or CEP sales to sales at a different LOT in the comparison market, where available data make it practicable, we make an LOT adjustment under section 773(a)(7)(A) of the Act. Finally, for CEP sales only, if the NV LOT is more remote from the factory than the CEP LOT and there is no basis for determining whether the difference in LOTs between NV and CEP affects price comparability (*i.e.*, no LOT adjustment was practicable), the Department shall grant a CEP offset, as provided in section 773(a)(7)(B) of the Act. *See Plate from South Africa*, 62 FR at 61732–33.

We obtained information from Ascometal regarding the marketing stages involved in making the reported comparison market and U.S. sales, including a description of the selling activities performed for each channel of distribution.

Ascometal reported that it made CEP sales to unaffiliated distributors in the U.S. market through its U.S. affiliate LUSA in a single channel of distribution. We examined the selling activities performed for this channel (after deducting expenses and profit pursuant to section 772(d) of the Act), and found that Ascometal performed the following selling functions: invoicing to LUSA, warranty claim services, technical support services, and freight and delivery services from France to the U.S. port. These selling activities were performed at the same relative level of intensity for all CEP sales. Accordingly, we find that all CEP sales constitute one LOT.

With respect to the home market, Ascometal sold the subject merchandise to unaffiliated distributors through a single channel of distribution. We examined the selling activities performed for this channel, and found that Ascometal performed the following selling functions: price negotiations with customers, invoicing to customers, warranty claim services, and freight and delivery services from the factory to the customer. These selling activities were performed at the same relative level of intensity for all home market sales. Accordingly, we find that all home market sales constitute one LOT.

Finally, we compared the CEP LOT to the home market LOT and found that the selling functions performed for home market customers are virtually the same as performed for U.S. customers, and that these selling functions were performed at the same relative level of intensity, with the exception of price negotiation and technical support services. The fact that Ascometal conducts price negotiations only for home market sales and performs technical support services only for U.S. sales is not sufficient to conclude that the home market and U.S. sales were made at a different LOT. Furthermore, Ascometal stated at page B–18 of its June 20, 2007, response to section B of the questionnaire that it ''does not believe there to be a difference in levels of trade between the home and U.S. markets.'' Therefore, we conclude that Ascometal's U.S. and home market sales were made at the same LOT, and as a result, no LOT adjustment or CEP offset under section 773(a)(7) of the Act is warranted.

Cost of Production Analysis

Based on our analysis of the petitioners' allegations that Ascometal made home market sales below the COP, we found that there were reasonable grounds to believe or suspect that Ascometal's sales of SSB in the home market were made at prices below their COP. Accordingly, pursuant to section 773(b) of the Act, we initiated a sales-below-cost investigation to determine whether Ascometal's sales were made at prices below their respective COPs. *See* COP Initiation Memo.

A. Calculation of Cost of Production

In accordance with section 773(b)(3) of the Act, we calculated Ascometal's COP based on the sum of Ascometal's costs of materials and fabrication for the foreign like product, plus amounts for general and administrative expenses and interest expenses (*see* ''Test of Home Market Sales Prices'' section below for treatment of home market selling expenses). The Department relied on the COP data submitted by Ascometal in its most recent supplemental section D questionnaire response, dated November 2, 2007, for the COP calculation.

B. Test of Home Market Sales Prices

On a product-specific basis, we compared the weighted-average COP to the home market sales of the foreign like product, as required under section 773(b) of the Act, in order to determine whether the sale prices were below the COP. For purposes of this comparison, we used COP exclusive of selling expenses. The prices (inclusive of billing adjustments, where appropriate) were exclusive of any applicable movement charges, and direct and indirect selling expenses, as described below under the ''Price-to-Price Comparisons'' section.[2]

C. Results of the COP Test

In determining whether to disregard home market sales made at prices below the COP, we examined, in accordance with sections 773(b)(1)(A) and (B) of the Act whether: (1) within an extended period of time, such sales were made in substantial quantities; and (2) such sales were made at prices which permitted the recovery of all costs within a reasonable period of time in the normal course of trade. Where less than 20 percent of the respondent's home market sales of a given product are at prices less than the COP, we do not disregard any below-cost sales of that product, because we determine that in such instances the below-cost sales were not made within an extended period of time and in ''substantial quantities.'' Where 20 percent or more of a respondent's sales of a given product are at prices less than the COP, we disregard the below-cost sales because: (1) they were made within an extended period of time in ''substantial quantities,'' in accordance with sections 773(b)(2)(B) and (C) of the Act, and (2) based on our comparison of prices to the weighted-average COPs for the POR, they were at prices which would not permit the recovery of all costs within a reasonable period of time, in accordance with section 773(b)(2)(D) of the Act.

We found that less than 20 percent of Ascometal's home market sales of a given product were at prices less than the COP. Accordingly, we did not disregard any below-cost sales in determining NV.

Price-to-Price Comparisons

We calculated NV based on delivered prices to unaffiliated customers. We made adjustments, where appropriate, to the starting price for billing adjustments. *See* 19 CFR 351.401(c). We made deductions, where appropriate, from the starting price for inland freight and inland insurance, under section 773(a)(6)(B)(ii) of the Act.

We made adjustments for differences in costs attributable to differences in the physical characteristics of the merchandise in accordance with section 773(a)(6)(C)(ii) of the Act and 19 CFR 351.411. In addition, we made adjustments under section 773(a)(6)(C)(iii) of the Act and 19 CFR 351.410 for differences in circumstances of sale for imputed credit expenses and liability insurance premium expenses.

[2] Ascometal reported that it did not incur any packing expenses.

Ascometal did not incur packing costs in either the U.S. or home market. Accordingly, no adjustment was warranted under section 773(a)(6)(A) and (B) of the Act.

Currency Conversion

We made currency conversions in accordance with section 773A(a) of the Act based on the exchange rates in effect on the dates of the U.S. sales as certified by the Federal Reserve Bank.

Preliminary Results of Review

As a result of this review, we preliminarily determine that the weighted-average dumping margin for the period March 1, 2006, through February 28, 2007, is as follows:

Manufacturer/Exporter	Percent Margin
Ascometal S.A.	0.00

Disclosure and Public Hearing

The Department will disclose to parties the calculations performed in connection with these preliminary results within five days of the date of publication of this notice. *See* 19 CFR 351.224(b). Interested parties may submit case briefs not later than 30 days after the date of publication of this notice. *See* 19 CFR 351.309(c)(1)(ii). Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the time limit for filing case briefs. *See* 19 CFR 351.309(d)(1). Parties who submit case briefs or rebuttal briefs in this proceeding are requested to submit with each argument: 1) a statement of the issue; 2) a brief summary of the argument; and 3) a table of authorities.

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Import Administration, Room 1870, within 30 days of the date of publication of this notice. Requests should contain: 1) the party's name, address and telephone number; 2) the number of participants; and 3) a list of issues to be discussed. *See* 19 CFR 351.310(c). Issues raised in the hearing will be limited to those raised in the respective case briefs.

The Department will issue the final results of this administrative review, including the results of its analysis of issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

The Department shall determine, and CBP shall assess, antidumping duties on all appropriate entries, in accordance with 19 CFR 351.212. The Department will issue appropriate appraisement instructions for the companies subject to this review directly to CBP 15 days after publication of the final results of this review.

For assessment purposes, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping margins calculated for the examined sales to the total entered value of those same sales. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate calculated in the final results of this review is above *de minimis* (*i.e.*, at or above 0.50 percent). See 19 CFR 351.106(c)(1). The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by this review.

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*). This clarification will apply to entries of subject merchandise during the POR produced by companies included in this review for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.*, a reseller, trading company, or exporter) was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediary involved in the transaction. *See Assessment Policy Notice* for a full discussion of this clarification.

Discontinuation of Cash Deposit Requirements

On January 31, 2008, the U.S. International Trade Commission determined, pursuant to section 751(c) of the Act (*i.e.*, as a result of a five-year ''sunset'' review), that revocation of the antidumping duty order on the subject merchandise would not be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time. *See Stainless Steel Bar From France, Germany, Italy, Korea, and The United Kingdom*, 73 FR 5869 (January 31, 2008). Accordingly, the antidumping duty order on SSB from France was revoked effective March 7, 2007. *See Revocation of Antidumping Duty Orders on Stainless Steel Bar From France, Germany, Italy, South Korea, and the United Kingdom and the Countervailing Duty Order on Stainless Steel Bar From Italy*, 73 FR 7258 (February 7, 2008). As a result, we have instructed CBP to discontinue collection of cash deposits of antidumping duties on entries of the subject merchandise made on or after March 7, 2007.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This administrative review and notice are published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221.

Dated: March 25, 2008.

David M. Spooner,

Assistant Secretary for Import Administration.

[FR Doc. E8–6568 File 3–28–08; 8:45 am]

BILLING CODE 3510–DS–S

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 08–C0004]

Reebok International Ltd., a Corporation, Provisional Acceptance of a Settlement Agreement and Order

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: It is the policy of the Commission to publish settlements which it provisionally accepts under the Federal Hazardous Substances Act in the **Federal Register** in accordance with the terms of 16 CFR 1118.20(e). Published below is a provisionally-accepted Settlement Agreement with Reebok International Ltd., a corporation, containing a civil penalty of $1,000,000.00.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by April 15, 2008.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to the Comment 08–C0004, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway,

Room 502, Bethesda, Maryland 20814–4408.

FOR FURTHER INFORMATION CONTACT: Dennis C. Kacoyanis, Trial Attorney, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814–4408; telephone (301) 504–7587.

SUPPLEMENTARY INFORMATION: The text of the Agreement and Order appears below.

Dated: March 17. 2008.

Todd A. Stevenson,

Secretary.

United States of America Consumer Product Safety Commission

[CPSC DOCKET NO. 08–C0084]

In the Matter of Reebok International Ltd., a Corporation

Settlement Agreement

1. This Settlement Agreement (''Agreement'') is made by and between the staff (''the staff'') of the United States Consumer Product Safety Commission (''the Commission'') and Reebok International Ltd. (''Reebok''), a corporation. This Agreement and the incorporated attached Order (''Order'') settle the staff's allegations set forth below.

The Parties

2. The Commission is an independent federal regulatory agency responsible for the enforcement of the Federal Hazardous Substances Act, 15 U.S.C. 1261–1278, (''FHSA'').

3. Reebok is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal corporate office located at 1895 J. W. Foster Boulevard, Canton, MA 02021. Reebok is a manufacturer of athletic footwear and apparel.

Staff Allegations

4. Between May 2004 and March 2006, Reebok introduced or caused the introduction into interstate commerce, or received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise approximately 300,000 Heart-Shaped Charm Bracelets (''charm bracelets''). The charm bracelets were provided as free gifts with the purchase of various styles of children's footwear.

5. Reebok failed to take action to ensure that the charm bracelets did not contain toxic levels of lead, thereby creating a risk of lead poisoning and adverse health effects to children.

6. In March 2006, Reebok received a report of the death of a four-year-old child allegedly caused by lead poisoning. The child reportedly swallowed the charm bracelet's heart-shaped pendant. Reebok immediately reported to the Commission.

7. In March 2006, the Commission staff obtained samples of the charm bracelets, which were tested at the CPSC Laboratory. The test results demonstrated that certain components of the charm bracelets contained a total lead content from 78 to 93 percent and accessible lead from 3,441 to 9,856 micrograms of lead. These levels of lead are ''toxic'' within the meaning of the FHSA.

8. The charm bracelets are a hazardous substance because they are toxic and may cause substantial personal injury or substantial illness during or as a proximate result of any customary foreseeable handling or use, including reasonably foreseeable ingestion by children. Accordingly, the charm bracelets are hazardous substances under section 2(f)(l)(A) of the FHSA, 15 U.S.C. 1261(f)(l)(A).

9. The charm bracelets were marketed with children's footwear and were intended for use by children. Therefore, the charm bracelets constitute banned hazardous substances under section 2(q)(1)(A) of the FHSA, 15 U.S.C. 1261(q)(1)(A).

10. Reebok knowingly introduced or delivered for introduction into interstate commerce, or caused such acts, or received in interstate commerce and delivered or proffered delivery thereof for pay or otherwise or caused such acts, with respect to the aforesaid banned hazardous charm bracelets, as the term ''knowingly'' is defined in section 5(c)(5) of the FHSA, 15 U.S.C. 1264(c)(5), in violation of section 4(a) and (c) of the FHSA, 15 U.S.C. 1263(a) and (c).

11. Pursuant to section 5(c)(1) of the FHSA, 15 U.S.C. 1264(c)(1), Reebok is subject to civil penalties for the aforementioned violation.

Reebok's Response

12. Reebok denies the staff's allegations that it violated the FHSA as set forth in paragraphs 4 through 11 above.

Agreement of the Parties

13. Under the FHSA, the Commission has jurisdiction over this matter and over Reebok.

14. In settlement of the staff's allegations, Reebok shall pay a civil penalty in the amount of one million dollars ($1,000,000.00) within twenty (20) calendar days of service of the final Order of the Commission. This payment shall be made by check payable to the order of the United States Treasury.

15. The parties enter into this Agreement for settlement purposes only. The Agreement does not constitute an admission by Reebok or a determination by the Commission that Reebok knowingly violated the FHSA.

16. Upon provisional acceptance of this Agreement, the Agreement shall be placed on the public record and be published in the **Federal Register** in accordance with the procedures set forth in 16 CFR 1118.20(e). If the Commission does not receive any written request not to accept the Agreement within 15 days, the Agreement shall be deemed finally accepted on the 16th calendar day after the date it is published in the **Federal Register** in accordance with 16 CFR 1118.20(f).

17. Upon the Commission's final acceptance of the Agreement and issuance of the final Order, Reebok knowingly, voluntarily, and completely waives any rights it may have in this matter to the following: (i) An administrative or judicial hearing, (ii) judicial review or other challenge or contest of the validity of the Commission's actions, (iii) a determination by the Commission as to whether Reebok failed to comply with the FHSA, (iv) a statement of findings of fact or conclusions of law, and (v) any claims under the Equal Access to Justice Act.

18. This Agreement and Order resolves the staffs allegations contained in paragraphs 4 through 11 herein. Upon final acceptance of this Agreement by the Commission and issuance of the final Order, the Commission and those acting on its behalf agree not to initiate any civil penalty action against Reebok based on the aforementioned allegations under the FHSA, 15 U.S.C. 1261–1278 or the Consumer Product Safety Act, 15 U.S.C. 2051–2084.

19. The Commission may publicize the terms of the Agreement and Order.

20. The Agreement and Order shall apply to, and be binding upon Reebok and each of its successors and assigns.

21. The Commission issues the Order under the provisions of the FHSA, 15 U.S.C. 1264(c)(4), and a violation of this Order may subject Reebok to appropriate legal action.

22. This Agreement may be used in interpreting the Order. Agreements, understandings, representations, or interpretations made outside of this Agreement and Order may not be used to vary or contradict its terms.

23. This Agreement shall not be waived, changed, amended, modified, or otherwise altered without written agreement thereto executed by the party

against whom such amendment, modification, alteration, or waiver is sought to be enforced.

24. If after the effective date hereof, any provision of this Settlement Agreement and Order is held to be illegal, invalid, or unenforceable under present or future laws effective during the terms of the Agreement and Order, such provision shall be fully severable. The balance of the Agreement and Order shall remain in full effect, unless the Commission and Reebok agree that severing the provision materially changes the purpose of the Settlement Agreement and Order.

25. Pursuant to section 6(b) of the Interim Delegation of Authority ordered by the Commission on February 1, 2008, the Commission delegated to the Assistant Executive Director for Compliance and Field Operations the authority to act, with the concurrence of the General Counsel, for the Commission under 16 CFR 1118.20 with respect to Staff allegations that Reebok and affiliated entities violated 15 U.S.C. 1263 and are therefore subject to civil penalties under 15 U.S.C. 1264.

Reebok International Ltd.

Dated: March 12, 2008.

Joseph W. Keane, *Chief Financial Officer Reebok International Ltd., 1895 J. W. Foster Boulevard Canton, MA 02021.*

Dated: March 12, 2008.

Peter L. Winik, *Esquire,* Latham & Watkins *LLP, 555 Eleventh Street, NW., Washington, DC 20004–1304 Attorneys for Reebok International Ltd.*

U.S. Consumer Product Safety Commission.

John Gibson Mullan, *Assistant Executive Director, Office of Compliance and Field Operations U. S. Consumer Product, Safety Commission, 4330 East West Highway Bethesda, MD 20814,*

Ronald O. Yelenik, *Acting Director, Legal Division.*

Office of Compliance and Field Operations.

Dated: March 12, 2008.

Dennis C. Kacoyanis, *Trial Attorney, Legal Division, Office of Compliance and Field Operations.*

United States of America Consumer Product Safety Commission

[CPSC DOCKET NO. 08–C0004]

In the Matter of Reebok International Ltd., a Corporation

Order

Upon consideration of the Settlement Agreement entered into between Reebok International Ltd. (''Reebok'') and the staff of the Consumer Product Safety Commission (''the Commission''); and the Commission having jurisdiction over the subject matter and Reebok; and pursuant to the authority delegated in section 6(b) of the Interim Delegation of Authority ordered by the Commission on February 1, 200; and it appearing that the Settlement Agreement and Order is in the public interest, it is ordered, that the Settlement Agreement be, and hereby, is accepted; and it is further ordered, that Reebok shall pay a civil penalty of one million dollars ($1,000,000.00). This payment shall be made by check payable to the order of the United States Treasury within (20) calendar days of service of the final Order of the Commission upon Reebok. Upon the failure of Reebok to make full payment in the prescribed time, interest on the outstanding balance shall accrue and be paid at the federal rate of interest under the provisions of 28 U.S.C. 1961(a) and (b).

Provisionally accepted and provisional Order issued on the 17th day of March, 2008.

By Order of the Commission.

Todd A. Stevenson,
Secretary Consumer Product Safety Commission.

[FR Doc. E8–6407 Filed 3–28–08; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket No. DoD–2007–OS–0093]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form, and OMB Number: ''Department of Defense Security Agreement'' ''Appendage to Department of Defense Security Agreement'' ''Certificate Pertaining to Foreign Interests''; DD Forms 441, 441–1 and SF 328; OMB Control Number 0704–0194.

Type of Request: Revision.

Number of Respondents: 2,641.

Responses per Respondent: 2.

Annual Responses: 5,282.

Average Burden per Response: 1.56 hours.

Annual Burden Hours: 8,240.

Needs and Uses: Executive Order (EO) 12829, ''National Industrial Security Program (NISP)'' stipulates that the Secretary of Defense shall serve as the Executive Agent for inspecting and monitoring the contractors, licensees, and grantees who require or will require access to or who store or will store classified information; and for determining the eligibility for access to classified information of contractors, licensees, and grantees and their respective employees. The specific requirements necessary to protect classified information released to private industry are set forth in DoD 5200.22–M. ''National Industrial Security Program Operating Manual (NISPOM).'' Respondents must execute DD Form 441, ''Department of Defense Security Agreement,'' which is the initial contract between industry and the government. This legally binding document details the responsibility of both parties and obligates the contractor to fulfill requirements outlined in DoD 5220.22–M. The DD Form 441–1, ''Appendage to Department of Defense Security Agreement,'' is used to extend the agreement to branch offices of the contractor. SF Form 328, ''Certificate Pertaining to Foreign Interests'' must be submitted to provide certification regarding elements of Foreign Ownership, Control or Influence (FOCI) as stipulated in paragraph 2–302b of the DoD 5220.22–M.

Affected Public: Business or other for-profit; not-for-profit institutions; state, local, or tribal government.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Sharon Mar.

Written comments and recommendations on the proposed information collection should be sent to Ms. Mar at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503. Comments may be e-mailed to Ms. Mar at *Sharon_Mar@omb.eop.gov*.

You may also submit comments, identified by docket number and title, by the following method:

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

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/

Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6528 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket No. DoD–2008–DARS–0031]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title And OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 247, Transportation, and related clauses in DFARS 252.247; OMB Control Number 0704–0245.

Type of Request: Extension.

Number of Respondents: 60,400.

Responses per Respondent: 7.71262.

Annual Responses: 465,842.

Average Burden per Response: .322242 hours.

Annual Burden Hours: 150,114.

Needs and Uses: DoD contracting officers use this information to verify that prospective contractors have adequate insurance prior to award of stevedoring contracts; to provide appropriate price adjustments to stevedoring contracts; and to assist the Maritime Administration in monitoring compliance with requirements for use of U.S.-flag vessels in accordance with the Cargo Preference Act of 1904 (10 U.S.C. 2631).

Affected Public: Business or other for-profit and not-for-profit institutions.

Frequency: On Occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6529 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket No. DoD–2008–DARS–0032]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Appendix F, Material Inspection and Receiving Report; DD Forms 250, 250c, and 250–1; OMB Control Number 0704–0248.

Type of Request: Extension.

Number of Respondents: 17,120.

Responses per Respondent: Approximately 217.

Annual Responses: 3,720,000.

Average Burden per Response: Approximately 2.5 minutes.

Annual Burden Hours: 153,800.

Needs and Uses: Collection of this information is necessary to process the shipping and receipt of materials and payment to contractors under DoD contracts.

Affected Public: Business or other for-profit and not-for-profit institutions.

Frequency: On Occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6530 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket No. DoD–2007–OS–0111]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form, and OMB Number: Military Critical Technical Data Agreement; DD Form 2345; OMB Control Number 0704–0207.

Type of Request: Extension.

Number of Respondents: 6,000.

Responses per Respondent: 2.

Annual Responses: 6,000.

Average Burden per Response: 20 minutes.

Annual Burden Hours: 2,000.

Needs and Uses: The information collection requirement is necessary as a basis for certifying enterprises or individuals to have access to DoD export-controlled militarily critical technical data subject to the Provisions of 32 CFR 250. Enterprises and individuals that need access to unclassified DoD-controlled militarily critical technical data must certify on DD Form 2345, Militarily Critical Technical Data Agreement, that data will be used only in ways that will inhibit unauthorized access and maintain the protection afforded by U.S. export control laws. The information collected is disclosed only to the extent consistent with prudent business practices, current regulations, and statutory requirements and is so indicated on the Privacy Act Statement of DD Form 2345.

Affected Public: Business or other for-profit; not-for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Sharon Mar.

Written comments and recommendations on the proposed information collection should be sent to Ms. Mar at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503. Comments may be e-mailed to Ms. Mar at *Sharon_Mar@omb.eop.gov*.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6532 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket No. DoD–2008–DARS–0033]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form and OMB Number: Defense Federal Acquisition Regulation Supplement (DFARS) Part 219, Small Business Programs, and the clause at DFARS 252.219–7003; OMB Control Number 0704–0386.

Type of Request: Extension.

Number of Respondents: 41.

Responses per Respondent: 1.

Annual Responses: 41.

Average Burden per Response: 1 hour.

Annual Burden Hours: 41.

Needs and Uses: DoD uses this information in assessing contractor compliance with small business subcontracting plans.

Affected Public: Business or other for-profit and not-for-profit institutions.

Frequency: On Occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be sent to Ms. Seehra at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6543 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Charter Amendment of Department of Defense Federal Advisory Committees

AGENCY: DoD.

ACTION: Charter Amendment of Federal Advisory Committee.

SUMMARY: Under the provisions of the Federal Advisory Committee Act of 1972, (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.85, the Department of Defense gives notice that it is amending the charter for the Board of Regents Uniformed Services University of the Health Sciences (hereafter referred to as the Board of Regents).

The Board of Regents is a non-discretionary federal advisory committee established by 10 U.S.C. 2166(e) to assist the Secretary of Defense in an advisory capacity in carrying out the Secretary's responsibility to conduct the business of the Uniformed Services University of the Health Sciences. Section 956 of Public Law 110–181 (National Defense Authorization Act for Fiscal Year 2008) amended the Board's membership provisions of 10 U.S.C. 2113(a). All other provisions of 10 U.S.C. 2113(a) remained unchanged.

Pursuant to 10 U.S.C. 2113(a), the Board of Regents shall be composed of fifteen members:

1. Nine persons outstanding in the fields of health and health education who shall be appointed from civilian life by the Secretary of Defense;

2. The Secretary of Defense, or his designee, who shall be an ex officio member;

3. The surgeons general of the uniformed services, who shall be ex officio members; and

4. The President of the University, who shall be a non-voting ex officio member. The terms of office for each member of the Board of Regents (other than ex officio members shall be six years except that:

1. Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; and

2. Any member who term of office has expired shall continue to serve until his successor is appointed.

One of the appointed members of the Board of Regents shall be designated as Chairman by the Secretary of Defense. The Chairman shall be the presiding officer of the Board.

Members of the Board of Regents appointed by the Secretary of Defense, who are not federal officers or employees, shall serve as Special Government Employees under the authority of 5 U.S.C. 3109, and pursuant to 10 U.S.C. 2113(e), shall receive compensation at a rate fixed by the Secretary of Defense, in addition to travel expense and per diem for official travel.

The Board of Regents shall be authorized to establish subcommittees, as necessary and consistent with its mission, and these subcommittees or working groups shall operate under the provisions of the Federal Advisory Committee Act of 1972, the Government in the Sunshine Act of 1976, and other appropriate federal regulations.

Such subcommittees or workgroups shall not work independently of the chartered Board, and shall report all their recommendations and advice to the Board of Regents for full deliberation and discussion. Subcommittees or workgroups have no authority to make decisions on behalf of the chartered Board nor can they report directly to the Department of Defense or any federal officers or employees who are not Board of Regents members.

SUPPLEMENTARY INFORMATION: The Board of Regents shall meet at the call of the Board's Designated Federal Officer, in consultation with the Board's chairperson. The Designated Federal Officer, pursuant to DoD policy, shall be a full-time or permanent part-time DoD employee, and shall be appointed in accordance with established DoD policies and procedures. The Designated Federal Officer or duly appointed Alternate Designated Federal Officer shall attend all committee meetings and subcommittee meetings.

Pursuant to 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written statements to the Board of Regents Uniformed Services University of the Health Sciences membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board of Regents Uniformed Services University of the Health Sciences.

All written statements shall be submitted to the Designated Federal Officer for the Board of Regents Uniformed Services University of the Health Sciences, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Board of Regents Uniformed Services University of the Health Sciences' Designated Federal Officer can be obtained from the GSA's FACA Database—*https://www.fido.gov/facadatabase/public.asp.*

The Designated Federal Officer, pursuant to 41 CFR 102–3.150, will announce planned meetings of the Board of Regents Uniformed Services University of the Health Sciences. The Designated Federal Officer, at that time, may provide additional guidance on the submission of written statements that are in response to the stated agenda for the planned meeting in question.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Deputy Committee Management Officer for the Department of Defense, 703–601–6128.

Dated: March 25, 2008.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6531 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary of Defense

Defense Business Board (DBB)

AGENCY: DoD.

ACTION: Meeting notice; correction.

The Department of Defense is correcting a meeting notice that appeared on March 21, 2008 (72 FR 11095). The document corrects the e-mail address for the **FOR FURTHER INFORMATION CONTACT**.

DATES: This action is effective March 21, 2008.

Correction

In the **Federal Register** of March 21, 2008, in FR Doc. E8–5739 on page 15144, correct the **FOR FURTHER INFORMATION CONTACT** e-mail address to read as follows: *linda.clay.ctr@osd.mil.*

Dated: March 24, 2008.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6526 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Open Meeting of the National Defense University Visitors (BOV)

AGENCY: Department of Defense; National Defense University.

ACTION: Notice of ''Open Meeting.''

SUMMARY: The National Defense University (NDU), Designated Federal Officer, has scheduled a meeting of the Board of Visitors. Request subject notice be published in the **Federal Register**. The National Defense University Board of Visitors is a Federal Advisory Board. The Board meets twice a year in proceedings that are open to the public.

DATES: The meeting will be held on May 5–6, 2008 from 11:00 to 17:00 on the 5th and continuing on the 6th from 8:30 to 13:30.

Location: The Board of Visitors meeting will be held at Building 62, Marshall Hall, Room 155, National Defense University, 300 5th Avenue, Fort McNair, Washington, DC 20319–5066.

FOR FURTHER INFORMATION CONTACT: The point of contact for this notice of an ''Open Meeting'' is Jeanette Tolbert, at (202) 685–3955, Fax (202) 685–3328 or *TolbertJ@ndu.edu.*

SUPPLEMENTARY INFORMATION: State of the University, National Security Professional Development, Accreditation, and Federal Policy. The meeting is open to the public; limited space is made available for observers and will be allocated on a first-come, first-serve basis.

Dated: March 24, 2008.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, DoD.

[FR Doc. E8–6527 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket No. USA–2007–0028]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form, and OMB Number: Uniform Tender of Rates and/or Charges for Domestic transportation Services (DoD/USCG Sponsored Household Goods); SDDC Form 43–R; OMB Control Number 0702–0018.

Type of Request: Extension.

Number of Respondents: 1,124.

Responses per Respondent: 2.

Annual Responses: 2,248.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 1,124.

Needs and Uses: Department of Defense approved household goods carrier files rates to engage in the movement of DOD and United States Coast Guard sponsored shipments within the continental United States. Headquarters, Military Surface Deployment and Distribution Command evaluates the rates and awards the traffic to low rate responsible carriers whose rates are responsive and most advantageous to the Government.

Affected Public: Business or other for-profit.

Frequency: Semi-annually.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Sharon Mar.

Written comments and recommendations on the proposed information collection should be sent to Ms. Mar at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503. Comments may be e-mailed to Ms. Mar at *Sharon_Mar@omb.eop.gov*.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6535 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army

[Docket No. USA–2007–0029]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form, and OMB Number: Statement of Accessorial Services Performed and Statement of Accessorial Services Performed (Storage-In-Transit Delivery and Reweigh); DD Forms 619 and 619–1; OMB Control Number 0702–0022.

Type of Request: Extension.

Number of Respondents: 989.

Responses per Respondent: 439.

Annual Responses: 434,171.

Average Burden per Response: 5 minutes.

Annual Burden Hours: 36,181.

Needs and Uses: Since household goods (HHG) move at Government expense, data is needed to choose the best service at lowest cost to the Government. The information provided by the carrier serves as a bid for contract to transport HHG, unaccompanied baggage, mobile homes, and boats. This information is collected on a regular basis, but is submitted intermittently throughout the year. Best-service-for-least-cost carrier receives the contract. DD Form 619 certifies that accessorial services were actually performed. The Government would not know which carriers to use for shipping personal property if they could not collect this information.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Sharon Mar.

Written comments and recommendations on the proposed information collection should be sent to Ms. Mar at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503. Comments may be e-mailed to Ms. Mar at *Sharon_Mar@omb.eop.gov*.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6537 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, Corps of Engineers

Notice of Cancellation of Intent To Prepare a Draft Environmental Impact Statement for Expansion of the Tampa Harbor (Hilisborough County) FL

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Cancellation of Notice of Intent.

SUMMARY: The Jacksonville District, U.S. Army Corps of Engineers hereby cancels

its Notice of Intent to prepare a Draft Environmental Impact Statement as published in FR, Vol. 66, No. 105, Pages 29557 and 29558, May 31, 2001.

FOR FURTHER INFORMATION CONTACT: Eric K. Gasch, (904) 232–3140, Environmental Branch, Planning Division, P.O. Box 4970, Jacksonville, FL 32232–0019.

SUPPLEMENTARY INFORMATION: The reason for this action is that project alternatives have been eliminated which proposed substantial environmental impacts. Alternatives that were eliminated include the creation of a secondary channel loop anchorage area. The project will still consider alternatives which widen and provide depth at the existing channels. These alternatives are not expected to have more than minimal impact on seagrass, hard bottoms, wetlands or other natural resources.

Dated: March 12, 2008.

Rebecca S. Griffith,

Chief, Planning Division.

[FR Doc. E8–6370 Filed 3–28–08; 8:45 am]

BILLING CODE 3710–AJ–M

DEPARTMENT OF DEFENSE

Department of the Navy

[No. USN–2007–0058]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form, and OMB Number: Academic Certification for Marine Corps Officer Candidate Program; NAV MC Form 10469; OMB Control Number 0703–0011.

Type of Request: Extension.

Number of Respondents: 3,500.

Responses per Respondent: 1.

Annual Responses: 3,500.

Average Burden Per Response: 15 minutes.

Annual Burden Hours: 875.

Needs and Uses: Used by Marine Corps officer procurement personnel, this form provides a standardized method for determining the academic eligibility of applicants for all reserve officer candidate programs. Use of this form is the only accurate and specific method to determine a reserve officer applicant's academic qualifications. Each applicant interested in enrolling in an undergraduate or graduate reserve officer commission program completes and returns the form.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Sharon Mar.

Written comments and recommendations on the proposed information collection should be sent to Ms. Mar at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503. Comments may be e-mailed to Ms. Mar at *Sharon_Mar@omb.eop.gov*.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6539 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

[No. USN–2007–0057]

Submission for OMB Review; Comment Request

ACTION: Notice.

The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

DATES: Consideration will be given to all comments received by April 30, 2008.

Title, Form, and OMB Number: Individual MCJROTC Instructor Evaluation Summary; NAV MC Form 10942; OMB Control Number 0703–0016.

Type of Request: Extension.

Number of Respondents: 450.

Responses per Respondent: 1.

Annual Responses: 450.

Average Burden per Response: 30 minutes.

Annual Burden Hours: 225.

Needs and Uses: This form provides a written record of the overall performance of duty of MCJROTC instructors who are responsible for implementing the MCJROTC curriculum. The Individual MCJROTC Instructor Evaluation Summary is completed by principals to evaluate the effectiveness of individual MCJROTC instructors. The form is further used as a performance related counseling tool and as a record of service performance to document performance and growth of individual MCJROTC instructors. Evaluating the performance of instructors is essential in ensuring that they provide quality training.

Affected Public: Individuals or households.

Frequency: Annually.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Ms. Sharon Mar.

Written comments and recommendations on the proposed information collection should be sent to Ms. Mar at the Office of Management and Budget, Desk Officer for DoD, Room 10236, New Executive Office Building, Washington, DC 20503. Comments may be e-mailed to Ms. Mar at *Sharon_Mar@omb.eop.gov*.

You may also submit comments, identified by docket number and title, by the following method:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DoD Clearance Officer: Ms. Patricia Toppings.

Written requests for copies of the information collection proposal should

be sent to Ms. Toppings at WHS/ESD/Information Management Division, 1777 North Kent Street, RPN, Suite 11000, Arlington, VA 22209–2133.

Dated: March 24, 2008.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. E8–6540 Filed 3–28–08; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Meeting of the Board of Advisors (BOA) to the President, Naval Postgraduate School (NPS)

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: Pursuant to the provisions of The Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given that the following meeting of the Board of Advisors to the President, Naval Postgraduate School will be held. This meeting will be open to the public.

DATES: The meeting will be held on Tuesday, April 22, 2008, from 8 a.m. to 4 p.m. (open) and on Wednesday, April 23, 2008, from 8 a.m. to 12 p.m. Pacific Time Zone.

ADDRESSES: The meeting will be held at the Naval Postgraduate School, Global Center for Security Cooperation's Didactic Room, 1 University Circle, Monterey, CA 93943–5001.

FOR FURTHER INFORMATION CONTACT: Ms. Jaye Panza, Naval Postgraduate School, Monterey, CA 93943–5001, telephone: 831–656–2514.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to elicit the advice of the Board on the Naval Service's Postgraduate Education Program and the collaborative exchange and partnership between NPS and the Air Force Institute of Technology (AFIT). The board examines the effectiveness with which the NPS is accomplishing its mission. To this end, the board will inquire into the curricula; instruction; physical equipment; administration; state of morale of the student body, faculty, and staff; fiscal affairs; and any other matters relating to the operation of the NPS as the board considers pertinent.

Individuals without a DoD government/CAC card require an escort at the meeting location. For access, information, or to send written comments regarding the NPS BOA contact Ms. Jaye Panza, Naval Postgraduate School, 1 University Circle, Monterey, CA 93943–5001 or by fax 831–656–3145 by April 10, 2008.

Dated: March 25, 2008.

T.M. Cruz,

Lieutenant, Office of the Judge Advocate General, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. E8–6512 Filed 3–28–08; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board Chairs

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB) Chairs. The Federal Advisory Committee Act (Pub. L. No. 92–463, 86 Stat. 770) requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, April 23, 2008, 8:30 a.m.–5 p.m., Thursday, April 24, 2008, 8:30 a.m.–4 p.m.

ADDRESSES: Red Lion Hotel Richland Hanford House, 802 George Washington Way, Richland, WA 99352, Phone: (509) 946–7611, Fax: (509) 943–8564.

FOR FURTHER INFORMATION CONTACT: E. Douglas Frost, Designated Federal Officer, U.S. Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585; Phone: (202) 586–5619.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda

Wednesday, April 23, 2008

8:30 a.m. Welcome/Introductions.
9 a.m. Waste Disposition Presentation.
10 a.m. Break.
10:15 a.m. Round Robin: Top Three Site-Specific Issues.
11:15 a.m. EM Program Update.
12 p.m. Lunch.
1:30 p.m. Presentations:
- Budget Timelines and Process.
- Baselines and Five-Year Plan.

3:30 p.m. Break.
3:45 p.m. Open Discussion.
4:45 p.m. Public Comment Period.
5 p.m. Adjourn.

Thursday, April 24, 2008

8:30 a.m. Welcome and Review of Wednesday's Proceedings.
8:45 a.m. Engineering and Technology Update.
10:15 a.m. Break.
10:30 a.m. EM SSAB Product Development Discussion.
11:30 a.m. Public Comment Period.
12 p.m. Lunch Break.
1:15 p.m. DOE–HQ ''News and Views''.
1:45 p.m. EM SSAB Product Wrap-Up.
3:45 p.m. Closing Remarks.
4 p.m. Adjourn.

Public Participation: The meeting is open to the public. Written statements may be filed either before or after the meeting with the Designated Federal Officer, E. Douglas Frost, at the address or telephone listed above. Individuals who wish to make oral statements pertaining to agenda items should also contact E. Douglas Frost. Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make public comment will be provided a maximum of five minutes to present their comments.

Minutes: Minutes will be available by writing or calling E. Douglas Frost at the address or phone number listed above. Minutes will also be available at the following Web site: *http://www.em.doe.gov/stakepages/ssabchairs.aspx.*

Issued at Washington, DC on March 25, 2008.

Rachel Samuel,

Deputy Committee Management Officer.

[FR Doc. E8–6519 Filed 3–28–08; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM08–2–000]

Pipeline Posting Requirements Under Section 23 of the Natural Gas Act; Notice of Agenda for Technical Conference

March 25, 2008.

The staff technical conference in the above-referenced proceeding is scheduled for April 3, 2008, at the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in the Commission Meeting Room (2–C) from 9:30 a.m. until 3 p.m. (EST).

As directed by the Commission in the Notice of Proposed Rulemaking

(NOPR),[1] the staff is holding this conference to address implementation issues associated with the pipeline posting proposal. The discussion will focus on establishing approaches to improving information available to market participants to foster a more transparent and efficient market for natural gas. Discussion at the conference will be organized around the major elements of the pipeline posting proposal: Obtaining and posting of actual flow information; obtaining and posting of scheduled flow information, and obtaining and posting of available capacity. The conference will address each element's connection with the overall purposes of the pipeline posting proposal and implementation issues related to each element for interstate pipelines, non-interstate pipelines and storage providers.

As stated in the February 7, 2008 Notice of Extension of Time, comments on the NOPR were to be filed on or before March 13, 2008 and reply comments are still to be filed on or before April 14, 2008.

All interested persons are invited to attend and there is *no* registration fee to attend. This conference will be neither web-cast nor transcribed.

Anyone with questions about the conference or interested in speaking at the conference may send brief descriptions of the issues they would like to address to *Saida.Shaalan@ferc.gov*, or 202–502–8278.

Commission conferences are accessible under section 508 of the Rehabilitation Act of 1973. For accessibility accommodations please send an e-mail to: *accessibility@ferc.gov* or call toll free 1–866–208–3372 (voice) or 202–208–1659 (TTY), or send a FAX to 202–208–2106 with the required accommodations.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–6533 Filed 3–28–08; 8:45 am]

BILLING CODE 6717–01–P

[1] *Pipeline Posting Requirements under Section 23 of the Natural Gas Act*, 73 FR 1116 (Jan. 7, 2008), FERC Stat. & Regs. ¶ 32,626 (2007).

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2479–010]

Pacific Gas and Electric Company; Notice of Intent To File License Application, Filing of Pre-Application Document, Commencement of Licensing Proceeding, Scoping, Solicitation of Comments on the Pad and Scoping Document, and Identification of Issues and Associated Study Requests

March 25, 2008.

a. *Type of Filing:* Notice of Intent to File License Application for a New License and Commencing Licensing Proceeding.

b. *Project No.:* 2479–010.

c. *Dated Filed:* February 21, 2008.

d. *Submitted by:* Pacific Gas and Electric Company (PG&E).

e. *Name of Project:* French Meadows Transmission Line Project.

f. *Location:* The French Meadows Transmission Line Project (Project) is located in Placer County, California and is entirely within the boundaries of the El Dorado and Tahoe National Forests. The Project includes three sections: (1) The French Meadows Transmission Line, a 60-kilovolt (kV) transmission line extending from Placer County Water Agency's (PCWA) French Meadows power plant to PCWA's Middle Fork power plant; (2) the Oxbow Tap, a 60-kV tap to PCWA's Oxbow power plant, and (3) the Ralston Tap, a 230-kV tap entirely contained within the switchyard of PCWA's Ralston power plant. Each of PCWA's facilities are associated with their Middle Fork Hydroelectric Project, FERC No. 2079, and are not included as part of the Project. The combined length of the Project is 13.37 miles with a right-of-way 40 feet in width.

g. *Filed Pursuant to:* 18 CFR Part 5 of the Commission's Regulations.

h. *Applicant Contact:* Mr. Forrest Sullivan, Senior Project Manager, Pacific Gas and Electric Company, 5555 Florin Perkins Road, Room 100, Sacramento, CA 95826, 916–386–5580.

i. *FERC Contact:* Carolyn Templeton at 202–502–8785 or e-mail *carolyn.templeton@ferc.gov.*

j. We are asking Federal, State, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues to cooperate with us in the preparation of the environmental document. Agencies who would like to request cooperating status should follow the instructions for filing comments described in paragraph (o) below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. See, 94 FERC ¶ 61,076 (2001).

k. With this notice, we are initiating informal consultation with: (a) The U.S. Fish and Wildlife Service and/or NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402 and (b) the California State Historic Preservation Officer, as required by section 106, National Historical Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating PG&E as the Commission's non-federal representative for carrying out informal consultation, pursuant to section 7 of the Endangered Species Act and section 106 of the National Historic Preservation Act.

m. PG&E filed a Pre-Application Document (PAD); including a proposed process plan and schedule with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*http://www.ferc.gov*), using the ''eLibrary'' link. Enter the docket number, excluding the last three digits in the docket number field to access the document. For assistance, contact FERC Online Support at *FERCONlineSupport@ferc.gov* or toll free at 1–866–208–3676, of for TTY, (202) 502–8659. A copy is also available for inspection and reproduction at the address in paragraph (h).

Register online at *http://ferc.gov/esubscribenow.htm* to be notified via e-mail of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. With this notice, we are soliciting comments on the PAD and Scoping Document 1 (SD1), as well as study requests. All comments on the PAD and SD1, and study requests should be sent to the address above in paragraph (h). In addition, all comments on the PAD and SD1, study requests, requests for cooperating agency status, and all communications to and from Commission staff related to the merits of the potential application (an original and eight copies) must be filed with the Commission at the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

All filings with the Commission must include on the first page, the project name (French Meadows Transmission Line Project) and number (P–2479–010), and bear the heading ''Comments on Pre-Application Document,'' ''Study Requests,'' ''Comments on Scoping Document 1,'' ''Request for Cooperating Agency Status,'' or ''Communications to and from Commission Staff.'' Any individual or entity interested in submitting study requests, commenting on the PAD or SD1, and any agency requesting cooperating status must do so by April 11, 2008.

Comments on the PAD and SD1, study requests, requests for cooperating agency status, and other permissible forms of communications with the Commission may be filed electronically via the Internet in lieu of paper. The Commission strongly encourages electronic filings. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov*) under the ''e-filing'' link.

p. Our intent is to prepare an Environmental Impact Statement for which the below meetings satisfied the NEPA scoping requirements.

Scoping Meetings

Because of the interconnection between the French Meadows Transmission Line Project and PCWA's Middle Fork American Project, the scoping meetings for these projects were held concurrently on March 4, 2008, at the Auburn Recreation District-Canyon View Community Center. Commission staff held two scoping meetings; one daytime meeting focused on resource agency, Indian tribes, and non-governmental organization concerns, and one evening meeting focused primarily on receiving input from the public. We invited all interested individuals, organizations, and agencies to attend one or both of the meetings, and to assist staff in identifying particular study needs, as well as the scope of environmental issues to be addressed in the environmental document. The meetings were recorded by a stenographer and became part of the formal record of the Commission proceeding on the projects. Transcripts from these meetings may be viewed on the Web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph (n).

SD1, which outlines the subject areas to be addressed in the environmental document, was mailed to the individuals and entities on the Commission's mailing list. Copies of SD1 were available at the scoping meetings, and may be viewed on the Web at *http://www.ferc.gov,* using the ''eLibrary'' link. Follow the directions for accessing information in paragraph (n). Based on all oral and written comments, a Scoping Document 2 (SD2) may be issued. SD2 may include a revised process plan and schedule, as well as a list of issues, identified through the scoping process.

Site Visit

Typically, a site visit is held together with the scoping meeting. However, because most of the project sites were not be accessible in early March, the licensees (PCWA and PG&E) and Commission staff will visit the project sites on Wednesday, June 25, 2008, starting at 8 a.m. All participants should meet at Auburn Recreation District Canyon View Community Center, located at 471 Maidu Drive, Auburn, California. PCWA and PG&E will provide transportation for participants. Anyone interested in attending the site visit should contact Mr. Forrest Sullivan of PG&E at 916–386–5580 by June 11, 2008. Depending on interest, a second day (Thursday, June 26, 2008) of site visits may be added to the schedule. Should this be the case, a notice will be issued in June stating as such.

Kimberly D. Bose,

Secretary.

[FR Doc. E8–6534 Filed 3–28–08; 8:45 am]

BILLING CODE 6717–01–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

Privacy Act of 1974; Publication of Notice of Proposed New Systems of Records and Amendment of Systems To Add New System Managers

AGENCY: Equal Employment Opportunity Commission.

ACTION: Notice; Publication of Notice of Proposed New Systems of Records and Amendment of System of Records.

SUMMARY: This notice proposes two new systems of records, and amends an existing system of records. The changes implement EEOC's personal identification verification (PIV) card system, and establish a system for EEOC emergency management files.

DATES: The changes to the existing systems of records and the proposed new systems of records will become effective, without further notice, on May 30, 2008 unless comments dictate otherwise.

ADDRESSES: Written comments should be submitted to Stephen Llewellyn, Executive Officer, Equal Employment Opportunity Commission, 1801 L Street, NW., Washington, DC 20507. As a convenience to commentators, the Executive Secretariat will accept comments transmitted by facsimile (''FAX'') machine. The telephone number of the FAX receiver is (202) 663–4114. (This is not a toll-free number.) Only comments of six or fewer pages will be accepted via FAX transmittal. This limitation is necessary to assure access to the equipment. Receipt of FAX transmittals will not be acknowledged, except that the sender may request confirmation of receipt by calling the Executive Secretariat staff at (202) 663–4070 (voice) or (202) 663–4074 (TTD). (These are not toll-free telephone numbers.) You may also submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Copies of comments submitted by the public will be available to review at the Commission's library, Room 6502, 1801 L Street, NW., Washington, DC 20507 between the hours of 9:30 a.m. and 5 p.m. or can be reviewed at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas J. Schlageter, Assistant Legal Counsel, or Kathleen Oram, Senior Attorney, at (202) 663–4640 (voice) or (202) 663–7026 (TTY). Copies of this notice are also available in the following alternate formats: large print, braille, audiotape and electronic file on computer disk. Requests for this notice in an alternative format should be made to EEOC's Publication Center at 1–800–669–3362 (voice) or 1–800–800–3302 (TTY).

SUPPLEMENTARY INFORMATION: The Equal Employment Opportunity Commission published all of its systems of records subject to the Privacy Act in a **Federal Register** notice dated July 30, 2002 (67 FR 49338). The Commission amended three of those systems and added two new systems of records in a **Federal Register** notice published on April 26, 2006 (71 FR 24704). The Commission now proposes to amend one existing system of records and add two new systems of records. Specifically, it proposes to amend its system of records covering its employee identification card records (EEOC–13, Employee Identification Cards), and to add a new system of records covering background investigation records and decisions regarding suitability, eligibility and fitness for service of EEOC employees and applicants (EEOC–22, EEOC Personnel Security Files). The changes to EEOC–13 and proposed new EEOC–22 implement the requirements of

Homeland Security Presidential Directive 12 (HSPD 12), including the personal identification verification (PIV) cards.

The Commission also proposes a new system of records to cover emergency management files (EEOC–21, Emergency Management Records). This system will allow EEOC to maintain EEOC employee and contractor emergency notification rosters and files, emergency contact information, and continuity of operations program files. This information would be used by EEOC officials to contact employees, contractors and others in case of an emergency or other event that may require the assistance of those employees or contractors.

The proposed routine uses for the amended systems of records, EEOC–13, and the two proposed new systems of records, EEOC–21 and EEOC–22, meet the compatibility requirement of the Privacy Act, 5 U.S.C. 552a(a)(7). The proposed new routine uses will permit disclosures of records that are compatible with the purposes for which the information is being collected in each system. We anticipate that any disclosure pursuant to these routine uses will not result in any unwarranted adverse effects on personal privacy.

For the Commission.

Naomi C. Earp,

Chair.

Accordingly, it is proposed that:

1. EEOC–13, Employee Identification Cards, most recently published at 67 FR 49338, 49339 (July 30, 2002), is amended as set forth below:

EEOC–13

SYSTEM NAME:

Employee Identification Cards.

SYSTEM LOCATION:

Central Services Division, Office of the Chief Financial Officer, EEOC, 1801 L Street, NW., Washington, DC 20507, and each of the field offices in Appendix A.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Current EEOC employees, and other individuals who require regular, ongoing access to EEOC facilities or information technology systems, including, but not limited to, federal employees, contractors, interns, volunteers, and individuals formerly in any of these positions. This system does not apply to occasional visitors or short-term guests to whom EEOC will issue temporary identification cards.

CATEGORIES OF RECORDS IN THE SYSTEM:

Records maintained on individuals issued identification cards, including Personal Identification Verification (PIV) cards, by EEOC include the following information: full name; signature; social security number; date of birth; photograph; fingerprints; hair color; eye color; height; weight; office of assignment; telephone number; copy of background investigation form; card issue and expiration dates; personal identification number; results of background investigation; PIV request form; PIV registrar approval signature; PIV card serial number; and a list of all persons who possess current identification cards. In addition, for office locations permitting access by proximity cards, numbered proximity cards and a list of all persons with their assigned proximity card numbers, all doors controlled by the proximity cards and all persons permitted access to each door.

AUTHORITY FOR MAINTENANCE OF SYSTEM:

44 U.S.C. 3101; 41 CFR 101–20.3; 5 U.S.C. 301; Federal Information Security Act (Pub. L. 104–106, 5113); Electronic Government Act (Pub. L. 104–347, 203); Homeland Security Presidential Directive (HSPD) 12, Policy for Common Identification Standard for Federal Employees and Contractors, August 27, 2004.

PURPOSE:

These records are maintained for the purpose of ensuring that EEOC offices and information systems are secure and that only authorized individuals have access to those offices and systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and information from these records may be used:

a. To provide information to a congressional office from the record of an individual in response to an inquiry from that congressional office made at the request of that individual.

b. To disclose to other government agencies and to the public whether an individual is a current employee of the EEOC.

c. To disclose information to another federal agency, to a court, or to a party in litigation before a court or in an administrative proceeding being conducted by a federal agency when the government is a party to the judicial or administrative proceeding.

d. To disclose pertinent information to the appropriate federal, state, or local agency responsible for investigating, prosecuting, enforcing or implementing a statute, rule, regulation or order, where EEOC becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

e. To disclose information to agency contractors who have been engaged to assist the agency in the performance of a contract or other activity related to this system of records and who need to have access to the records in order to perform their activity.

f. To notify another federal agency when, or verify whether, a PIV card is no longer valid.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are maintained in paper files and in electronic media.

RETRIEVABILITY:

Records are retrieved by name, social security number, other ID number, PIV card serial number, photograph, or fingerprint.

SAFEGUARDS:

Records are maintained and stored in file cabinets in a secured area to which only authorized personnel have access. Access to computerized records is limited, through use of access codes and entry logs, to those whose official duties require access.

RETENTION AND DISPOSAL:

Records are destroyed not later than five years after the separation or transfer of the employee. In accordance with HSPD–12, PIV cards are deactivated within 18 hours of cardholder separation, loss of card, or expiration. The information on PIV cards is maintained in accordance with General Records Schedule 11, Item 4. PIV cards are destroyed by cross-cut shredding no later than 90 days after deactivation.

SYSTEM MANAGER AND ADDRESS:

Director, Central Services Division, Office of Chief Financial Officer, EEOC, 1801 L Street, NW., Washington, DC 20507, and the Directors of the field offices listed in Appendix A.

NOTIFICATION PROCEDURES:

Inquiries concerning this system of records should be addressed to the system manager. It is necessary to provide the following information: (1) Name; (2) date of birth; (3) social security number; and (4) mailing address to which response is to be sent.

RECORD ACCESS PROCEDURES:

Same as above.

CONTESTING RECORD PROCEDURES:

Same as above.

RECORD SOURCE CATEGORIES:

Information contained in this system is obtained from the employee, or contractor; other federal agencies; contract employer; or former employer.

2. EEOC–21, Emergency Management Records, is added as set forth below:

EEOC–21

SYSTEM NAME:

Emergency Management Records.

SYSTEM LOCATION:

Headquarters, District, Field, Area and Local Offices may maintain emergency contact files. The Office of Human Resources maintains emergency management and continuity of operations (COOP) files.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

EEOC employees, contractors and other governmental and non-governmental persons essential to carrying out emergency activities.

CATEGORIES OF RECORDS IN THE SYSTEM:

The records, composed of emergency notification rosters and files, emergency contact information, and COOP files, may contain the following personal information: name; office, cellular and home telephone numbers; home address; email address; primary contact name, relationship, address, cellular, work and home telephone numbers; alternate contact's name, relationship, address, cellular, work and home telephone numbers. Each office may collect a different set of information. System records may include special needs information such as medical, mobility, and transportation requirements for individuals. Additional information may include official titles and emergency assignments.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 301; 44 U.S.C. 3101; Executive Order 12565, Assignment of Emergency Preparedness Responsibilities, (Nov. 18, 1989); Presidential Decision Directive 67, Ensuring Constitutional Government and Continuity of Government Operations.

PURPOSE:

To maintain current information on EEOC employees and other persons covered by this system to allow persons with emergency management responsibilities to notify or contact them about conditions that require their urgent assistance or attention during an emergency.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

These records and information in these records may be used:

a. To disclose pertinent information to the appropriate federal, state, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where EEOC becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

b. To disclose information to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

c. To disclose information to an expert, consultant or contractor in the performance of a federal government duty involving EEOC emergency management.

d. To disclose information about an individual during an emergency in order to locate or contact that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are maintained in paper files and in electronic media.

RETRIEVABILITY:

Records are retrieved by name, organization, or location.

SAFEGUARDS:

Records are maintained and stored in file cabinets in a secured area to which only authorized personnel have access. Access to electronic records is limited through use of passwords, access codes and entry logs to those whose official duties require access.

RETENTION AND DISPOSAL:

Records are destroyed one year after termination of employment relationship or contract termination.

SYSTEM MANAGER(S) AND ADDRESS:

Headquarters, District, Field, Area and Local Office Directors. Addresses listed in Appendix A.

NOTIFICATION PROCEDURES:

Inquiries concerning this system of records should be made to the system manager. It is necessary to provide the name of the individual and the mailing address to which the response should be sent.

RECORD ACCESS PROCEDURES:

Same as above.

CONTESTING RECORD PROCEDURES:

Same as above.

RECORD SOURCE CATEGORIES:

Information in this system is obtained from the individuals themselves, their supervisors or office.

3. EEOC–22, EEOC Personnel Security Files, is added as set forth below:

EEOC–22

SYSTEM NAME:

EEOC Personnel Security Files.

SYSTEM LOCATION:

Office of Human Resources, 1801 L Street, NW., Washington, DC 20507.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

EEOC employees, applicants, former employees, and contractors.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, former names, birth date, birth place, social security number, home address, telephone numbers, employment history, residential history, education and degrees earned, names of associates and references and their contact information, citizenship, names of relatives, citizenship of relatives, names of relatives who work for the federal government, criminal history, drug use, financial information, fingerprints, summary report of investigation, results of suitability decisions, requests for appeal, witness statements, investigator's notes, tax return information, credit reports, security violations (including circumstances of violation and agency action taken).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 U.S.C. 3101; 5 CFR Parts 732, and 736; Executive Orders 10450, 10865, 12333, and 12356; and Homeland Security Presidential Directive 12 (HSPD 12), Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004.

PURPOSE:

The records in this system are used to document and support decisions regarding the suitability, eligibility, and fitness for service of applicants for EEOC employment and contract positions, including interns, or volunteers to the extent their duties require access to federal facilities, information, systems, or applications. The records may be used to document security violations and supervisory actions taken.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

a. To provide information to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

b. Except as noted on Standard Forms 85, 85P, and 86, to disclose pertinent information to the appropriate federal, state, or local agency responsible for investigating, prosecuting, enforcing, or implementing a statute, rule, regulation, or order, where EEOC becomes aware of an indication of a violation or potential violation of civil or criminal law or regulation.

c. To disclose information to another federal agency, to a court, or to a party in litigation before a court or in an administrative proceeding being conducted by a federal agency when the government is a party to the judicial or administrative proceeding.

d. To disclose information to any source or potential source from which information is requested in the course of an investigation concerning the retention of an employee or other personnel action (other than hiring), to the extent necessary to identify the individual, inform the source of the nature and purpose of the investigation, and to identify the type of information requested.

e. To disclose information to employees of contractors who have been engaged by EEOC to perform an activity related to suitability, eligibility, and fitness for service of EEOC applicants and employees.

POLICIES AND PRACTICE FOR STORING, RETRIEVING, ACCESSING, RETAINING AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

These records are maintained in paper files and in electronic media.

RETRIEVABILITY:

Background investigation files are retrieved by name, social security number, or fingerprint.

SAFEGUARDS:

Records are maintained and stored in file cabinets in a secured area to which only authorized personnel have access. Access to electronic records is limited through use of passwords, access codes and entry logs to those whose official duties require access.

RETENTION AND DISPOSAL:

These records are destroyed upon notification of death or not later than five years after separation or transfer of employee to another agency or department.

SYSTEM MANAGER AND ADDRESS:

Office of Human Resources, EEOC, 1801 L Street, NW., Washington, DC 20507.

NOTIFICATION PROCEDURE:

Inquiries concerning this system of records should be addressed to the system manager. It is necessary to provide the following information: (1) Name; (2) date of birth; (3) social security number; and (4) mailing address to which response is to be sent.

RECORDS ACCESS PROCEDURES:

Same as above.

CONTESTING RECORD PROCEDURES:

Same as above.

RECORD SOURCE CATEGORIES:

Information is obtained from a variety of sources, including the employee, contractor or applicant via use of the SF–85, SF–85P, or SF–86 and personal interviews; employers' and former employers' records; FBI criminal history records and other databases; financial institutions and credit reports; interviews of witnesses, such as neighbors, friends, co-workers, business associates, teachers, landlords, or family members; tax records; and other public records. Security violation information is obtained from a variety of sources, such as guard reports, security inspections, witnesses, supervisor's reports, audit reports.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE PRIVACY ACT:

Upon publication of a final rule in the **Federal Register**, this system of records will be exempt in accordance with 5 U.S.C. 552a(k)(5) from subsection (c)(3) and (d)(1) of the Privacy Act, but only to the extent that the information identifies witnesses promised confidentiality as a condition of providing information during the course of the background investigation.

[FR Doc. E8–6619 Filed 3–28–08; 8:45 am]

BILLING CODE 6570–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collections Being Reviewed by the Federal Communications Commission; Comments Requested

March 25, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to comment on the following information collections, as required by the Paperwork Reduction Act (PRA) of 1995, Public Law No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid control number. Comments are requested concerning (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 estimate; (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.

DATES: Written PRA comments should be submitted on or before May 30, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: You may submit all PRA comments by e-mail or U.S. Postal mail. To submit your comments by e-mail, send them to *PRA@fcc.gov*. To send your comments by U.S. Postal mail, mark them to the attention of: Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collections, send an e-mail to *PRA@fcc.gov* or contact Cathy Williams at 202–418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0419.

Title: Sections 76.94, Notification; 76.95, Exceptions; 76.105, Notification; 76.106, Exceptions; 76.107, Exclusivity Contracts; and 76.1609, Non-Duplication and Syndicated Exclusivity.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 5,555 respondents; 199,304 responses.

Estimated Time per Response: 0.5–2.0 hours.

Frequency of Response: Third party disclosure requirement; One time reporting requirement.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 183,856 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: 47 CFR 76.94(a) and 76.105(a) require television stations and program distributors to notify cable television system operators of non-duplication protection and exclusivity rights being sought. The notification shall include (1) the name and address of the party requesting non-duplication protection/exclusivity rights and the television broadcast station holding the non-duplication right; (2) the name of the program or series for which protection is sought; and (3) the dates on which protection is to begin and end.

47 CFR 76.94(b) requires broadcasters entering into contracts providing for network non-duplication protection to notify cable systems within 60 days of the signing of such a contract. If they are unable to provide notices as provided for in Section 74.94(a), they must provide modified notices that contain the name of the network which has extended non-duplication protection, the time periods by time of day and by network for each day of the week that the broadcaster will be broadcasting programs from that network, and the duration and extent of the protection.

47 CFR 76.94(d) requires broadcasters to provide the following information to cable television systems under the following circumstances: (1) In the event the protection specified in the notices described in 47 CFR 76.94(a) or (b) has been limited or ended prior to the time specified in the notice, or in the event a time period, as identified to the cable system in a notice pursuant to Section 76.94(b) for which a broadcaster has obtained protection is shifted to another time of day or another day (but not expanded), the broadcaster shall, as soon as possible, inform each cable television system operator that has previously received the notice of all changes from the original notice. Notice to be furnished ''as soon as possible'' under this subsection shall be furnished by telephone, telegraph, facsimile, overnight mail or other similar expedient means. (2) In the event the protection specified in the modified notices described in Section 76.94(b) has been expanded, the broadcaster shall, at least 60 calendar days prior to broadcast of a protected program entitled to such expanded protection, notify each cable system operator that has previously received notice of all changes from the original notice.

47 CFR 76.94(e)(2) and 76.105(c)(2) state that if a cable television system asks a television station for information about its program schedule, the television station shall answer the request.

47 CFR 76.94(f) and 76.107 require a distributor or broadcaster exercising exclusivity to provide to the cable system, upon request, an exact copy of those portions of the contracts, such portions to be signed by both the network and the broadcaster, setting forth in full the provisions pertinent to the duration, nature, and extent of the non-duplication terms concerning broadcast signal exhibition to which the parties have agreed. Providing copies of relevant portions of the contracts is assumed to be accomplished in the notification process set forth in Sections 76.94 and 76.105.

47 CFR 76.95 states that the provisions of Sections 76.92 through 76.94 (including the notification provisions of Section 76.94) shall not apply to a cable system serving fewer than 1,000 subscribers. Within 60 days following the provision of service to 1,000 subscribers, the operator of each such system shall file a notice to that effect with the Commission, and serve a copy of that notice on every television station that would be entitled to exercise network non-duplication protection against it.

47 CFR 76.105(d) requires that in the event the exclusivity specified in Section 76.94(a) has been limited or has ended prior to the time specified in the notice, the distributor or broadcaster who has supplied the original notice shall, as soon as possible, inform each cable television system operator that has previously received the notice of all changes from the original notice. In the event the original notice specified contingent dates on which exclusivity is to begin and/or end, the distributor or broadcaster shall, as soon as possible, notify the cable television system operator of the occurrence of the relevant contingency. Notice to be furnished ''as soon as possible'' under this subsection shall be furnished by telephone, telegraph, facsimile, overnight mail or other similar expedient means.

47 CFR 76.106(b) states that the provisions of Sections 76.101 through 76.105 (including the notification provisions of Section 76.105) shall not apply to a cable system serving fewer than 1,000 subscribers. Within 60 days following the provision of service to 1,000 subscribers, the operator of each such system shall file a notice to effect with the Commission, and serve a copy of that notice on every television station that would be entitled to exercise syndicated exclusivity protection against it.

47 CFR 76.1609 states that network non-duplication provisions of Sections 76.92 through 76.94 shall not apply to cable systems serving fewer than 1,000 subscribers. Within 60 days following the provision of service to 1,000 subscribers, the operator of each system shall file a notice to that effect with the Commission, and serve a copy of that notice on every television station that would be entitled to exercise network non-duplication or syndicated exclusivity protection against it.

OMB Control Number: 3060–0548.

Title: Section 76.1708, Principal Headend; Sections 76.1709 and 76.1620, Availability of Signals; Section 76.56, Signal Carriage Obligations; Section 76.1614, Identification of Must-Carry Signals.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 11,000 respondents; 935,000 responses.

Estimated Time per Response: 0.5–1.0 hour.

Frequency of Response: Recordkeeping requirement; Third party disclosure requirement; On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 66,000 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: 47 CFR 76.1708 requires that the operator of every cable television system shall maintain for public inspection the designation and location of its principal headend. If an operator changes the designation of its principal headend, that new designation must be included in its public file.

47 CFR 76.1709(a) states effective June 17, 1993, the operator of every cable television system shall maintain for public inspection a file containing a list of all broadcast television stations carried by its system in fulfillment of the must-carry requirements pursuant to 47 CFR Section 76.56. Such list shall include the call sign; community of license, broadcast channel number, cable channel number, and in the case of a noncommercial educational broadcast station, whether that station was carried by the cable system on March 29, 1990.

47 CFR 76.1614 and 1709(c) states that a cable operator shall respond in

writing within 30 days to any written request by any person for the identification of the signals carried on its system in fulfillment of the requirements of 47 CFR 76.56.

47 CFR 76.1620 states that if a cable operator authorizes subscribers to install additional receiver connections, but does not provide the subscriber with such connections, or with the equipment and materials for such connections, the operator shall notify such subscribers of all broadcast stations carried on the cable system which cannot be viewed via cable without a converter box and shall offer to sell or lease such a converter box to such subscribers. Such notification must be provided by June 2, 1993, and annually thereafter and to each new subscriber upon initial installation. The notice, which may be included in routine billing statements, shall identify the signals that are unavailable without an additional connection, the manner for obtaining such additional connection and instructions for installation.

47 CFR 76.56 requires cable television systems to carry signals of all qualified local Noncommercial Educational (NCE) sting carriage.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E8–6555 Filed 3–28–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection Approved by the Office of Management and Budget

March 24, 2007.

SUMMARY: The Federal Communications Commission (Commission) has received Office of Management and Budget (OMB) approval for the following public information collection(s) pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). An agency may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number, and no person is required to respond to a collection of information unless it displays a currently valid OMB control number. Comments concerning the accuracy of the burden estimate(s) and any suggestions for reducing the burden should be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT:** section below.

FOR FURTHER INFORMATION CONTACT: Sue Gilgenbach, *Sue.Gilgenbach@fcc.gov*, (202) 418–0639.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1003.

OMB Approval Date: July 21, 2007.

Expiration Date: July 31, 2010.

Title: Communications Disaster Information Reporting Systems (DIRS).

Form No.: Not applicable.

Estimated Annual Burden: 5,300 responses; 0.7 hours (42 minutes) per response; 3,710 hours total per year.

Obligation to Respond: Voluntary.

Nature and Extent of Confidentiality: Because the information that communications companies input to DIRS is sensitive, for national security and/or commercial reasons, DIRS filings shall be treated as presumptively confidential upon filing. The Federal Communications Commission's Public Safety & Homeland Security Bureau Launches Disaster Information Reporting System, 72 FR 52879 (Sept. 17, 2007); The FCC's Public Safety & Homeland Security Bureau Launches Disaster Information Reporting System (DIRS), *Public Notice,* 22 FCC Rcd 16757 (PSHSB 2007). DIRS filings will, however, be shared with the Department of Homeland Security's National Communications System (NCS) on a confidential basis.

Needs and Uses: This voluntary information collection will better enable the Commission to assist communications companies with the restoration of communications in times of crisis, including in the aftermath of terrorist attacks or natural disasters. Through DIRS, wireless, wireline, broadcast, and cable communications providers can provide their emergency contact information and report communications infrastructure status and situational awareness information during times of crisis (*e.g.,* status of their communications equipment, restoration efforts, and source and status of their power supply). The Commission will be able to use this information to ensure that the public and public safety, public health, and other emergency and defense personnel have effective communications services available to them in the immediate aftermath of a disaster.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E8–6562 Filed 3–28–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority, Comments Requested

March 25, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and other Federal agencies to take this opportunity to (PRA) of 1995 (PRA), Public Law No. 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. Subject to the PRA, no person shall be subject to any penalty for failing to comply with a collection of information that does not display a valid control number. Comments are requested concerning (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 estimate; (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.

DATES: Written PRA comments should be submitted on or before May 30, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: You may submit all PRA comments by e-mail or U.S. postal mail. To submit your comments by e-mail, send them to *PRA@fcc.gov.* To submit your comments by U.S. mail, mark them to the attention of Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection(s), contact Cathy Williams at (202) 418–2918 or send an e-mail to *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0175.

Title: Section 73.1250, Broadcasting Emergency Information.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents and Responses: 50 respondents; 50 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits.

Total Annual Burden: 50 hours.

Total Annual Cost: None.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality.

Needs and Uses: 47 CFR 73.1250(e) requires that immediately upon cessation of an emergency during which broadcast facilities were used for the transmission of point-to-point messages or when daytime facilities were used during nighttime hours by an AM station, a report in letter form shall be forwarded to the FCC in Washington, DC, setting forth the nature of the emergency, the dates and hours of the broadcasting of emergency information and a brief description of the material carried during the emergency. A certification of compliance with the non-commercialization provision must accompany the report where daytime facilities are used during nighttime hours by an AM station.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E8–6585 Filed 3–28–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to OMB for Review and Approval, Comments Requested

March 25, 2008.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden, invites the general public and other Federal agencies to take this opportunity to comment on the following information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (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 estimate; (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.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before April 30, 2008. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via Internet at *Nicholas_A._Fraser@omb.eop.gov* or via fax at (202) 395–5167 and to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street, SW., Washington, DC or via Internet at *Cathy.Williams@fcc.gov* or *PRA@fcc.gov.* To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain*, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the title of this ICR (or its OMB control number, if there is one) and then click on the ICR Reference Number to view detailed information about this ICR.''

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0647.

Title: Annual Cable Price Survey and Supplemental Questions.

Form Number: Not applicable.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; State, local or tribal government.

Number of Respondents: 758.

Estimated Time per Response: 2 hours to 10 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 9,096 hours.

Total Annual Cost: None.

Privacy Impact Assessment: No impact(s).

Nature of Response: Mandatory.

Confidentiality: No need for confidentiality required.

Needs and Uses: Section 623(k) of the Cable Television Consumer Protection and Competition Act of 1992 requires the Commission to publish annually a statistical report on average rates for basic cable service, cable programming service, and equipment. The report must compare the prices charged by cable operators subject to ''effective competition'' and those not subject to effective competition. The data from these supplemental questions are needed to complete this report.

The Commission determined that a small number of additional questions related to the cable industry's carriage of digital broadcast signals would be needed to complete the 2007/2008 report on cable industry prices that will be prepared later this year based on the findings from the survey. The increased burden to this information collection represents the burden associated with the supplemental questionnaire.

Federal Communications Commission.

William F. Caton,

Deputy Secretary.

[FR Doc. E8–6594 Filed 3–28–08; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested

persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 25, 2008.

A. Federal Reserve Bank of Atlanta (David Tatum, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Verity Capital Group, Inc., Dahlonega, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of Verity Bank, Winder, Georgia (in organization).

B. Federal Reserve Bank of St. Louis (Glenda Wilson, Community Affairs Officer) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. First Cecilian Bancorp, Inc., Cecilia, Kentucky; to acquire 16.38 percent of Hambac,Inc., Hodgenville, Kentucky and thereby indirectly acquire The Lincoln National Bank of Hodgenville, Kentucky.

Board of Governors of the Federal Reserve System, March 26, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–6525 Filed 3–28–08; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act. Additional information on all bank holding companies may be obtained from the National Information Center website at *www.ffiec.gov/nic/*.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 15, 2008.

A. Federal Reserve Bank of Atlanta (David Tatum, Vice President) 1000 Peachtree Street, N.E., Atlanta, Georgia 30309:

1. Banco Bilbao Vizcaya Argentaria, S.A., Bilbao, Spain; to acquire 100 percent of the voting shares of Proxima Alfa Investments (USA) LLC, New York, New York, and thereby engage in (i) providing investment and financial advisory services, including acting as a registered investment adviser and as a registered commodity trading adviser; (ii) providing as agent transactional services with respect to derivatives, forward contracts, futures, options, swaps and similar transactions; (iii) serving as investment adviser to, general partner or managing member of (and, if appropriate, acting as a commodity pool operator for), and holding and placing equity interests in, private investment funds (including limited partnerships, limited liability companies and similar investment vehicles) (Private Investment Funds) that invest only in securities, derivatives, commodity contracts, and other assets and instruments that a bank holding company would be permitted to hold directly under the BHCA (Private Investment Fund Activities). These activities have been approved by Board Order (see e.g. Meridian Bancorp, Inc., 80 Fed Res. Bull. 736 (1994); The Bessemer Group, Inc., 82 Fed. Res. Bull. 569 (1996); Dresdner Bank AG, 84 Fed. Res. Bull. 985 (1998); UBS AG, 84 Fed. Res, Bull. 684 (1998); Travelers Group Inc., 84 Fed. Res. Bull. 985 (1998); KeyCorp, 84 Fed. Res. Bull. 1075 (1998); First Security Corporation, 85 Fed. Res. Bull 207 (1999); Banque National de Paris, 86 Fed. Res. Bull. 118 (2000); Letter from the Federal Reserve Bank of New York, dated June 3, 2003 (approval for Commerzbank); and Letter from the Federal Reserve Bank of Boston, dated December 16, 2002 (approval for Boston Private Financial Holdings, Inc.); (iv) investing and trading as principal in (A) foreign exchange; (B) forward contracts, options, futures, options on futures, swaps and similar contracts, whether traded on exchanges or not, based on any rate, price, financial asset nonfinancial asset, group of assets, other than a bank-ineligible security, subject to certain conditions and (C) forward contracts, options, options on futures, swaps, and similar contracts, whether traded on exchanges or not, based on an index of a rate, a price, or the value of any financial asset, nonfinancial asset, or group of assets, if the contract requires cash settlement, pursuant to sections 225.28(b)(6)(i); (b)(6)(iv); (b)(7)(v); and (b)(8)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, March 26, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8–6524 Filed 3–28–08; 8:45 am]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–08–0138]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–0164 or send an e-mail to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395–6974. Written comments should be received within 30 days of this notice.

Proposed Project

Pulmonary Function Testing Course Approval Program, 29 CFR 1910.1043 (OMB No. 0920–0138)—Reinstatement—The National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC).

Background

NIOSH has the responsibility under the Occupational Safety and Health Administration's Cotton Dust Standard, 29 CFR 1920.1043, for approving courses to train technicians to perform

pulmonary function testing in the cotton industry. Successful completion of a NIOSH-approved course is mandatory under the Standard. To carry out its responsibility, NIOSH maintains a Pulmonary Function Testing Course Approval Program. The program consists of an application submitted by potential sponsors (universities, hospitals, and private consulting firms) who seek NIOSH approval to conduct courses, and if approved, notification to NIOSH of any course or faculty changes during the approval period, which is limited to five years. The application form and added materials, including an agenda, curriculum vitae, and course materials are reviewed by NIOSH to determine if the applicant has developed a program which adheres to the criteria required in the Standard. Following approval, any subsequent changes to the course are submitted by course sponsors via letter or e-mail and reviewed by NIOSH staff to assure that the changes in faculty or course content continue to meet course requirements. Course sponsors also voluntarily submit an annual report to inform NIOSH of their class activity level and any faculty changes. Sponsors who elect to have their approval renewed for an additional 5 year period submit a renewal application and supporting documentation for review by NIOSH staff to ensure the course curriculum meets all current standard requirements. Approved courses that elect to offer NIOSH-Approved Spirometry Refresher Courses must submit a separate application and supporting documents for review by NIOSH staff. Institutions and organizations throughout the country voluntarily submit applications and materials to become course sponsor and carry out training. Submissions are required for NIOSH to evaluate a course and determine whether it meets the criteria in the Standard and whether technicians will be adequately trained as mandated under the Standard. The estimated annual burden to respondents is 197 hours.

There will be no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Forms for respondents	Number of respondents	Number of responses/ respondent	Average burden/ response (in hrs)
Initial Application	3	1	4
Annual Report	35	1	30/60
Renewal Application	13	1	6
Refresher Course Application	10	1	8
Report for Course Changes	12	1	45/60

Dated: March 20, 2008.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Office of the Chief Science Officer, Centers for Disease Control and Prevention.

[FR Doc. E8–6471 Filed 3–28–08; 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 Project:

Title: Communities Empowering Youth Evaluation Study.

OMB No.: New Collection.

Description: The information collection activity proposed under this notice will obtain information about lead and partner organizations funded under the Communities Empowering Youth (CEY) program. The information collected will complement a survey (OMB No. 0970–0335) that is examining the organizational and partnership capacity building experienced by organizations funded under the CEY program. The proposed information collection will allow in-depth examination of a select number of lead organizations and their partners. Information collection will be through on-site observations of organizations and partnerships and structured discussions with key staff, using uniform protocols. On-site information collection will occur three times: near the beginning, at the mid point, and at the end of the three-year CEY grant period. Periodic telephone follow-ups may be conducted as necessary between on-site data collection in order to clarify or update information collected earlier and to prepare for future site visits.

Respondents: Executive directors and key staff of faith based and community organizations that received three-year CEY grants beginning in 2007.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Lead Organization Executive Director	10	1	2.5	25
Lead Organization Key Staff	20	1	1.5	30
Partner Organization Executive Director	60	1	2.5	150
Partner Organization Key Staff	60	1	1.5	90
Estimated Total Annual Burden Hours	.....	.....	.....	295

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447. Attn: ACF Reports Clearance Officer. E-mail address: *OPREIfoCollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 20, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E8–6340 Filed 3–28–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: HHS/ACF/OPRE Head Start Classroom-based Approaches and Resources for Emotion and Social skill promotion (CARES) project: Site Recruitment Materials.

OMB No.: New Collection.

Description: The Head Start Classroom-based Approaches and Resources for Emotion and Social skill promotion (CARES) project will evaluate program enhancements within Head Start settings serving three- and four-year-old children. This project focuses on identifying the central features of effective programs to provide the information Federal policy makers and Head Start providers will need if they are to increase Head Start's capacity to improve the social and emotional skills and school readiness of preschool-age children. The project is sponsored by the Office of Planning, Research and Evaluation (OPRE) of the Administration for Children and Families (ACF), part of the Department of Health and Human Services (HHS).

The Head Start CARES project will use a group-based randomized design to test the effects of several different evidence-based strategies designed to improve the social and emotional development of children in Head Start classrooms.

The purpose of the proposed information collection is to recruit Head Start grantees to participate in the project, through informing grantee staff about the project, soliciting their interest in participating, and collecting information to assess their programs' eligibility to participate in the project.

Respondents: Respondents will include staff in Head Start grantee and delegate agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Project Description	40	1	.5	20
Phone Discussion Points & Screener	40	1	1	40
Discussion Guide for Site Visits	130	1	2	260
Estimated Total Annual Burden Hours:				320

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 Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *OPREInfoCollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

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: March 20, 2008.

Brendan C. Kelly,

OPRE Reports Clearance Officer.

[FR Doc. E8–6343 Filed 3–28–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0143] (formerly Docket No. 2006D–0056)

Compliance Policy Guide Sec. 500.500 Guidance Levels for 3–MCPD (3-chloro-1, 2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of compliance policy guide (CPG) Sec. 500.500 Guidance Levels for 3–MCPD (3-chloro-1, 2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces. The CPG provides regulatory action guidance for FDA staff regarding 3–MCPD in acid-hydrolyzed

protein (acid-HP) and Asian-style sauces.

DATES: Submit written or electronic comments regarding the CPG at any time.

ADDRESSES: Submit written comments on the CPG 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.regulations.gov*.

Submit written requests for single copies of CPG Sec. 500.500 Guidance Levels for 3–MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–632–6860. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 240–632–6861. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the document.

FOR FURTHER INFORMATION CONTACT: Judith L. Kidwell, Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD, 20740–3835, 301–436–1071.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of May 23, 2006 (71 FR 29651), FDA announced the availability of draft CPG Sec. 500.500 Guidance Levels for 3–MCPD (3-chloro-1,2-propanediol) in Acid-Hydrolyzed Protein and Asian-Style Sauces. FDA received one comment on the draft CPG. The International Hydrolyzed Protein Council (IHPC) offered clarification for the following sentence found in the **BACKGROUND** section of the draft CPG: ''Since 1996, many countries * * * have recommended or required that industry take steps to ensure that 3–MCPD is not detectable in acid-HP or Asian-style sauces at levels ranging from 0.01 parts per million (ppm) to 1 ppm.'' IHPC suggested that we revise the sentence as follows: ''Since 1996, many countries * * * have recommended or required that industry take steps to ensure that 3–MCPD in acid-HP or Asian-style sauces does not exceed levels ranging from 0.01 parts per million (ppm) to 1 ppm.'' IHPC explained that using the phrase ''not detectable'' and then listing allowable levels is confusing. We concur with the comment and have revised the final CPG accordingly. FDA also revised the **SPECIMEN CHARGES** section in the final CPG to provide operational guidance regarding reference to the United States Code (U.S.C.) when citing the violation charged in a domestic seizure and reference to the Federal Food, Drug, and Cosmetic Act when citing the violation charged in an import detention. We also have made other editorial changes to the CPG for clarification.

This CPG is being issued as level 1 guidance consistent with FDA's good guidance practices regulations (21 CFR 10.115). The CPG represents the agency's current thinking on 3–MCPD in acid-HP and Asian-style sauces. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the CPG at any time. 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 brackets in the heading of this document. The CPG and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA through FDMS only.

III. Electronic Access

Persons with access to the Internet may obtain the CPG from the Office of Regulatory Affairs home page at *http://www.fda.gov/ora* under ''Compliance Reference.''

Dated: March 14, 2008.

Margaret O'K. Glavin,

Associate Commissioner for Regulatory Affairs.

[FR Doc. E8–6504 Filed 3–28–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Office of Clinical and Preventive Services; Elder Care Initiative Long-Term Care Grant Program

Announcement Type: New.
Funding Announcement Number: HHS–2008–IHS–EHC–0001.

Catalog of Federal Domestic Assistance Numbers: 93.933.

Key Dates:
Letter of Intent Deadline: May 2, 2008.
Application Deadline Date: June 20, 2008.
Review Date: July 21–August 1, 2008.
Earliest Anticipated Start Date: September 1, 2008.

I. Funding Opportunity Description

The Indian Health Service (IHS) announces the availability of up to $600,000 for competitive grants through the Elder Care Initiative Long Term Care (ECILTC) Grant Program to support planning and implementation of sustainable long-term care services for American Indians and Alaska Native (AI/AN) elders. This program is authorized under the Snyder Act, Indian Health Care Improvement Act, as amended, 25 U.S.C. 1653(c), and Public Health Service Act, Section 301, as amended. This program is described at 93.933 in the Catalog of Federal Domestic Assistance (CFDA).

The AI/AN elder population is growing rapidly and the Al/AN population as a whole is aging. The prevalence of chronic disease in this population continues to increase, contributing to a frail elder population with increasing long-term care (LTC) needs.

LTC is best understood as an array of social and health care services that support an individual who has needs for assistance in activities of daily living over a prolonged period. LTC supports elders and their families with medical, personal, and social services delivered in a variety of settings to support quality of life, maximum function, and dignity. While families continue to be the backbone of LTC for Al/AN elders, there is well documented need to support this care with formal services. The way these services and systems of care are developed and implemented can have a profound impact on the cultural and spiritual health of the community.

Home and community-based services have the potential for meeting the needs of the vast majority of elders requiring LTC services, supporting the key roles of the family in the care of the elder and

the elder in the care of the family and community. A LTC system with a foundation in HCBS will also comply with the United States Supreme Court interpretation of the Americans with Disabilities Act in *Olmstead* v. *L.C.*, 527 U.S. 581 (1999). The 28 CFR 35.130(d) ruling obligates States and localities to provide care for persons with disability ''in the most integrated setting appropriate to the needs of qualified individuals with disabilities.'' An efficient and effective LTC system would make use of all available resources, integrating and coordinating services to assist families in the care of their elders.

The primary focus for planning and program development for AI/AN LTC is at the Tribal and urban community level. Tribes and communities have very different histories, capabilities, and resources with regard to LTC program development. Each Tribe or community will have different priorities in building LTC infrastructure. It is critical that the development of LTC services be well grounded in an assessment of need based on population demographics and rates of functional impairment. LTC services should be acceptable to elders and their families and consistent with community values in their implementation. The services should be a part of an overall vision and plan for a LTC system to support elders and their families.

There are a number of elements (Tribal sovereignty and the government-to government relationship, the unique funding structure of Indian health, and the importance of the cultural context) that distinguish AI/AN LTC. Tribes and AL/AN organizations have found it useful to look both inside and outside of the Indian Health system (IHS, Tribal, and urban Indian health programs) for LTC strategies and models.

The planning and design of LTC services must identify the revenue source(s) that will support the delivery of care. Finding resources for LTC services presents a formidable challenge. Funds appropriated through the IHS (whether direct service or Tribal) can provide healthcare services which are part of a LTC system, but do not provide for a comprehensive set of LTC services and cannot support housing or social services of a non-medical nature. Programs funded through the Administration on Aging American Indian, Alaska Native and Native Hawaiian Program (e.g. Title VI A and Title VI C Family Caregiver Support Program) have been key elements in the LTC infrastructure in AI/AN communities. Additional Older American Act resources may be available through State Units on Aging and Area Agencies on Aging. Other resources are available to provide LTC services on a reimbursable basis for eligible AI/AN elders. The majority of formal LTC services in this country are funded by reimbursements from state Medicaid and HCBS programs. The Veterans Administration may be a source of reimbursement for LTC services for eligible AI/AN veterans. Federal housing programs are a potential resource in developing the housing component of the LTC infrastructure. Each of these resources has unique eligibility requirements. Development of reimbursement-based LTC services often requires an ongoing investment of funds to support delivery of services during the initial period of client recruitment, start-up of services, and the receipt of reimbursement for those services.

This grant program is designed to provide support for the development of AI/AN LTC, with funding for either assessment and planning, or program implementation. LTC services developed with support of this grant program must be those which the IIHS has the authority to provide, either directly or through funding agreement, and must be designed to serve IRS beneficiaries. Most Tribes and urban communities are building toward their ideal LTC system incrementally, adding new or integrating existing services over time. The goal of this grant program is to support Tribes, Tribal Organizations, Tribal consortia, and Urban Indian health programs as they build LTC systems and services that meet the needs of their elders and that keep elders engaged and involved in the lives of their families and communities.

II. Award Information

Type of Awards: Grant.

Estimated Funds Available: The total amount identified for fiscal year (FY) 2008 is up to $600,000. The project period for the grants is 24 months in duration and each budget period is approximately 12 months. The award amounts are set at $50,000–$75,000 each year, depending on the project category. Continuation awards are subject to the availability of funds and satisfactory performance.

Anticipated Number of Awards: 8–10 awards will be made under this program announcement.

Project Period: Two Years (24 months).

Award Amount:

$50,000 per year for Category 1—Assessment and Planning Awards.

$75,000 per year for Category 2—Implementation Awards.

Category 1—Assessment and Planning awards will support the following activities:

a. Demographic assessment of the population and assessment of LTC needs on a population basis.

b. Evaluation of existing services and resources for LTC.

c. Evaluation of potential resources to fund LTC services.

d. Assessment of cultural and religious values regarding care of the elder for the population(s) served.

e. Assessment of elder preferences for type, structure, and setting of services.

f. Establishment of a comprehensive vision for LTC services with priorities for implementation.

g. Identification of potential funding sources for program development and for ongoing financing of service delivery.

h. The integration and incorporation of the above elements into a report or other document that guides LTC services/system implementation, including a plan for sustainability.

Category 2—Implementation awards will support the following activities: Implementation of a service or group of services that add capacity to the LTC system of the applicant's Tribe or organization. The implementation plan should be based on a comprehensive assessment and plan, including a business plan, The services should be designed to be self-sustaining at the end of the project period.

Applications must be for only one Project Type. Applications that address more than one Project Type will be considered ineligible and will be returned to the applicant. The maximum funding level includes both direct and indirect costs. Applications with budgets which exceed the maximum funding level or project period identified for a Project Type will not be reviewed.

III. Eligibility Information

1. The AI/AN applicant must be one of the following:

A. A Federally-recognized Indian Tribe; or

B. Tribal organization as defined by 25 U.S.C. 1603(e); or

C. Urban Indian organization as defined by 25 U.S.C. 1603(h); or

D. A consortium of eligible Tribes, Tribal organization or urban Indian health programs authorized by governing bodies to apply for and receive awards on their behalf under this program announcement.

Applicants must provide proof of non-profit status with the application.

2. Cost Sharing or Matching—The ECILTC Grant Program does not require matching funds or cost sharing.

3. Other Requirements:

A. A Letter of Intent (LOI) to apply is required and must be postmarked no later than May 2, 2008. The LOI is a mandatory but non-binding request for information that will assist in planning both the review and post award phase. There is no penalty for submitting a LOI and not proceeding with the grant application but a grant will not be reviewed if a LOI was not submitted. See Section IV.6.a for detailed instructions for submission of the LOI.

B. The following documentation (as applicable) is required for an application to be considered complete:

1. Tribal Resolution—A resolution of the Indian Tribe served by the project must accompany the application submission. An Indian Tribe that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. Applications by Tribal organizations will not require a specific Tribal resolution if the current Tribal resolution(s) under which they operate would encompass the proposed grant activities. Draft resolutions are acceptable in lieu of an official resolution. However, an official signed Tribal resolution must be received by the Division of Grants Operations (DGO) prior to the beginning of the Objective Review, July 21, 2008. If an official signed resolution is not received by July 21, 2008, the application will be considered incomplete, ineligible for review, and returned to the applicant without consideration. Applicants submitting additional documentation after the initial application submission are required to ensure the information was received by the IBS by obtaining documentation confirming delivery (i.e. FedEx tracking, postal return receipt, etc.).

2. Tribal Consortium—If a consortium is submitting an application it must:

- Identify each of the consortium member Tribes.
- Identify if any of the member Tribes intend to submit a LTC grant application of their own.
- Demonstrate that Tribes, Tribal organizations, urban Indian health programs, or Tribal consortia's application does not duplicate or overlap any objectives of the other consortium members who may be submitting their own LTC grant application.

Any application received from a Consortium that does not meet the requirements above will be considered ineligible for review.

- Tribes, Tribal organizations, urban Indian health programs, or Tribal consortia's receiving Category I (Assessment and Planning funding) in the FY2006–2007 [ITIS Elder Care Initiative grant cycle will be considered ineligible for FY2008 Category I (Assessment and Planning) funding unless they can demonstrate that the current application serves a different population than the FY2006–2007 grant. (*e.g.* a consortium may target different Tribes).
- Tribes, Tribal organizations, urban Indian health programs, or Tribal consortias receiving Category II (Implementation) grants in the FY2006–2007 IHS Elder Health Care Initiative Grants cycle will be considered ineligible for FY2008 Category II (Implementation) funding unless they can demonstrate that they will be implementing an entirely new service or program (*e.g.* an applicant with current funding to implement an Adult Day Health Program may now apply for funding to implement a personal care program).

IV. Application and Submission Information

1. Applicant package may be found in Grants.gov (www.grants.gov) or at: *http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp.* Information regarding the electronic application process may be directed to Michelle G. Bulls, at (301) 443–6290.

Information regarding the Letter of Intent may be obtained from: Ms. Orlinda Platero, Office Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 220, Rockville, Maryland 20852, (301) 443–2522, Fax: 301–594–6213.

The entire application package along with downloadable application instructions is available at: *http://www.grants.gov.* Details regarding the ECILTC Grant Program are available at: *http://www.ihs.gov/MedicalPrograms/ElderCare/.* Detailed application instructions for this announcement are downloadable on Grants.gov.

2. Content and Form of Application Submission:

- Be single spaced.
- Be typewritten.
- Have consecutively numbered pages.
- Use black type not smaller than 12 characters per one inch.
- Contain a narrative that does not exceed ten-typed pages. See Section V for instructions for the content of the narrative. The ten page narrative does not include the detailed work plan with timeline, standard forms, Tribal resolutions or letters of support (if necessary), table of contents, budget, budget justifications, budget narrative, and/or other appendix items.

Public Policy Requirements: All Federal-wide public policies apply to IRS grants with the exception of the discrimination public policy.

3. Submission Dates and Times:

Applications must be submitted electronically through Grants.gov by 12:00 midnight Eastern Standard Time (EST). If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant should contact Grants Policy Staff (UPS) at (301) 443–6290 at least fifteen days prior to the application deadline and advise of the difficulties that your organization is experiencing. The grantee must obtain prior approval, in writing (e-mails are acceptable) allowing the paper submission. If submission of a paper application is requested and approved, the original and two copies may be sent to the appropriate grants contact that is listed in Section P1.2., above. Applications not submitted through Grants.gov, without an approved waiver, may be returned to the applicant without review or consideration. Late applications will not be accepted for processing, will be returned to the applicant, and will not be considered for funding.

4. Intergovernmental Review:

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions:

- Pre-award costs are allowable pending prior approval from the awarding agency. However, in accordance with 45 CFR Part 74, all pre-award costs are incurred at the recipient's risk. The awarding office is under no obligation to reimburse such costs if for any reason the applicant does not receive an award or if the award to the recipient is less than anticipated.
- The available funds are inclusive of direct and appropriate indirect costs.
- Only one grant will be awarded per applicant.
- IHS will not acknowledge receipt of applications.

6. Other Submission Requirements:

- If the applicant is unable to submit via Grants.gov and obtains a waiver from the standard application requirements, please use the following forms: SF–424, 424A, 424B, and certification forms, as appropriate. One original and two copies must be submitted to: attn: Norma Jean Dunne; Division of Grants Operations; 801 Thompson Avenue, Rockville, MD 20852. Copies of the forms may be found at: *http://www.ihs.gov/*

NonMedicalPrograms/gogp/index.cfm?module=forms. Applications are due by June 20, 2008.

• A LOI to apply is required and must be postmarked no later than May 2, 2008. The LOI is a mandatory but non-binding request for information that will assist in planning both the review and post award phase. There is no penalty for submitting a LOI and not proceeding with the grant application, but a grant will not be reviewed if a LOI was not submitted. Applicants will be notified by fax or e-mail that their LOI has been received, as it is received.

The LOI should be sent to Ms. Orlinda Platero at the following address: Ms. Orlinda Platero, Office Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 326, Rockville, Maryland 20852, Telephone: (301) 443–2522, Fax: (301) 594–6213, E-mail: *Orlinda.Platero@ihs.gov.*

The LOI must contain:

• The name of the applying organization.

• The individual who is responsible for correspondence regarding the application, and contact information for that individual. Please indicate whether fax or e-mail notification of receipt of LOl is preferred, and provide e-mail address and/or fax number.

• The name of all member Tribes if the applicant is a Tribal Consortium and those Tribes involved in the proposal.

• Whether the intent is to apply for a Category I or Category II grant.

Electronic Submission—The preferred method for receipt of applications is electronic submission through Grants.gov. However, should any technical challenges arise regarding the submission, please contact Grants.gov Customer Support at 1–800–518–4726 or *support@grants.gov.* The Contact Center hours of operation are Monday–Friday from 7 a.m. to 9 p.m. EST. The applicant must seek assistance at least fifteen days prior to the application deadline. Applicants that don't adhere to the timelines for Central Contractor Registry (CCR) and/or Grants.gov registration and/or requesting timely assistance with technical issues will not be a candidate for paper applications.

To submit an application electronically, please use *http://www.Grants.gov* and select the ''Apply for Grants'' link on the home page. Download a copy of the application package on the Grants.gov Web site, complete it offline and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to IHS.

Please be reminded of the following:

• Under the new IHS application submission requirements, paper applications are not the preferred method. However, if you have technical problems submitting your application on-line, please contact directly Grants.gov Customer Support at: *http://www.grants.gov/CustomerSupport.*

• Upon contacting Grants.gov, obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver request from GPS must be obtained.

• If it is determined that a formal waiver is necessary, the applicant must submit a request, in writing (emails are acceptable), to *Michelle.Bulls@ihs.gov* that includes a justification for the need to deviate from the standard electronic submission process. Upon receipt of approval, a hard-copy application package must be downloaded by the applicant from: *http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?rnodule=forms.* Please use the following forms for the standard application requirements: SF–424, 424A, 424B, and certification forms, as appropriate. One original and two copies must be submitted to: Attn: Norma Jean Dunne; Division of Grants Operations; 801 Thompson Avenue, TMP 360, Rockville, MD 20852 by the application due date of June 20, 2008.

• Upon entering the Grants.gov site, there is information available that outlines the requirements to the applicant regarding electronic submission of an application through Grants.gov, as well as the hours of operation. We strongly encourage all applicants not to wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR and Grants.gov could take up to fifteen working days.

• To use Grants.gov, you, as the applicant, must have a Data Universal Numbering System (DUNS) number and register in the CCR. You should allow a minimum often days working days to complete CCR registration. See below on how to apply.

• You must submit all documents electronically, including all information typically included on the SF–424 and all necessary assurances and certifications.

• Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by IHS.

• Your application must comply with any page limitation requirements described in the 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 IRS, DGO will download your application from Grants.gov and provide necessary copies to the cognizant program office. DGO will not notify applicants that the application has been received.

• You may access the electronic application for this program on *http://www.Grants.gov.*

• You may search for the downloadable application package either by the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.

• The applicant must provide the Funding Opportunity Number: HHS–2008–IHS–EHC–0001. E-mail applications will not be accepted under this announcement.

DUNS Number

Applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

Applications submitted electronically must also be registered with the CCR. A DUNS number is required before CCR registration can be completed. Many organizations may already have a DUNS number. Please use the number listed above to investigate whether or not your organization has a DUNS number. Registration with the CCR is free of charge.

Applicants may register by calling 1–888–227–2423. Please review and complete the CCR Registration Worksheet located on *http://www.grants.gov/CCRRegister.*

More detailed information regarding these registration processes can be found at *http://www.grants.gov.*

V. Application Review Information

Note: Only those programs or services which the IHS is authorized to provide, either directly or through funding agreement, can be supported by this grant program. UNLESS CONGRESS PROVIDES OTHERWISE, those services which are primarily housing or custodial in nature are not eligible for support (*e.g.* assisted living facility, board and care, or nursing home which is primarily custodial in nature). Supportive services delivered in those facilities, with the intent to promote the health and wellness of elders, are eligible for

funding. Programs and services developed with support of this grant program must be designed for the benefit of IHS beneficiaries.

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses. The narrative should include only the first year of activities; information for multi-year projects should be included as an appendix. See ''Multi-year Project Requirements'' at the end of this section for more information. The narrative section should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to understand the project fully.

1. Criteria

A. Category I (Assessment and Planning)

1. Introduction and Need for Assistance (35 Points)

Provide an understanding of the LTC needs of the elderly in the Tribe or service area and identify the additional information needed for planning. The number of elders that will be affected by the program will be considered a factor in the review as will the relationship of the amount of funding requested to the number of elders to be served. The applicant should use the best data available, understanding that, for most programs, many of these data elements will not be available or be poor in quality and that improved data for future planning will be an outcome of this grant-funded project. Data that is not available should be noted as such and addressed in the work plan (Section 2). Identify all information sources.

a. Currently available information for use in planning and service development:

i. Currently available information regarding population and need for services.

1. Demographics of the population and assessment of LTC needs on a population basis.

2. Geographic and social factors, including availability of caregivers.

3. Cultural and religious values regarding care of the elder for the population(s) to be served.

4. Elder preferences for type, structure, and setting of services.

ii. Currently available information regarding existing services and resources for LTC:

1. Availability and organization of existing aging and LTC services, including services available to Tribal or community members provided by non-Tribal/non-AI/AN organization programs.

2. Availability and organization of health services for the elderly, including Native healing systems.

3. Assessment of the capacity of available LTC services to support care provided ''in the most integrated setting appropriate to the needs of qualified individuals with disabilities'' (*Olmstead* v. *L.C*).

4. Assessment of caregiver workforce.

iii. Funding streams currently paying for LTC services.

iv. Current collaborations in program development or service delivery.

b. Current vision for LTC system/services and priorities for development.

c. Elder care assessment and planning activities within the past ten years:

i. Funding sources.

ii. Dates of funding.

iii. Summary of project accomplishments.

iv. Relationship to the current proposal. Copies of reports will not be accepted.

d. Unmet need for LTC services.

e. Information needed for planning and service implementation which is not currently available.

2. Work Plan (35 Points)

This section should demonstrate the soundness and effectiveness of the applicant's proposal. The work plan should be designed to produce as an end product the readiness to develop LTC service(s) and should include all information not already available. For an example of the information needed to demonstrate readiness to develop LTC service(s), see Section 1 Introduction and Need for Assistance in the Category II Implementation criteria.

Note that attendance and presentation at the AI/AN Long Term Care Conference and participation in periodic grantee teleconferences are a requirement of the grant and should be included as activities in the work plan.

a. State the proposed assessment or planning process.

b. List the objectives clearly.

i. Identify the data elements needed.

ii. Indicate the function of each data element in the plan.

c. Describe the approach to the project.

i. Tasks.

ii. Resources needed to implement and complete the project.

iii. Timeline.

iv. Specialized technical resources for data collection or analysis.

v. Training needs.

- Include in work plan attendance and presentation at the annual AI/AN Long Term Care Conference.

d. Identify the final product of the assessment/plan and the strategy for dissemination.

e. Submit a work plan in the appendix which includes the following information:

i. Action steps on a time line for implementation of the work plan.

ii. Identify who will perform the action steps.

iii. Identify who will supervise the action steps.

iv. Identify who will accept and/or approve work products at the end of the proposed project.

v. Include any additional training that will take place during the proposed project, who will conduct the training, and who will be attending the training.

vi. Include the following information if consultants or contractors will be used during the proposed project, their position description and scope of work (or note if consultants/contractors will not be used):

- Educational requirements.
- Desired qualifications and work experience.
- Expected work products.
- Contractor's supervisor.
- Include a resume and letter of commitment in the appendix for potential consultant/contractor.

3. Project Evaluation (10 Points)

This section should show how progress on this project will be assessed and how the success of this project will be judged.

a. Describe and list outcomes by which this project will be evaluated. Each proposed project objective and task of the work plan should be evaluated and the evaluation activities should appear on the work plan.

b. Identify the responsible person for the evaluation (need not be an outside evaluator).

4. Organizational Capabilities and Qualifications (10 Points)

This section outlines the broader capacity of the Tribe, Tribal organization, or urban health program to complete the project outlined in the work plan. It includes the identification of personnel responsible for completing tasks and chain of responsibility for successful completion of the project outlined in the work plan.

a. Describe the organizational structure of the Tribe/Tribal organization beyond health care activities.

b. Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance as well as other

grants and projects successfully completed.

c. Describe what equipment (i.e., fax machine, phone, computer, etc.) and facility space (*i.e.*, office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased through the grant.

d. List key personnel who will work on the project.

i. Identify existing personnel and new program staff to be hired.

ii. Include in the appendix, position descriptions and resumes for all key personnel. Position descriptions should clearly describe each position and duties, indicating desired qualifications experience, requirements related to the proposed project and how they will be supervised. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities and who will determine if the work of a contractor is acceptable.

iii. Note who will be writing the progress reports.

iv. Indicate if a position is to be filled for a proposed position description.

v. Note and address how additional personnel beyond those covered by the grant funds, (i.e., IT support, volunteers, interviewers, etc.), will be filled and if funds are required, list the funding source.

vi. Indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual's salary if personnel are to be only partially funded by this grant.

5. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the project program costs and justification for expenses for the entire grant period. The budget and budget justification should be consistent with the tasks identified in the work plan.

a. Categorical budget (Form SF 424A, Budget Information Non Construction Programs) completing each of the budget periods requested.

b. Include a narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project. Include sufficient details to facilitate the determination of cost allowability.

c. Indicate any special start-up costs.

d. Include a brief program narrative budget justification for the second year.

e. If indirect costs are claimed, indicate and apply the current negotiated rate to the budget. Include a copy of the rate agreement in the appendix.

B. Category II (Program Implementation)

1. Introduction and Need for Assistance (35 points)

Provide an understanding of current need for and availability of LTC services for the elderly in the Tribe or service area. Identify the number of elders to be served. The number of elders that will be affected by the program will be considered a factor in the review as will the relationship of the amount of funding requested to the number of elders to be served. Demonstrate the necessary assessment and planning to successfully implement new service(s) and show that the services fit within a comprehensive vision or plan for elder care. If significant elements listed below are not available, programs should consider applying for Category I funding to support the assessment and planning activities necessary for successful program development.

a. Demographic assessment of the population and assessment of LTC needs on a population basis.

i. Population distribution. Number of elderly of different age and gender groups in the population.

ii. Rates of functional impairment and numbers of elders with need for assistance in activities in daily living with adequate detail to project need for services.

b. Geographic and social factors that affect access to services and availability of caregivers.

i. Rural vs. urban; population density.

ii. Family structure and organization.

c. Assessment of cultural and religious values regarding care of the elder for the population(s) to be served.

d. Assessment of elder preferences for type, structure, and setting of services.

e. Evaluation of existing services and resources for LTC.

i. Availability and organization of existing aging and LTC services. Include services available to Tribal or community members provided by programs or organizations that are not Tribal or AI/AN organizations.

ii. Availability and organization of health services for the elderly, including Native healing systems.

iii. Capacity of existing LTC services to support care provided ''in the most integrated setting appropriate to the needs of qualified individuals with disabilities'' (*Olmstead* v. *L.C*).

f. Assessment of caregiver workforce.

i. Availability of potential caregivers (formal and informal).

ii. Training resources for formal and informal caregivers.

g. Identification of potential resources for new LTC service.

i. Funding for program development.

ii. Funding for ongoing service delivery.

iii. Potential partners in program development.

h. Relevant Federal, 11-IS, Tribal and/or State standards, laws and regulations and codes and relevant licensure or certification requirements.

i. A comprehensive vision or plan for LTC systems/services which incorporates the information above and identifies priorities for implementation.

j. Unmet need for LTC services.

2. Work Plan (35 points)

This section should demonstrate the soundness and effectiveness of the applicant's proposal. This includes both the work plan for program implementation and the underlying plan or strategy for sustainability of the service(s) past the point of grant support. Note that attendance and presentation at the AI/AN LTC Conference and participation in periodic grantee teleconferences are a requirement of the grant and should be included as activities in the work plan.

a. Identify the LTC service(s) to be implemented and:

i. Show how it is consistent with the results of the assessment/planning process described above (Introduction and Need for Assistance).

ii. Integrates with existing LTC and health services.

b. Summarize the business plan or plan for self-sufficiency and sustainability, including:

i. Funding stream(s) to support ongoing services.

ii. Clearly indicate whether the program will be self-supporting (and if so, when) or not. If not self-supporting, what will be the source of additional revenue for services?

iii. Timeline with projections for client recruitment, expected revenue and shortfalls, resources for funds needed to bridge between onset of services and collection of reimbursement, etc.

iv. Licensure or certification requirements.

v. Indicate if Tribal revenue is expected to pay in part or in whole for services. A letter from the Tribal Council or administration indicating that these funds have been budgeted for this purpose should be included in the appendix.

c. Describe the approach to implementation.

i. Tasks.

ii. Resources needed to implement and complete the project.

iii. Timeline for implementation.

iv. Specialized technical resources.

v. Training needs.

• Include in work plan attendance and presentation at the annual AI/AN Long Term Care Conference.

vi. Consultation needs (if any).

d. Include a detailed work plan in the appendix, containing the following information:

i. Action steps on a time line for implementation of the work plan.

ii. Identify who will perform the action steps.

iii. Identify who will supervise the action steps.

iv. Identify who will accept and/or approve work products at the end of the proposed project.

v. Include any additional training that will take place during the proposed project,

vi. Include the following information if consultants or contractors will be used during the proposed project, their position description and scope of work (or note if consultants/contractors will not be used):

• Educational requirements.

• Desired qualifications and work experience.

• Expected work products.

• Contractor's supervisor.

• Include a resume and letter of commitment in the appendix for potential consultant/contractor.

e. Include a detailed business plan in the appendix, containing the following information:

i. Timeline with detailed expense and revenue projections.

ii. Timeline with client recruitment projections.

iii. Timeline with licensure or certification requirements and tasks.

iv. Identification of shortfall funding during implementation with documentation of the availability of budgeted funds to support the program until it is self-sustaining (if applicable).

3. Project Evaluation (10 Points)

This section should show how progress on this project will be assessed and how the success of this project will be judged.

a. Specifically list and describe the outcomes by which this project will be evaluated.

b. Identify the evaluator and/or the individual with responsibility for the evaluation (need not be an outside evaluator).

c. Each proposed project objective and task of the work plan should be able to be evaluated and the evaluation activities should appear on the work plan.

4. Organizational Capabilities and Qualifications (10 Points)

This section outlines the broader capacity of the Tribe, Tribal organization, or urban health program to complete the project outlined in the work plan. This includes the identification of personnel responsible for completing tasks and chain of responsibility for successful completion of the project outlined in the work plan.

a. Describe the organizational structure of the Tribe/Tribal organization beyond health care activities.

b. If management systems are already in place, simply note it.

c. Describe the ability of the organization to manage the proposed project. Include information regarding similarly sized projects in scope and financial assistance as well as other grants and projects successfully completed.

d. Describe what equipment (*i.e.*, fax machine, phone, computer, etc.) and facility space (*i.e.*, office space) will be available for use during the proposed project. Include information about any equipment not currently available that will be purchased through the grant.

e. List key personnel who will work on the project.

i. Identify existing personnel and new program staff to be hired.

ii. Include position descriptions and resumes for all key personnel in the appendix. Position descriptions should clearly describe each position and duties, indicating desired qualifications experience, requirements related to the proposed project and how they will be supervised. Resumes must indicate that the proposed staff member is qualified to carry out the proposed project activities and who will determine if the work of a contractor is acceptable.

iii. Note who will be writing the progress reports.

iv. Indicate if a position is to be filled for a proposed position description.

v. Note and address how additional personnel beyond those covered by the grant funds, (*i.e.*, IT support, volunteers, interviewers, etc.), will be filled and if funds are required, list the funding source.

vi. Indicate the percentage of time to be allocated to this project and identify the resources used to fund the remainder of the individual's salary if personnel are to be only partially funded by this grant.

5. Categorical Budget and Budget Justification (10 Points)

This section should provide a clear estimate of the project program costs and justification for expenses for the entire grant period. The budget and budget justification should be consistent with the tasks identified in the work plan.

a. Categorical budget (Form SF 424A, Budget Information Non-Construction Programs) completing each of the budget periods requested.

b. Include a narrative justification for all costs, explaining why each line item is necessary or relevant to the proposed project. Include sufficient details to facilitate the determination of cost allowability.

c. Indicate any special start-up costs.

d. Include a brief program narrative budget justification for the second year.

e. Indicate and apply the current negotiated rate to the budget if indirect costs are claimed. Include a copy of the rate agreement in the appendix.

2. Review and Selection Process

In addition to the above criteria/requirements, applications are considered according to the following:

a. Letter of Intent Submission (Deadline: May 2, 2008); and

b. Application Submission (Application Deadline: June 20, 2006). Applications submitted in advance of or by deadline and verified by the postmark will undergo a preliminary review to determine that:

• The applicant and proposed project type is eligible in accordance with this grant announcement.

• The application is not a duplication of a previously funded project.

• The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation; otherwise, it may be returned.

c. Competitive Review of Eligible Applications (Objective Review: July 21–August 1, 2008).

Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed for merit by the Ad Hoc Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on these applications. The review will be conducted in accordance with the IHS Objective Review Guidelines. The technical review process ensures selection of quality projects in a national competition for limited funding. Applications will be evaluated and rated on the basis of the evaluation criteria listed in Section V.1. and V.2. The criteria are used to evaluate the quality of a proposed project, determine the likelihood of success, and assign a numerical score to each application. The scoring of approved applications will assist the IHS in determining which proposals will be funded if the amount of funding is not sufficient to support all approved applications. Applications

recommended for approval, having a score of 60 or above by the ORC and scored high enough to be considered for funding, are ranked. Additional considerations in final ranking include: geographic diversity among funded programs, diversity in population size among Tribes and communities served by funded programs, and unique features with regard to type of program planned or population served. Applications scoring below 60 points will be disapproved and returned to the applicant. Applications that are approved but not funded will not be carried over into the next cycle for funding consideration.

3. Anticipated Announcement and Award Dates

Anticipated Award Notification: August 18, 2008.

Anticipated Award Start Date: September 1, 2008.

VI. Award Administration Information

1. Award Notices

The Notice of Award (NoA) will be initiated by DGO and will be mailed via postal mail to each entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer, and this is the authorizing document for which funds are dispersed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is the legally binding document. Applicants who are approved but unfunded or disapproved based on their Objective Review score will receive a copy of the Executive Summary which identifies the weaknesses and strengths of the application submitted.

2. Administrative Requirements

Grants are administrated in accordance with the following documents:

- This Program Announcement.
- Administrative Requirements: 45 CFR Part 92, ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments,'' or 45 CFR Part 74, ''Uniform Administrative Requirements for Awards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations.''
- Grants Policy Guidance: HHS Grants Policy Statement, January 2007.
- Cost Principles: OMB Circular A–87, ''State, Local, and Indian'' (Title 2 Part 225).
- Cost Principles: OMB Circular A–122, ''Non-profit Organizations'' (Title 2 Part 230).
- Audit Requirements: OMB Circular A–133, ''Audits of States, Local Governments, and Non-profit Organizations.''

3. *Indirect Costs:* This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part 11–27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate means the rate covering the applicable activities and the award budget period. If the current rate is not on file with the DGO at the time of award, the indirect cost portion of the budget will be restricted and not available to the recipient until the current rate is provided to the DGO.

Generally, indirect costs rates for IFIS grantees are negotiated with the Division of Cost Allocation (DCA) *http://rates.psc.gov/* and the Department of Interior (National Business Center) *http://www.nbc.gov/acquisition/ics/icshome.html.* If your organization has questions regarding the indirect cost policy, please contact the DGO at (301) 443–5204.

4. Reporting

A. Progress Report. Program progress reports are required within 30 days of the completion of the semi annual report. These reports will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Status Report. Semi-annual financial status reports must be submitted within 30 days of the end of the half year. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting.

C. Reports. Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports which are generally due semi-annually. Financial Status Reports (SF–269) are due 90 days after each budget period and the final SF–269 must be verified from the grantee records on how the value was derived. Grantees must submit reports in a reasonable period of time.

Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) the imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.

5. Telecommunication for the hearing impaired is available at: TTY (301) 443–6394.

VII. Agency Contact(s)

For program-related information regarding the IHS Elder Care Program: Bruce Finke, MD, Nashville Area Elder Health Consultant, 45 Vernon Street, Northampton, MA 01060, (413) 584–0790, *bruce.flnke@ihs.gov.*

For general information regarding this announcement: Ms. Orlinda Platero, Office Clinical and Preventive Services, Indian Health Service, 801 Thompson Avenue, Suite 326, Rockville, Maryland 20852, (301) 443–2522, Fax: (301) 594–6213.

For specific grant-related and business management information: Ms. Norma Jean Dunne, Division of Grant Operations, Indian Health Service, 801 Thompson Avenue, TMP 360–79, Rockville, Maryland 20852, (301) 443–5204, Fax: (301) 443–9602.

VIII. Other Information

The Department of Health and Human Services (HHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2010, a HHS led activity for setting priority areas. This project will aid the accomplishment of Healthy People 2010 Focus Area 1—Access. Specifically, it will aid the accomplishment of objective 1–15, ''Increase the proportion of persons with long-term care needs who have access to the continuum of long-term care services.'' Potential applicants may obtain a printed copy of Healthy People 2010, (Summary Report No, 017–001–00549–5) or CD-ROM, Stock No. 0 17–001–00549–5, through the Superintendent of Documents, Government Printing Office, P.O. Box

371954, Pittsburgh, PA 15250–7945, (202) 512–1800. You may also access this information at the following Web site; *http://www.healthypeople.gov/Publications.*

The IHS is focusing efforts on three Health Initiatives that, linked together, have the potential to achieve positive improvements in the health of AI/AN people. These three initiatives are Health Promotion/Disease Prevention, Management of Chronic Disease, and Behavioral Health. Further information is available at the Health Initiatives Web site: *http://www.ihs.gov/NonMedicalPrograms/DirInitiatives/index.cfm.*

Dated: March 24, 2008.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. E8–6409 Filed 3–28–08; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

RIN 0917–ZA22

Reimbursement Rates for Calendar Year 2008

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001 (a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 *et seq.*), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2008 for Medicare and Medicaid beneficiaries and beneficiaries of other Federal programs. The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient rates set forth below do not include all physician services and practitioner services, additional payment may be available to the extent that those services meet applicable requirements. Public Law 106–554, section 432, dated December 21, 2000, authorized IHS facilities to file Medicare Part B claims with the carrier for payment for physician and certain other practitioner services provided on or after July 1, 2001.

INPATIENT HOSPITAL PER DIEM RATE (EXCLUDES PHYSICIAN/PRACTITIONER SERVICES)

[Calendar Year 2008]

Lower 48 States	$1,811
Alaska	2,255
Outpatient per Visit Rate (Excluding Medicare)	
Lower 48 States	$253
Alaska	423
Outpatient per Visit Rate (Medicare)	
Lower 48 States	$215
Alaska	365
Medicare Part B Inpatient Ancillary per Diem Rate	
Lower 48 States	$373
Alaska	650
Outpatient Surgery Rate (Medicare)	
Established Medicare rates for freestanding Ambulatory Surgery Centers	

Effective Date for Calendar Year 2008 Rates

Consistent with previous annual rate revisions, the Calendar Year 2008 rates will be effective for services provided on/or after January 1, 2008 to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: November 29, 2007.

Robert G. McSwain,

Acting Director, Indian Health Service.

Editorial Note: This document was received at the Office of the Federal Register on March 25, 2008.

[FR Doc. E8–6431 Filed 3–28–08; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Self-Governance Program; Negotiation Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: HHS–2008–IHS–TSGP–0001.

Catalog of Federal Domestic Assistance Numbers(s): 93.210.

Key Dates: Application Deadline Date: April 28, 2008.

Review Date: May 8–9, 2008.

Earliest Anticipated Start Date: June 1, 2008.

I. Funding Opportunity Description

The purpose of the program is to award cooperative agreements that provide negotiation resources to Tribes interested in participating in the Tribal Self-Governance Program (TSGP) as authorized by Title V, Tribal Self-Governance Amendments of 2000 of the Indian Self-Determination and Education Assistance Act of Public Law (Pub. L.) 93–638, as amended. There is limited competition under this announcement because the authorizing legislation, Public Law 106–260, Title V, restricts eligibility to Tribes that meet specific criteria (Refer to Section III.l.A., ELIGIBLE APPLICANTS in this announcement). The TSGP is designed to promote self-determination by allowing Tribes to assume more control of Indian Health Service (IHS) programs and services through compacts negotiated with the IHS. The Negotiation Cooperative Agreement provides Tribes with funds to help cover the expenses involved in preparing for and negotiating with the IHS and assists eligible Indian Tribes to prepare Compacts and Funding Agreements (FAs). This program is described at 93.210 in the Catalog of Federal Domestic Assistance (CFDA).

The Negotiation Cooperative Agreement provides resources to assist Indian Tribes to conduct negotiation activities that include but are not limited to:

1. Determine what programs, services, functions, and activities (PSFAs) will be negotiated.

2. Identification of Tribal shares that will be included in the FA.

3. Development of the terms and conditions that will be set forth in the FA.

The award of a Negotiation Cooperative Agreement is not required as a prerequisite to enter the TSGP. Indian Tribes that have completed comparable health planning activities in previous years using Tribal resources but have not received a Tribal self-governance planning award are also eligible to apply.

II. Award Information

Type of Awards: Cooperative Agreement.

Estimated Funds Available: The total amount identified for Fiscal Year (FY) 2008 is $240,000 for approximately twelve (12) Tribes. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: The estimated number of awards under the program to be funded is approximately 12.

Project Period: 12 months.

Award Amount: $20,000 per year.

Programmatic Involvement: IHS TSGP funds will be awarded as cooperative agreements and will have substantial programmatic involvement to establish a process through which Tribes can effectively approach the IHS to identify PSFAs and associated funding that could be incorporated into their programs.

The IHS roles and responsibilities will include:

Providing a description of PSFAs and associated funding at all levels, including funding formulas and methodologies related to determining Tribal shares.

Identification of IHS staff that will consult with applicants on methods currently used to manage and deliver health care.

Provide applicants with statutes, regulations, and policies that provide authority for administering IHS programs, including contract support costs criteria for new or expanded programs.

The Grantee's roles and responsibilities are essential to the overall success of the project.

Therefore the grantee must:

Determine the PSFAs and associated funding the Tribe may elect to assume.

Prepare to discuss each PSFA in comparison to the current level of services provided, so that an informed decision can be made on new program assumption.

Develop a compact and FA to submit to the Agency Lead Negotiator prior to negotiations.

III. Eligibility Information

1. Eligible Applicants

To be eligible for a negotiation cooperative agreement under this announcement, an applicant must meet all of the following criteria:

A. Be a Federally-recognized Tribe as defined in Title V, Public Law 106–260, Tribal Self-Governance Amendments of 2000, of the Indian Self-Determination and Education Assistance Act (ISDA), Public Law 93–638, as amended. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity already participating in ISDA compacting (25 U.S.C. 458aaa–2(e)). Those Tribes not represented by a self-governance Tribal consortium compact, within their area, may still be considered to participate in the TSGP.

2. Cost Sharing or Matching

The Self-Governance Negotiation Cooperative Agreement does not require matching funds or cost sharing to participate in the competitive grant process.

3. Other Requirements

The following documentation is required (if applicable):

A. This program is described at 93.210 in the CFDA.

B. Request participation in self-governance by resolution from the governing body of the Indian Tribe. An Indian Tribe that is proposing a Cooperative Agreement affecting another Indian Tribe must include resolutions from all affected Tribes to be served.

C. Tribal Resolution—A resolution of the Indian Tribe served by the project must accompany the application submission. For Tribal Consortia applying for a Negotiation Cooperative Agreement, individual Tribal Council Resolutions from all individual Tribes whose PSFAs will be compacted must be submitted. Draft resolutions are acceptable in lieu of an official resolution to submit with the application. However, an official signed Tribal resolution must be received by the Division of Grants Operations (DGO), Attn: John Hoffman, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, by Friday, April 25, 2008. If an official signed resolution is not submitted by April 25, 2008 the application will be considered incomplete and will be returned to the applicant without further consideration.

* It is highly recommended that the Tribal resolution be sent by Federal Express for proof of receipt.

D. Demonstrate, for three FYs, financial stability and financial management capability, which is defined as no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's self-determination contracts or self-governance funding agreements with any Federal agency.

E. Grantees are required to submit a current version of the organization's audit report. Audit reports can be lengthy; therefore, the applicants may submit them separately via regular mail by the due date, April 28, 2008. If the grantee determines that the audit reports are not lengthy, the applicants may scan the documents and attach them to the electronic application. While all of the other components of the application will be submitted through *www.Grants.gov* (Grants.gov), the applicants must submit two copies of the audits that reflect three previous fiscal years under separate cover directly to the Division of Grants Operations, Attn: John Hoffman, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, referencing the Funding Opportunity Number, HHS–2008–IHS–TSGP–0002, as prescribed by Public Law 98–502, the Single Audit Act, as amended (see 0MB Circular A–133, revised June 24, 1997, Audits of States, Local Governments, and Non-Profit Organizations). If this documentation is not submitted with the application by the application receipt date, April 28, 2008, the application will be considered as incomplete and be returned to the applicant without further consideration. Applicants must include the grant tracking number assigned to their electronic submission by Grants.gov and the date submitted via Grants.gov in their cover letter transmitting the required audits for the previous three fiscal years.

If the application budget exceeds the stated dollar amount that is outlined within this announcement, the application will be returned to the applicant without further consideration.

IV. Application and Submission Information

1. Applicant package may be found in Grants.gov or at: *http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp.* Information regarding the electronic application process may be directed to Michelle G. Bulls at (301) 443–6528.

The entire application package is available at: *http://www.ihs.gov/NonMedicalPrograms/SelfGovernance/index.cfm?module=planning_negotiation.*

Detailed application instructions for this announcement are downloadable on Grants.gov.

2. Content and Form of Application Submission:

Be single spaced.

Be typewritten.

Have consecutively numbered pages.

Use black type not smaller than 12 characters per one inch.

Be printed on one side only of standard size 8½″ x 11″ paper.

Contain a narrative that does not exceed seven typed pages that includes the other submission requirements below. The seven page narrative does not include the work plan, standard forms, Tribal resolutions or letters of support (if necessary), table of contents, budget, budget justifications, narratives, and/or other appendix items.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with the exception of the

Lobbying and Discrimination public policy.

3. Submission Dates and Times:

Applications must be submitted electronically through Grants.gov by 12 midnight Eastern Standard Time (EST). If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant should contact Michelle G. Bulls, Grants Policy Staff (GPS), at least fifteen days prior to the application deadline and advise of the difficulties. The grantee must obtain prior approval, in writing (e-mails are acceptable) allowing the paper submission. If submission of a paper application is requested and approved, the original and two copies may be sent to the appropriate grants contact that is listed in Section IV.1. above. Applications not submitted through Grants.gov, without an approved waiver, may be returned to the applicant without review or consideration. Late applications will not be accepted for processing, will be returned to the applicant, and will not be considered for funding.

4. Intergovernmental Review:

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions:

A. Only one negotiation cooperative agreement will be awarded per applicant.

B. Each negotiation cooperative agreement shall not exceed $20,000.

C. The available funds are inclusive of direct and appropriate indirect costs.

D. IHS will not acknowledge receipt of applications.

6. Other Submission Requirements:

A. Table of Contents.

B. Abstract (one page)—Summarizes the project.

C. Narrative (no more than 7 pages) and should include the following:

(1) Background information on the Tribe.

(2) Proposed scope of work, objectives, and activities that provide a description of what will be accomplished including a one-page Time Frame Chart.

D. Budget narrative and justification.

E. Tribal Resolution.

F. Appendices to include:

(1) Resumes or position descriptions of key staff.

(2) Contractors/Consultants resumes or qualifications and scope of work.

(3) Current Indirect Cost Agreement.

(4) Organizational Chart (Optional) Abstract (one page)—Summarizes the project.

Electronic Submission—The preferred method for receipt of applications is electronic submission through Grants.gov. However, should any technical challenges arise regarding the submission, please contact Grants.gov Customer Support at 1–800–518–4726 or *support@grants.gov.* The Contact Center hours of operation are Monday–Friday from 7 a.m. to 9 p.m. EST. If you require additional assistance please call (301) 443–6290 and identify the need for assistance regarding your Grants.gov application. Your call will be transferred to the appropriate grants staff member. The applicant must seek assistance at least fifteen days prior to the application deadline. Applicants that do not adhere to the timelines for Central Contractor Registry (CCR) and/or Grants.gov registration and/or requesting timely assistance with technical issues will not be a candidate for paper applications.

To submit an application electronically, please use *http://www.Grants.gov* and select ''Apply for Grants'' link on the home page. Download a copy of the application package on the Grants.gov Web site, complete it offline, and then upload and submit the application via the Grants.gov site. You may not e-mail an electronic copy of a grant application to IHS.

Please be reminded of the following:

Under the new IHS application submission requirements, paper applications are not the preferred method. However, if you have technical problems submitting your application on-line, please directly contact Grants.gov Customer Support at: *http://www.grants.gov/CustomerSupport.*

Upon contacting Grants.gov obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver request from GPS must be obtained.

If it is determined that a formal waiver is necessary, the applicant must submit a request, in writing (e-mails are acceptable), to *Michelle.Bulls@ihs.gov* that includes a justification for the need to deviate from the standard electronic submission process. Upon receipt of approval, a hard-copy application package must be downloaded by the applicant from Grants.gov, and sent directly to the Division of Grants Operations (DGO), 801 Thompson Avenue, TMP 360, Rockville, MD 20852 by the due date, April 28, 2008.

Upon entering the Grants.gov site, there are application instructions available to applicants under this announcement that outline the requirements of the Grants.gov submission process, as well as the hours of operation. We strongly encourage all applicants not to wait until the deadline date to begin the application process through Grants.gov as the registration process for CCR and Grants.gov could take up to fifteen working days.

To use Grants.gov, you, as the applicant, must have a DUNS Number and register in the CCR. You should allow a minimum of ten days working days to complete CCR registration. See below on how to apply.

You must submit all documents electronically, including all information typically included on the SF–424 and all necessary assurances and certifications.

Please use the optional attachment feature in Grants.gov to attach additional documentation that may be requested by IHS.

Your application must comply with any page limitation requirements described in the 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 Indian Health Service, DGO will retrieve your application from Grants.gov. DGO will not notify applicants that the application has been received.

You may access the electronic application for this program on *http://www.Grants.gov.*

You may search for the downloadable application package either by the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.

The applicant must provide the Funding Opportunity Number: HHS–2008–IHS–TSGP–0001.

E-mail applications will not be accepted under this announcement.

DUNS Number

Applicants are required to obtain a DUNS number from Dun and Bradstreet to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

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organization has a DUNS number. Registration with the CCR is free of charge.

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More detailed information regarding these registration processes can be found at *http://www.grants.gov.*

V. Application Review Information

The instructions for preparing the application narrative also constitute the evaluation criteria for reviewing and scoring the application. Weights assigned to each section are noted in parentheses.

1. Criteria

Demonstration of Previous Planning Activities (30 points)

Has the Indian Tribe determined the PSFAs to be assumed? Has the Indian Tribe determined it has the administrative infrastructure to support the assumption of the PSFAs? Are the results of what was learned or is being learned during the planning process clearly stated?

Thoroughness of Approach (25 points)

Is a specific narrative provided regarding the direction the Indian Tribe plans to take in the TSGP? How will the Tribe demonstrate improved health and services to the community it serves? Are proposed time lines for negotiations indicated?

Project Outcome (25 points)

What beneficial contributions are expected or anticipated for the Tribe? Is information provided on the services that will be assumed? What improvements will be made to manage the health care system? Are Tribal needs discussed in relation to the proposed programmatic alternatives and outcomes which will serve the Tribal community?

Administrative Capabilities (20 points)

Does the Indian Tribe clearly demonstrate knowledge and experience in the operation and management of health programs? Is the internal management and administrative infrastructure of the applicant described?

Appendix Items

Work plan for proposed objectives. Position descriptions for key staff. Resumes of key staff that reflect current duties. Consultant proposed scope of work (if applicable). Indirect Cost Agreement. Organizational chart (optional). Audits.

2. Review and Selection Process

In addition to the above criteria/requirements, applications are considered according to the following:

A. Application Submission (Application Deadline: April 28, 2008). Applications submitted in advance of or by the deadline and verified by the tracking number will undergo a preliminary review to determine that:

The applicant and proposed project type is eligible in accordance with this cooperative agreement announcement.

The application is not a duplication of a previously funded project.

The application narrative, forms, and materials submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation; otherwise, it may be returned.

B. Competitive Review of Eligible Applications (Objective Review: May 8–9, 2008). Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed for merit by the Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on these applications. The review will be conducted in accordance with the IHS Objective Review Guidelines. The technical review process ensures selection of quality projects in a national competition for limited funding. Applications will be evaluated and rated on the basis of the evaluation criteria listed in Section V.1. The criteria are used to evaluate the quality of a proposed project, determine the likelihood of success, and assign a numerical score to each application. The scoring of approved applications will assist the IHS in determining which proposals will be funded if the amount of TSGP funding is not sufficient to support all approved applications. Applications recommended for approval, having a score of 60 or above by the ORC are forwarded to the DGO for cost analysis and further recommendation. The program official forwards the approval list to the IHS Director for final review and approval. Applications scoring below 60 points will be disapproved.

Note: In making final selections, the IHS Director will consider the ranking factors and the status of the applicant's single audit reports. The comments from the ORC will be advisory only. The IHS Director will make the final decision on awards.

VI. Award Administration Information

1. Award Notices.

The Notice of Award (NoA) will be initiated by the DGO and will be mailed via postal mail to each entity that is approved for funding under this announcement. The NoA will be signed by the Grants Management Officer and this is the authorizing document under which funds are dispersed to the approved entities. The NoA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NoA is the legally binding document. Applicants who are approved but unfunded or disapproved based on their Objective Review score will receive a copy of the Final Executive Summary which identifies the weaknesses and strengths of the application submitted. Any other correspondence announcing to the Project Director that an application was selected is not an authorization to begin performance.

2. Administrative Requirements.

Cooperative Agreements are administered in accordance with the following documents:

This Program Announcement.

Program Regulations, 42 CFR Part 136.101 et seq., 45 CFR Part 92, ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments,'' or 45 CFR Part 74, ''Uniform Administrative Requirements for Awards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations.''

Grants Policy Guidance: HHS Grants Policy Statement, January 2007.

Cost Principles: 0MB Circular A–87, ''Cost Principles for State, Local, and Indian Tribal Governments'' (Title 2 Part 225).

Administrative Requirements: 0MB Circular A–122, ''Non-Profit Organizations'' (Title 2 Part 230).

Audit Requirements: 0MB Circular A–133, ''Audits of States, Local Governments, and Non-Profit Organizations.''

3. Indirect Costs.

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate means the rate covering the applicable activities and the award budget period. If the current

rate is not on file with the Division of Grants Operations at the time of award, the indirect cost portion of the budget will be restricted and not available to the recipient until the current rate is provided to DGO.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *http://rates.psc.gov/* and the Department of Interior (National Business Center) *http://www,nbc.gov/acquisition/ics/icshome.htrnl.* If your organization has questions regarding the indirect cost policy, please contact the DGO at 301–443–5204 or Grants Policy Staff at 301–443–6290.

4. Reporting.

A. *Progress Report.* Program progress reports are required semi-annually. These reports must be submitted within 30 days of the end of the half year and will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. *Financial Status Report.* Semi-annual financial status reports must be submitted within 30 days of the end of the half year. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting. The final SF–269 must be verified from the grantee's records on how the value was derived. Grantees must submit reports in a reasonable period of time.

Failure to submit required reports within the time allowed may result in suspension or termination of an active cooperative agreement, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.

5. Telecommunication for the hearing impaired is available at: TTY 301–443–6394.

VII. Agency Contact(s)

1. Questions on the programmatic issues may be directed to: Matt Johnson, Policy Analyst Office of Tribal Self-Governance Telephone No.: 301–443–7821 Fax No.: 301–443–1050 E-mail: *matthew.johnson@ihs,gov.*

2. Questions on grants management and fiscal matters may be directed to: John Hoffman, Grants Management Specialist Division of Grants Operations Telephone No.: 301–443–5204 Fax No.: 301–443–9602 E-mail: *john.hoffman2@ihs.gov.*

VIII. Other Information

The Public Health Service (PHS) strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Dated: March 24, 2008.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. E8–6428 Filed 3–28–08; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Self-Governance Program Planning Cooperative Agreement

Announcement Type: New.

Funding Announcement Number: 1–[HS–2008–IHS–TS GP–0002.

Catalog of Federal Domestic Assistance Numbers(s): 93.210.

Key Dates: Application Deadline Date: April 28, 2008.

Review Date: May 8–9, 2008.

Earliest Anticipated Start Date: June 1, 2008.

I. Funding Opportunity Description

The purpose of the program is to award cooperative agreements that provide planning resources to Tribes interested in participating in the Tribal Self-Governance Program (TSGP) as authorized by Title V, Tribal Self-Governance Amendments of 2000 of the Indian Self-Determination and Education Assistance Act of Public Law (Pub. L.) 93–638, as amended. There is limited competition under this announcement because the authorizing legislation restricts eligibility to Tribes that meet specific criteria (Refer to Section 111.1.A., ELIGIBLE APPLICANTS in this announcement). The TSGP is designed to promote self-determination by allowing Tribes to assume more control of Indian Health Service (IHS) programs and services through compacts negotiated with the IRS. The Planning Cooperative Agreement allows a Tribe to gather information to determine the current types of Programs, Services, Functions, and Activities (PSFAs), and related funding available at the Service Unit, Area, and Headquarters levels and provide the opportunity to improve and enhance the healthcare delivery system to better meet the needs of the Tribal community. This program is described at 93.210 in the Catalog of Federal Domestic Assistance (CFDA).

II. Award Information

Type of Awards: Cooperative Agreement.

Estimated Funds Available: The total amount identified for Fiscal Year (FY) 2008 is $600,000 for approximately twelve (12) Tribes. Awards under this announcement are subject to the availability of funds.

Anticipated Number of Awards: The estimated number of awards to be funded is approximately 12.

Project Period: 12 months.

Award Amount: $50,000 per year.

Programmatic Involvement: TSGP funds will be awarded as cooperative agreements and will have substantial IHS programmatic involvement to establish a basic understanding of PSFAs and associated funding at the Service Unit, Area, and Headquarters levels.

The IHS roles and responsibilities will include:

- Providing a description of PSFAs and associated funding at all levels, including funding formulas and methodologies related to determining Tribal shares.
- Identifying IHS staff who will consult with applicants on methods currently used to manage and deliver health care.
- Providing applicants with statutes, regulations and policies that provide authority for administering IHS programs.

The grantee roles and responsibilities are critical to the success of the program and will include:

- Researching and analyzing the complex IHS budget, to gain a thorough understanding of funding distribution at all levels to determine which PSFAs the Tribe may elect to assume.
- Establishing a process by which Tribes can effectively approach the IHS

to identify programs and associated funding which could be incorporated into their current programs.

• Determining the Tribe's share of each PSFA and evaluating the current level of health care services being provided to make an informed decision on new program assumption(s).

III. Eligibility Information

1. Eligible Applicants

To be eligible for a Planning Cooperative Agreement under this announcement, an applicant must meet all of the following criteria:

A. Be a Federally-recognized Tribe as defined in Title V, Public Law 106 260, Tribal Self-Governance Amendments of 2000, of the Indian Self-Determination and Education Assistance Act (the Act), Public Law 93–638, as amended. However, Alaska Native Villages or Alaska Native Village Corporations are not eligible if they are located within the area served by an Alaska Native regional health entity already participating in compact status (25 U.S.C. 458aaa–2(e)). Those Tribes not represented by a self-governance Tribal consortium compact, within their area, may still be considered to participate in the TSGP.

2. Cost Sharing or Matching

The Tribal Self-Governance Planning Cooperative Agreement announcement does not require matching funds or cost sharing to participate in the competitive grant process.

3. Other Requirements

The following documentation is required (if applicable):

A. This program is described at 93.210 in the CFDA.

B. Tribal Resolution—Submit a Tribal resolution from the governing body authorizing the submission of the application for the Tribal Self-Governance Planning Cooperative Agreement. Tribal Consortia applying for a Tribal Self-Governance Planning Cooperative Agreement shall submit Tribal Council Resolutions from each Tribe in the consortium. Draft resolutions, submitted with the application, are acceptable in lieu of an official signed resolution. However, an official signed Tribal resolution must be received by the Division of Grants Operations (DGO), Attn: John Hoffman, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, by Friday, April 25, 2008. If an official signed resolution is not received by April 25, 2008, the application will be considered incomplete and will be returned without consideration.

C. Demonstrate, for three fiscal years, financial stability and financial management capability, which is defined as no uncorrected significant and/or material audit exceptions in the required annual audit of the Indian Tribe's self-determination contracts or self governance funding agreements with any Federal agency. Applicants are required to submit a current version of the organization's audit report. The applicants may scan the documents and attach them to the electronic application. If the applicant determines that the audit reports are too lengthy, the applicants may submit them separately via regular mail by the due date, April 28, 2008. Applicants, sending in audits via regular mail, must submit two copies of the audits for three previous fiscal years under separate cover directly to the Division of Grants Operations, Attn: John Hoffman, 801 Thompson Avenue, TMP 360, Rockville, MD 20852, referencing the Funding Opportunity Number, HHS–2008–IHS–TSGP–0001, as prescribed by Public Law 98–502, the Single Audit Act, as amended (see OMB Circular A–133, revised June 24, 1997, Audits of States, Local Governments, and Non-Profit Organizations), for the three previous fiscal years. If this documentation is not received by April 28, 2008, the application will be considered as incomplete and will be returned to the applicant without further consideration.

D. If application budgets exceed the stated dollar amount that is outlined within this announcement, the application will be returned to the applicant without further consideration.

IV. Application and Submission Information

1. Applicant package and detailed instructions for this announcement may be found in Grants.gov *(www.grants.gov)* or at: *http://www.ihs.gov/NonMedicalPrograms/gogp/gogp_funding.asp*.

Information regarding the electronic application process may be directed to Michelle G. Bulls, at (301) 443–6290.

Information regarding this announcement may also be found on the Office of Tribal Self-Governance Web site at: *http://www.ihs.gov/NonMedicalPrograms/SelfGovernance/index.cfm?module=planning_negotiation*.

2. Content and Form of Application Submission:

• Be single spaced.

• Be typewritten.

• Have consecutively numbered pages.

• Use black type not smaller than 12 characters per one inch.

• Be printed on one side only of standard size 8½″ x 11″ paper.

• Contain a narrative that does not exceed seven typed pages that includes the other submission requirements below. The seven page narrative does not include the work plan, standard forms, Tribal resolutions or letters of support (if necessary), table of contents, budget, budget justifications, narratives, and/or other appendix items.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with exception of the Lobbying and Discrimination public policy.—Include Letter of Intent requirements under Public Policy Requirements.

3. Submission Dates and Times:

Applications must be submitted electronically through Grants.gov by 12 midnight Eastern Standard Time (EST). If technical challenges arise and the applicant is unable to successfully complete the electronic application process, the applicant should contact Michelle G. Bulls, Grants Policy Staff (GPS), fifteen days prior to the application deadline and advise of the difficulties that your organization is experiencing. The grantee must obtain prior approval, in writing (e-mails are acceptable) allowing the paper submission. If submission of a paper application is requested and approved, the original and two copies may be sent to the appropriate grants contact that is listed in Section IV.1. above. Applications not submitted through Grants.gov, without an approved waiver, may be returned to the applicant without review or consideration. Late applications will not be accepted for processing, will be returned to the applicant, and will not be considered for funding.

4. Intergovernmental Review: Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions:

A. Tribes are only eligible to be awarded one Tribal Self-Governance Planning Cooperative Agreement award.

B. Each planning cooperative agreement shall not exceed $50,000. The available funds are inclusive of direct and appropriate indirect costs.

C. The available funds are inclusive of direct and indirect costs.

D. IHS will not acknowledge receipt of applications.

6. Other Submission Requirements:

The application must comply with the following:

A. Table of Contents.

B. Abstract (one page)—Summarizes the project.

C. Narrative (no more than 7 pages) and should include the following:

(1) Background information on the Tribe.

(2) Proposed scope of work, objectives, and activities that provide a description of what will be accomplished including a one-page Time Frame Chart.

D. Budget narrative and justification.

E. Tribal Resolution.

F. Appendices to include:

(1) Resumes or position descriptions of key staff.

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- If it is determined that a formal waiver is necessary, the applicant must submit a request, in writing (e-mails are acceptable), to *Michelle.Bulls@ihs.gov* that includes a justification for the need to deviate from the standard electronic submission process. Upon receipt of approval, a hard-copy application package must be downloaded by the applicant from Grants.gov and sent directly to John Hoffman, Division of Grants Operations (DGO), 801 Thompson Avenue, TMP 360, Rockville, MD 20852 by the due date, April 28, 2008.
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- To use Grants.gov, you, as the applicant, must have a Data Universal Numbering System (DUNS) Number and register in the CCR. You should allow a minimum of ten days working days to complete CCR registration. See below on how to apply.
- You must submit all documents electronically, including all information typically included on the SF–424 and all necessary assurances and certifications.
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- You may access the electronic application for this program on *http://www.Grants.gov.*
- You may search for the downloadable application package by either the CFDA number or the Funding Opportunity Number. Both numbers are identified in the heading of this announcement.
- The applicant must provide the Funding Opportunity Number: HHS–2008–IHS–TSGP–0002.

E-mail applications will not be accepted under this announcement.

DUNS Number

Applicants are required to obtain a DUNS number from Dun and Bradstreet to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DLTNS number is easy and there is no charge. To obtain a DUNS number, access *http://www.dunandbradstreet.com* or call 1–866–705–5711. Interested parties may wish to obtain their DUNS number by phone to expedite the process.

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Applicants may register by calling 1–888–227–2423. Please review and complete the CCR Registration Worksheet located on *http://www.grants.gov/CCRRegister.* More detailed information regarding these registration processes can be found at *http://www.grants.gov.*

V. Application Review Information

1. Criteria

A. Goals and Objectives of the Project (30 points)

Are the goals and objectives measurable; are they consistent with the purpose of the program and the needs of the people to be served, and are they achievable as demonstrated by the proposed time frame chart?

B. Methodology (20 points)

Describe fully and clearly the methodology and activities that will be used to accomplish the goals and objectives of the project.

C. Management of Health Program(s) (10 points)

Does the applicant propose an improved approach to managing the health program(s) and state/demonstrate how the delivery of quality health services will be maintained under self-governance?

D. Organizational Capabilities and Qualifications (25 points)

Describe the organizational structure of the Tribe and their ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise and, where applicable, include

resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Budget and Budget Justification (15 points)

Submit a line-item budget with a narrative justification for all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

2. Review and Selection Process

In addition to the above criteria/requirements, applications are considered according to the following:

A. Application Submission:

(1) The applicant and proposed project type is eligible in accordance with this cooperative agreement announcement.

(2) The applicant has not previously received a Tribal Self Governance Planning Cooperative Agreement award.

(3) Abstract, narrative, budget, required forms, appendices and other material submitted meet the requirements of the announcement allowing the review panel to undertake an in-depth evaluation.

B. Competitive Review of Eligible Applications:

Applications meeting eligibility requirements that are complete, responsive, and conform to this program announcement will be reviewed for merit by the Objective Review Committee (ORC) appointed by the IHS to review and make recommendations on these applications. The review will be conducted in accordance with the IHS Objective Review Guidelines. The technical review process ensures selection of quality projects in a national competition for limited funding. Applications will be evaluated and rated on the basis of the evaluation criteria listed in Section V.1. The criteria are used to evaluate the quality of a proposed project, determine the likelihood of success, and assign a numerical score to each application. The scoring of approved applications will assist the IHS in determining which proposals will be funded if the amount of TSGP funding is not sufficient to support all approved applications. Applications recommended for approval, having a score of 60 or above by the ORC are forwarded to the DGO for cost analysis and further recommendation. The program official forwards the recommended approval list to the IHS Director for final review and approval. Applications scoring below 60 points will be disapproved.

Note: In making final selections, the IHS Director will consider the ranking factor and the status of the applicant's three previous years' single audit reports. The comments from the ORC will be advisory only. The IHS Director will make the final decision on awards.

VI. Award Administration Information

1. Award Notices:

The Notice of Award (NOA) will be initiated by the DGO and will be mailed via postal mail to each entity that is approved for funding under this announcement. The NOA will be signed by the Grants Management Officer and this is the authorizing document for which funds are dispersed to the approved entities. The NOA will serve as the official notification of the grant award and will reflect the amount of Federal funds awarded, the purpose of the grant, the terms and conditions of the award, the effective date of the award, and the budget/project period. The NOA is the legally binding document. Applicants who are approved but unfunded or disapproved based on their Objective Review score will receive a copy of the Final Executive Summary which identifies the weaknesses and strengths of the application submitted.

2. Administrative Requirements:

Grants are administrated in accordance with the following documents:

- This Program Announcement.
- 45 CFR Part 92, ''Uniform Administrative Requirements for Grants and Cooperative Agreements to State, Local and Tribal Governments,'' or 45 CFR Part 74, ''Uniform Administrative Requirements for Awards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations.''
- Grants Policy Guidance: HHS Grants Policy Statement, January 2007.
- Cost Principles: OMB Circular A–87, ''Cost Principles for State, Local, and Indian Tribal Governments'' (Title 2 Part 225).
- Administrative Requirements: OMB Circular A–122, ''Non-profit Organizations'' (Title 2 Part 230).
- Audit Requirements: OMB Circular A–133, ''Audits of States, Local Governments, and Non-profit Organizations.''

3. Indirect Costs:

This section applies to all grant recipients that request reimbursement of indirect costs in their grant application. In accordance with HHS Grants Policy Statement, Part II–27, IHS requires applicants to have a current indirect cost rate agreement in place prior to award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate means the rate covering the applicable activities and the award budget period. If the current rate is not on file with the DGO at the time of award, the indirect cost portion of the budget will be restricted and not available to the recipient until the current rate is provided to DGO.

Generally, indirect costs rates for IHS grantees are negotiated with the Division of Cost Allocation (DCA) *http://rates.psc.gov/* and the Department of Interior (National Business Center) *http://www.nbc.gov/acquisition/ics/icshome.html*. If your organization has questions regarding the indirect cost policy, please contact the DGO at 301–443–5204.

4. Reporting:

A. Progress Report. Program progress reports are required semiannually. These reports must be submitted within 30 days of the end of the half year and will include a brief comparison of actual accomplishments to the goals established for the period, or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 90 days of expiration of the budget/project period.

B. Financial Status Report. Semi-annual financial status reports must be submitted within 30 days of the end of the half year. Final financial status reports are due within 90 days of expiration of the budget/project period. Standard Form 269 (long form) will be used for financial reporting. The final SF–269 must be verified from the grantee's records on how the value was derived. Grantees must submit reports in a reasonable period of time.

Failure to submit required reports within the time allowed may result in suspension or termination of an active grant, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in one or both of the following: (1) The imposition of special award provisions; and (2) the non-funding or non-award of other eligible projects or activities. This applies whether the delinquency is attributable to the failure of the grantee organization or the individual responsible for preparation of the reports.

5. Telecommunication for the hearing impaired is available at: TTY 301–443–6394.

VII. Agency Contact(s)

1. Questions on the programmatic issues may be directed to: Matt Johnson,

Policy Analyst Office of Tribal Self-Governance, Telephone No.: 301–443–7821, Fax No.: 301–443–1050, E-mail: *matthew.johiison@ihs.gov.*

2. Questions on grants management and fiscal matters may be directed to: John Hoffman, Grants Management Specialist, Division of Grants Operations, Telephone No.: 301–443–5204, Fax No.: 301–443–9602, E-mail: *john.hoffman2@ihs.gov.*

VIII. Other Information

The Public Health Service (PHS) strongly encourages all cooperative agreement and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Dated: March 24, 2008.

Robert G. McSwain,

Acting Director, Indian Health Service.

[FR Doc. E8–6406 Filed 3–28–08; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Pharmacology Special.

Date: April 10, 2008.

Time: 12 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Mary Custer, PhD, Scientific Review Administrator, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4148, MSC 7850, Bethesda, MD 20892–7850, (301) 435–1164, *custerm@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: March 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6465 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

The meeting will be open to the public, with attendants limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: May 1–2, 2008.

Time: May 1, 2008, 8:30 a.m. to 5 p.m.

Agenda: NICHD Director's Report presentation, NCMRR Director's report presentation and various reports on Medical Research Initiatives.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Time: May 2, 2008, 8 a.m. to 12 p.m.

Agenda: Other business dealing with the NABMRR Board.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Ralph M Nitkin, PhD, Director, BSCD, National Center for Medical Rehabilitation Research, National Institute of Child Health and Human Development, NIH, 6100 Building, Room 2A03, Bethesda, MD 20892, (301) 402–4206.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nichd.nih.gov/about/ncmrr.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 39.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 24, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6463 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Cohort Studies.

Date: April 11, 2008.

Time: 12 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Shanta Rajaram, PhD, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Blvd., Suite 3208,

MSC9529, Bethesda, MD 20852, (301) 435–6033, *rajarams@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: March 21, 2008

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6326 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Conference/Meeting Application Review Panel.

Date: April 4, 2008.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6101 Executive Boulevard, Rockville, MD 20852. (Virtual Meeting)

Contact Person: Mark R. Green, PhD., Deputy Director, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301)435–1431, *mgreen1@nida.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: March 20, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6327 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel, Assessment of Potential Cocaine Pharmacotherapies in Monkeys.

Date: April 23, 2008.

Time: 9 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Courtyard by Marriott Rockville, 2500 Research Boulevard, Rockville, MD 20850.

Contact Person: Lyle Furr, Contract Review Specialist, Office of Extramural Affairs, National Institute on Drug Abuse, NIH, DHHS, Room 220, MSC 8401, 6101 Executive Boulevard, Bethesda, MD 20892–8401, (301) 435–1439, *lf33c.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: March 20, 2008.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6329 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set form in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Bacterial Immunology & Vaccine Development.

Date: April 22, 2008.

Time: 12:30 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Jo Ann S. Rinaudo, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, MSC 7616, Room 3264, Bethesda, MD 20892–7616, 301–402–5658, *rinaudo@mail.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Innate Immunity to Human Pathogens.

Date: April 23, 2008.

Time: 8:30 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Jo Ann S. Rinaudo, PhD, Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health/NIAID, 6700B Rockledge Drive, Room 3264, MSC 7616, Bethesda, MD 20892–7616, 301–402–5658, *rinaudo@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 24, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6458 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; To Review R21/R33 Grant Applications.

Date: April 21–22, 2008.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Chevy Chase, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Barney Duane Price, PhD, Scientific Review Officer, Scientific Review Program, DHHS/NIH/NIAID/DEA, Room 3139, 6700B Rockledge Drive, MSC 7616, Bethesda, MD 20892–7616, 301–496–2550, *pricebd@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: March 24, 2008.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6459 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Normal Fetal Growth.

Date: April 28, 2008.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Sathasiva B. Kandasamy, PhD, Scientific Review Administrator, Division of Scentific Review, National Institute of Child Health and Human Development, 6100 Executive Boulevard, Room 5B01, Bethesda, MD 20892–9304, (301) 435–6680, *skandasa@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS).

Dated: March 24, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6460 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Partners in Research Program.

Date: April 20–22, 2008.

Time: 6 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Marita R. Hopmann, PhD, Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, 6100 Building, Room 5B01, Bethesda, MD 20892, (301) 435–6911, *hoppmannm@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 39.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 24, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6461 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set form in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning

individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel; Loan Repayment Program.

Date: April 29, 2008

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Katrina L Foster, PhD, Scientific Review Administrator, National Inst. on Alcohol Abuse & Alcoholism, National Institutes of Health, 5635 Fishers Lane, Rm. 3037, Rockville, MD 20852, 301–443–3037, *katrina@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants, National Institutes of Health, HHS)

Dated: March 24, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6462 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which should constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Psychoactive Drug Screening.

Date: April 17, 2008.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Peter J. Sheridan, PhD, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6142, MSC 9606, Bethesda, MD 20892, 301–443–1513, *psherida@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: March 25, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E8–6464 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information: NIH Public Access Policy

AGENCY: The National Institutes of Health (NIH) of the U.S. Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: With this notice, the National Institutes of Health (NIH) of the U.S. Department of Health and Human Services (HHS) requests input from the community regarding the NIH Policy on Enhancing Public Access to Archived Publications Resulting From NIH-Funded Research (NIH Public Access Policy). Complete and detailed information about the law at Division G, Title II, section 218 of Public Law 110–161 (Consolidated Appropriations Act, 2008), the NIH Public Access Policy, and implementation procedures issued to date are available at *http://publicaccess.nih.gov/index.htm.* This request for information (RFI) seeks input on the Public Access Policy as described on the above Web site. This RFI will be active from March 31, 2008 to May 31, 2008 on *http://publicaccess.nih.gov/comments.htm.* The NIH will post analysis and results from this RFI for public view onto *http://publicaccess.nih.gov* by September 30, 2008.

Background: The National Institutes of Health (NIH)—The Nation's Medical Research Agency—is comprised of 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. It is the primary Federal agency for conducting and supporting basic, clinical, and translational medical research, and investigates the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit *http://www.nih.gov.*

PubMed Central is an archive of full-text biomedical journal articles available online without a fee. Articles on PubMed Central contain links to other scientific databases such as GenBank (*http://www.ncbi.nlm.nih.gov/Genbank/*) and PubChem (*http://pubchem.ncbi.nlm.nih.gov/*). Articles collected under the Public Access Policy are archived on PubMed Central. More information about PubMed Central is available at *http://www.pubmedcentral.nih.gov/about/faq.html.*

Prior to the Consolidated Appropriations Act of 2008, NIH's voluntary Public Access Policy (NOT–OD–05–022 available at *http://grants.nih.gov/grants/guide/notice-files/NOT–OD–05–022.html* and in the section on **SUPPLEMENTARY INFORMATION**) encouraged but did not require those receiving NIH funding to deposit their peer reviewed manuscripts into PubMed Central.

Division G, Title II, section 218 of Public Law 110–161 (Consolidated Appropriations Act of 2008) states:

> SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

On January 11, 2008, NIH issued a revised policy implementing this law. As described in the NIH Guide for Grants and Contracts (NOT–OD–08–033 available at *http://grants.nih.gov/grants/guide/notice-files/NOT–OD–08–033.html* and in the section on **SUPPLEMENTARY INFORMATION**), as of April 7, 2008, applicable manuscripts arising from NIH funds must be submitted to PubMed Central upon acceptance for publication. As of May 25, 2008, NIH applications, proposals, and progress reports must include the PMC reference number when citing a manuscript that falls under the policy. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

NIH has posted responses to frequently asked questions that provide authors, their institutions, and their publishers with preliminary guidance on the implementation of this policy, including guidance on the transfer of copyright. This document can be viewed at *http://publicaccess.nih.gov/FAQ.htm#content* and in the section on **SUPPLEMENTARY INFORMATION.**

The NIH Public Access Policy is a point of interest and discussion between NIH and many members of the public, including grantees (institutions and their authors), publishers, libraries, medical practitioners, patients and others with health concerns. For example, some of these stakeholders have expressed concern about copyright issues, and others about the length of time before manuscripts are made publicly available. Still others have offered suggestions on NIH's Public Access training materials, and have developed compliance strategies that may benefit others.

The NIH is seeking to engage formally with the broader community on the Public Access Policy in a transparent and participatory manner. The first step of this process was an open meeting, conducted March 20, 2008 (announced in the March 10, 2008 **Federal Register** notice 73 FR 12745). Comments collected to date, can be found at *http://publicaccess.nih.gov/comments/comments_web_listing.htm*. The NIH intends to make comments publicly available as they are collected; and, to facilitate independent analysis, the NIH will make comments available for download in bulk at the end of the comment period.

Request for Information: Via this RFI, NIH is seeking information from the public, including all stakeholders, about the NIH Public Access Policy (NOT–OD–05–022 available at *http://grants.nih.gov/grants/guide/notice-files/NOT–OD–05–022.html*), as revised by the NIH Guide for Grants and Contracts (NOT–OD–08–033 available at *http://grants.nih.gov/grants/guide/notice-files/NOT–OD–08–033.html*) to incorporate requirements in Public Law 110–161, and the responses to frequently asked questions available at *http://publicaccess.nih.gov/FAQ.htm#content*. NIH will consider all comments and suggestions regarding the Public Access Policy. Among other issues, the NIH is particularly interested in information about the following:

- Do you have recommendations for alternative implementation approaches to those already reflected in the NIH Public Access Policy?
- In light of the change in law that makes NIH's public access policy mandatory, do you have recommendations for monitoring and ensuring compliance with the NIH Public Access Policy?
- In addition to the information already posted at *http://publicaccess.nih.gov/communications.htm,* what additional information, training or communications related to the NIH Public Access Policy would be helpful to you?

As suggested above, previous comments have focused on such issues as copyright, the length of time before articles are made publicly available, and on NIH's training materials, and we anticipate that comments would continue to address these issues.

Individuals, groups, and organizations interested in responding may do so in their discretion at the following NIH Web site: *http://publicaccess.nih.gov/comments.htm.* In voluntarily providing information, respondents are consenting to its use and consideration by the NIH. The following identifying information will be made publicly available on the internet along with the information submitted by that commenter: Name (first and last), Degree (if provided), Affiliation, City, State, Country and Role. Roles are defined as: NIH-funded Investigator; Representative of University and Other NIH Awardee Organizations; Publisher (including Commercial Organizations, Professional Societies and Journal Editors); Patient or Representative of a Public Health Advocacy Organization; Other Member of the Public; Other (not listed above). If respondents provide information through alternative means, the entire submission will be made public. NIH will not post responses that are not related to the Public Access Policy or are otherwise inappropriate or offensive.

Report and Response: The NIH will analyze all submissions collected through this RFI, along with comments collected before and during the March 20th meeting. The NIH will report its analysis by September 30, 2008. This report will be made available at *http://publicaccess.nih.gov.*

Contact Person for Information: Questions concerning this RFI may be addressed to: Neil M. Thakur, Ph.D., Special Assistant to the NIH Deputy Director for Extramural Research, Building 1, Room 134, Bethesda, MD 20892, Telephone 301–496–1096, Fax 301–402–3469, *PublicAccessComments@NIH.gov*. Note that this facility is not intended to collect RFI responses. Please submit RFI responses via *http://publicaccess.nih.gov/comments.htm.*

SUPPLEMENTARY INFORMATION:

Notice Number: NOT–OD–05–022.

Key Dates

Release Date: February 3, 2005.
Effective Date: May 2, 2005.

Issued By

National Institutes of Health (NIH), (*http://www.nih.gov/*).

Department of Health and Human Services Action

Notice; Final Policy Statement.

Update: The following update relating to this Notice has been issued:

- *January 11, 2008* (NOT–OD–08–033)—Revised Policy on Enhancing Public Access to Archived Publications Resulting from NIH-Funded Research.

Summary

The National Institutes of Health (NIH) announces its policy on enhancing public access to archived publications resulting from NIH-funded research. Beginning May 2, 2005, NIH-funded investigators are requested to submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs [1] from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

This policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The policy is intended to: (1) Create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings; (2) secure a searchable compendium of these peer-reviewed research publications that NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and (3) make published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.

This final NIH Public Access Policy (the Policy) reflects modifications and clarifications to the proposed policy released September 3, 2004, in the NIH Guide for Grants and Contracts and September 17, 2004, in the **Federal**

Register and the more than 6,000 public comments received through November 16, 2004. The most significant change in the Policy from that originally proposed is to provide more flexibility for authors to specify the timing of the posting of their final manuscripts for public accessibility through PMC. The proposed policy indicated a six-month delay of posting through PMC. The Policy now requests and strongly encourages that authors specify posting of their final manuscripts for public accessibility as soon as possible (and within 12 months of the publisher's official date of final publication). The Policy also clarifies that the publication date is the publisher's official date of final publication.

Effective Date: May 2, 2005.

FOR FURTHER INFORMATION CONTACT: Office of Extramural Research, National Institutes of Health, 6705 Rockledge Drive, Room 350, Bethesda, MD 20892–7963 or by e-mail to: *PublicAccess@nih.gov.*

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I. Background

It has long been NIH policy that the results and accomplishments of the activities that it funds should be made available to the public. Principal Investigators (PI) and grantee organizations are expected to make the results and accomplishments of their activities available to the research community and to the public at large.[2] It is estimated that the results of NIH-supported research were described in 60,000–65,000 published papers in 2003.[3] We believe that widespread access to and sharing of peer-reviewed research publications generated with NIH support will advance science and improve communication of peer-reviewed, health-related information to scientists, health care providers, and the public.

As part of on-going efforts to gather perspectives on the issue of public access to research publications, the NIH held a series of meetings to hear and consider the opinions and concerns of publishers, scientists, patient advocates, and representatives of scientific associations and other organizations. The meetings were designed to ensure that discussions of stakeholder issues could occur. The NIH extended invitations to a broad base of participants to ensure balanced representation of opinions. In many cases, a participant represented more than one perspective, such as a scientist who was also a journal editor and reviewer of scientific manuscripts.

After carefully considering the views of publishers, patient advocates, scientists, university administrators, and others, the NIH published its proposed NIH Public Access Policy in the NIH Guide for Grants and Contracts on September 3, 2004, *http://grants.nih.gov/grants/guide/notice-files/NOT–OD–04–064.html* and in the **Federal Register** on September 17, 2004, *http://a257.g.akamaitech.net/7/257/2422/06jun20041800/edocket.access.gpo.gov/2004/04–21097.htm* for public comment. During the comment period, the NIH received over 6,000 comments via web, fax, mail, and e-mail. Many comments were received from organizations representing multiple constituents. The NIH developed Questions and Answers to clarify the proposal as issues were raised regarding it; these are available at: *http://www.nih.gov/about/publicaccess/publicaccess_QandA.htm.*

This final Policy reflects consideration of public comments received on the proposed policy through November 16, 2004, *i.e.*, 60 days from the date of publication of the proposed policy in the **Federal Register**.

The Policy is intended to: (1) Create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings; (2) secure a searchable compendium of these peer-reviewed research publications that NIH and its awardees can use to manage more efficiently and to understand better their research portfolios, monitor scientific productivity, and ultimately, help set research priorities; and (3) make published results of NIH-funded research more readily accessible to the public, health care providers, educators, and scientists.

II. Public Comments and NIH Responses

A. Need for the Policy

The public comments were largely supportive of the proposed policy to enhance public access to archived publications resulting from NIH-funded research. Comments noted that this policy provides equal and timely access to all via the Internet and that this accessibility should improve individual health outcomes. Many scientists appreciated that the policy would improve the visibility of their work. A large number of comments suggested that publicly funded research publications should be made accessible to the public in full-text version in a timely manner. Many commenters expressed support for the policy given their concerns about the high and rising cost of subscriptions to scholarly journals, especially in the areas of science, technology, and medicine.

Other commenters questioned the need for the policy and considered it redundant to existing information sources and systems. Some questioned the added value of the policy and noted that journals increasingly are making full-text articles available immediately upon or within one year of publication through a variety of sources. Commenters noted that many of these articles are already linkable through the NLM PubMed web-based literature retrieval system that contains citations and abstracts from thousands of journals, dating back to 1950.[4] A significant number of comments also questioned why the NLM could not simply provide a link to the publisher's Web site, or work with existing vendors to broaden offerings to include peer-reviewed publications not associated with NIH funding.

The primary purpose of the NIH Public Access Policy is the creation of a stable archive to ensure the permanent preservation of vital, peer-reviewed research publications resulting from NIH-funded research findings now and for future generations. While links exist to journal articles that are publicly accessible, these are not sufficient because publishers' Web sites are not permanently available nor consistently maintained. Additionally, the formatting of journal articles may vary significantly among publishers' Web sites. The Policy addresses this deficiency in that all articles in PMC, regardless of their original format, are converted into a single, explicit, and well-specified data format. This format is known as the NLM Journal Article Extensible Markup Language (XML) Document Type Definition (DTD). Further, as new needs arise, and as technology and applications change, there is a single, uniform base upon which to build.

Preservation of the biomedical literature is a responsibility that is specifically mandated in NLM's authorizing legislation, found at 42 U.S.C. 286(b)(1), and one that has successfully been carried out by the NLM since 1836. It is logical in this electronic era to expect libraries, and particularly national libraries, to continue this vital function, including keeping pace with the ever-changing technology surrounding document preservation. Updating the data formats to keep up with the changes in

technology and the needs of biomedical research requires an ongoing investment in research and development, which is within the NIH mission. As the electronic article increasingly becomes the authoritative and most useful document for researchers and as scientists are actually computing on the contents of these documents—the text itself as well as the associated data—the impermanence of the publishers' Web sites presents a substantial risk. Creating such an archive is a historical and necessary NIH responsibility.

NIH believes that the NIH Public Access Policy will effectively advance its stated goals. By storing research publications from diverse sources in a searchable, electronic archive with a common format, PMC facilitates greater integration with related resources in other NLM databases such as DNA and protein sequences, protein structures, clinical trials, small molecules (PubChem), and taxonomy, thus providing the opportunity to develop unprecedented scientific search and analysis capabilities for the benefit of science. One of the primary goals of PMC is the creation of a permanent, digital archive of journal literature, which by definition means the full text must be deposited in PMC. This searchable archive will enable NIH program officials to manage their research portfolios more efficiently, monitor scientific productivity, and ultimately, help set research priorities. This strategy also will enable NIH to advance its goal of creating an end-to-end, paperless grants management process. Finally, it will make the publications of NIH-funded research more accessible to and searchable for the public, health care providers, educators, and scientists.

A few commenters asked NIH to strengthen the proposed policy to make submission to PMC a requirement instead of a request. We believe that the voluntary nature of the final policy is preferable to a ''one size fits all'' requirement, as it permits sufficient flexibility to accommodate the needs of different stakeholders and leaves the ultimate decision in the hands of our scientific investigators who are the best to judge the scientific circumstances and the time frame under which their work may be made accessible to the public at large. It is worth clarifying that NIH does not require or expect that PMC be the sole repository for NIH-funded research publications. Others may choose to post and/or archive peer-reviewed publications resulting from NIH-funded research, subject to applicable laws or permission from any copyright holders.

B. Scope of the Policy

The NIH Public Access Policy applies only to peer-reviewed research publications that have been supported, in whole or in part, with direct costs from NIH. Numerous comments reflected misunderstandings about the scope of the policy as it was proposed. Some comments sought to broaden the Policy to include publications from non-NIH-supported investigators, and others asked that it include publications that did not contain original research findings, *e.g.*, book reviews.

The Policy does not apply to contributed book chapters, editorials, reviews, or conference proceedings. Although PMC does contain articles from non-NIH-supported research, the Policy is focused on final, peer-reviewed manuscripts and publications that result from research supported, in whole or in part, with direct costs from NIH.

C. Potential for Public Misunderstanding of Research Findings

A number of comments questioned the lay public's ability to understand fully original research publications, and expressed fear that potential harm could result from misinterpretation of them.

We believe that individuals who seek to read publications concerning a particular disease, health condition, or treatment should not be denied access because of the possibility that they will misunderstand the publications. Rather, NIH encourages such individuals to become educated consumers about their health care and related research, and to consult with health care professionals for specific guidance. It is important that NIH-supported research publications be made more readily available to provide credible information and to improve public understanding of the benefits of scientific research. The public demand for credible health information is clear. About 93 million Americans searched for at least one of 16 health topics online within the past year.[5] In a 2003 survey, 58 percent of Internet users said they brought information obtained from the Internet to their doctor's office.[6]

The NIH is strongly committed to conveying the importance of the research it funds to the public. Each NIH Institute and Center has an active staff that produces high-quality educational and informational materials on various health and research topics, many of which highlight the publications of NIH-funded researchers. Institute and Center staff, often with the assistance of third parties and patient advocacy groups, works diligently to develop, review, and disseminate these products. For example, the National Library of Medicine's consumer health site, Medline Plus (*http://www.nlm.nih.gov/medlineplus/*) houses extensive information on over 650 health conditions. NIH believes that these products effectively advance NIH's strong commitment to improving public health through research.

The Policy specifically relates to original research publications. NIH needs to compile these publications into a single archive in order to manage its research portfolio better and monitor its funding choices. NIH recognizes that providing public access to this electronic archive may also help scientists, policymakers, doctors, patients and the lay public to understand better the research that NIH funds.

D. Version Control and Quality of Manuscripts

Some commenters raised concerns about potential confusion resulting from differences between the author's final manuscript within PMC and the published version of the corresponding article at journal-sponsored Web sites. Others questioned how corrections, retractions, and other post-publication changes will be accommodated.

Through this Policy, NIH is requesting that NIH-funded investigators submit an electronic version of the author's final manuscripts resulting from research supported, in whole or in part, with direct costs from NIH, after all changes resulting from the peer review publication process have been incorporated. A growing number of journals are currently posting final author manuscripts to provide timely access to their subscribers prior to final publication of the publisher's copy edited version. In addition, under the Policy, the final manuscript will not be made available to the public through PMC until after the copyedited version is published by the journal. Corrections and other necessary revisions of author's final manuscripts will be accommodated. Furthermore, when publicly available, the published article on the journal-sponsored Web site and the author's final manuscript in PMC will be appropriately linked through PubMed. Corrections and post-publication comments referring to a publication are currently identified and linked in PubMed, and this capability will be linked to the corresponding manuscript in PMC. If publishers wish to provide PMC with the publisher's final version, this version will supersede the author's final manuscript in PMC.

E. Potential for Acceleration of Medical Cures

A few commenters questioned whether the proposed policy, and enhanced access to NIH-funded publications, will facilitate scientific progress and accelerate research for medical cures.

We believe that improved access through PMC to peer-reviewed, final manuscripts of NIH-supported investigators will facilitate scientific progress because it will enable NIH to manage better its research portfolio and funding choices. The NIH encourages the sharing of ideas, data, and research findings to help accomplish its important public mission to uncover new knowledge that will lead to better health for everyone. As such, we envision that the PMC resource will have widespread and varied uses for the research community. It will create a stable, permanent, and searchable archive of peer-reviewed research publications that NIH and the public can access, without a fee, to review scientific productivity, monitor the state-of-the-science, and apply such knowledge in other ways to accelerate medical research. Greater interconnectivity and functional integration between the multiple and large research data bases (e.g., Genbank and PubChem) and an archive of NIH-funded publications has the potential to enhance research in novel ways.

F. Potential Economic Impact on Journal Publishers

Commenters contended that NIH had not carefully considered the potential adverse economic impact of its proposed policy on publishers, in particular, not-for-profit professional and learned societies and associations that rely on subscriptions to cover costs. The consequences of the proposed policy for many small journals, as well as bimonthly and quarterly journals, were of particular concern to some. Concern also was raised that relative to commercial publishers, not-for-profit publishers would be more disadvantaged because they often support highly specialized areas that tend to draw greater representation by NIH-funded researchers. Others questioned the fairness of allowing publishers to continue to profit by restricting access to health-related information.

Publishing patterns vary from year to year and from one journal to another. Using 2003 data, NLM estimates that, on an annual basis, publications resulting from NIH-funded research represent approximately 10 percent of the articles in nearly 5,000 journals indexed by PubMed. In addition, for only one percent of these journals do NIH-funded articles account for more than half of the total published articles.[7] As such, it is unlikely that scientists and libraries would use the NIH Public Access Policy as the rationale for replacing their journal subscriptions. If they did, they would be able to access only a fraction of a journal's content. It also is important to note that there are many other journal offerings, such as science news, industry information, literature reviews, job announcements, functional Web sites, and other time-sensitive products that bring value to the reader but are not a part of the PMC archive. Access to journal articles through the NIH archive might increase Internet traffic to those journals, by both the scientific community and the general public.

The NIH supports the current publishing process by providing its funded investigators with an estimated $30 million[8] annually in direct costs for publication expenses, including page and color charges and reprints. In addition, NIH provides funds, through indirect costs, to research institutions for library journal subscriptions and electronic site licenses. NIH also supports the current process by encouraging publication of NIH-supported original research in scientific journals.

NIH has made modifications to the proposed policy to provide greater flexibility to accommodate the range of business models represented by large commercial publishing houses through the smaller specialized journals of learned societies. The most significant change is to allow authors to specify the timing of the posting for public accessibility through PMC of their final manuscript. The NIH intends to maintain its dialogue with publishers and professional and learned societies as experience is gained with the Policy.

A NIH Public Access Advisory Working Group of the NLM Board of Regents[9] will be established. The Working Group will be composed of stakeholders that will advise NIH/NLM on implementation and assess progress in meeting the goals of the NIH Public Access Policy. Once the system is operational, modifications and enhancements will be made as needed with the Working Group, or a permanent subcommittee of the Board, providing ongoing advice on improvements.

G. Potential Impact on Journal Peer Review

NIH recognizes the enormous value and critical role that peer-reviewed journals play in the scientific quality control process. Only peer-reviewed articles accepted for publication will be posted in PMC. Some commenters asked if scientific integrity would be compromised if journals were to go out of business, thus significantly narrowing journal options for authors. A few commenters feared that the NIH proposed policy would limit an author's freedom to publish how, when, and where he or she chooses.

We do not believe that the Policy will compromise scientific integrity or significantly narrow journal options for authors. While NIH encourages investigators to publish and share the results of the research that it funds, NIH does not dictate the means of publishing the research it supports. This Policy is designed to preserve the critical role of journals and publishers in peer review, editing, and scientific quality control processes. It is not intended to alter in any way the manuscript submission process, investigator choice of journal for publication, or existing publication process.

NIH highly values traditional routes of research information dissemination through publication in scientific, peer-reviewed journals. Peer review is a hallmark of quality for journals and is vital for validating the accuracy and interpretation of research results. Publication in peer-reviewed journals is a major factor in determining the professional standing of scientists; institutions use publication in peer-reviewed journals in making hiring, promotion, and tenure decisions. NIH also values the communities of research created by scientific organizations and the journals they publish. By not mandating but instead requesting from our investigators that access be provided to the public within a range of acceptable delays extending from 0 to 12 months, the NIH believes that its Public Access Policy addresses the concerns raised by both for-profit and not-for-profit publishers and will ensure that peer review of scientific articles is preserved. The NIH believes that archiving and making publicly accessible NIH-funded biomedical and behavioral literature after a reasonable time delay can preserve the critical role of journals and publishers in peer review, editing, and scientific quality control. The policy should have no effect on the author's choice of journal. We expect that greater access to research publications will increase the impact of

the publicly-funded research. For example, there is emerging evidence that easier access increases impact as measured by the number of times a paper is cited.[10]

H. Potential Impact on Scientists

A number of comments expressed the concern that researchers would be adversely affected by the proposed policy if publishers experienced a decline in subscriptions and subsequently chose to increase charges to authors. It was suggested that higher charges would disadvantage disproportionately researchers with more limited resources. In addition, some researchers were concerned that the proposed policy would create an additional burden on them.

NIH-funded investigators are expected to make the results and accomplishments of their activities available to the research community and to the public at large. Consequently, NIH considers publication costs, which include fees charged by a publisher, such as color and page charges, or fees for digital distribution, to be allowable charges to NIH research awards.

Concerning burden, public access submissions will provide NIH-supported investigators with an alternate means by which they can meet and fulfill the current requirement to provide a copy of each publication in their progress reports and other application and close-out procedures. It is anticipated that investigators applying for new and competing renewal support from the NIH will utilize this resource by providing links in their applications to their PMC-archived information. NIH, therefore, anticipates that this process may reduce, rather than increase, burden for investigators.

It is also worth noting that the development of a searchable archive of published findings from NIH-supported research will be a rich resource for all scientists. Access to such information not only will make it easier to investigate a specific area of research, but also may lead to identification of new research questions.

I. Open Access Publication and the NIH Public Access Policy

Some commenters believed that the NIH Public Access Policy constitutes an open access model of publishing. The NIH Policy is not a form of publishing; rather, it creates a stable archive of peer-reviewed research publications resulting from NIH-funded research. In addition, the Policy does not dictate the means of publishing but is compatible with any publishing model that authors and journals choose to employ. For example, some subscription journals already allow free electronic access to published manuscripts directly from their Web sites after an embargo period. In addition, one survey reports as many as 92 percent of journals allow authors to self-archive either a postprint (79 percent) or preprint (13 percent) of the article on personal Web sites or on their institution's Web site. [11] Copyright to all material deposited in PMC remains with the publisher, individual authors, or awardees, as applicable. PMC currently includes a copyright notice alerting the public to the rights of copyright holders and will continue to post this notice as it has done in the past.

J. Waiting Time to Public Access

The proposed policy published in September 2004 indicated that with the author's permission, the NIH would make the author's final manuscript available to the public no later than 6 months after the date of official publication as determined by the publisher. Many commenters considered the 6-month waiting time to be a reasonable compromise, though some believed the waiting time should be considerably shortened. Some recommended that the waiting time be 12 months or longer, particularly because 12 months rather than 6 months is currently the prevailing model among journals that already provide free, delayed, full-text access. Some commenters also noted that the vast majority of journals currently offer no free public access at all, thus arguing that a 6-month waiting time is too aggressive.

The NIH has tried to balance the legitimate needs of journal publishers with its interest in creating a permanent archive of peer-reviewed research publications resulting from NIH-funded research. There is a wide range of time-to-access policies within the publishing world. Some of the variables that affect time-to-access include differences among scientific fields (e.g., clinical versus basic research), and variability in business models determined by a range of issues including number of article submissions, acceptance rate and subscription base.

After considering the views of scientists, publishers, patient advocates, librarians, research administrators, professional societies, and others, the final Policy provides authors with the ability to specify when their final manuscript will be made available to the public through PMC. Posting for public accessibility through PMC is strongly encouraged as soon as possible (and within twelve months of the publisher's official date of final publication). This Policy provides greater flexibility for participation. Further, it addresses the agency's interest in establishing a permanent archive of peer-reviewed research publications resulting from NIH-funded research in a timely manner.

K. Politicization of Science

Some commenters suggested that a centralized, government-operated repository could compromise the integrity of the scientific record, be subject to government censorship, and be susceptible to the politicization of science and the variability of funding levels and changes in agency management.

Congress assigned to the NLM the responsibility to acquire, organize, disseminate, and preserve biomedical information for the benefit of public health. As part of this responsibility, the Policy will create a stable archive of peer-reviewed research publications resulting from NIH-funded research to ensure the permanent preservation of these vital published research findings. Agency policy is not to restrict or suppress the content of PMC.

L. Implementation Costs

Many commenters expressed concern that the costs associated with archiving NIH-funded manuscripts in PMC have not been clarified, or that costs are understated. Some publishers reported spending on the order of hundreds of millions of dollars over the past decade to improve online access to their journal offerings, which led to skepticism about the validity of NIH's estimates. These commenters are concerned that allocating funds for an expanded PMC archive would compete with funds available to support original research. Other commenters expressed concern that continued funding for the system may not be available in the future.

By building on an existing information technology infrastructure housed at the NLM, the NIH Public Access Policy can be an exceptionally cost-effective means to accomplish its goals of archiving, facilitating program management, and enhancing accessibility. Estimates of $2–$4 million per year reflect incremental costs to create and then maintain a Web site for submitting authors' final manuscripts and for Extensible Markup Language (XML) tagging of the manuscripts into PMC's archival format. These estimates reflect PMC's experience with a back-scanning project which has generated and tagged electronic versions of more than 200,000 printed articles in the last year. The roughly 50,000–70,000

manuscripts a year for the new NIH Policy will be tagged in a similar manner and incorporated into PMC using a single, consistent digital format. The NIH is committed to maintaining and enhancing the existing PMC infrastructure to achieve the agency's goals.

Some questioned if additional support will be provided to investigators to cover potential increases in publication costs. The NIH awards direct costs to many investigators who request publication costs in their proposed budgets. The NIH estimates that it pays over $30 million annually in direct costs for publication and other page charges in grants to its investigators. Generally, page charges for publications in professional journals are allowable, if the published paper reports work supported by the grant and the charges are levied impartially on all papers published by the journal, whether or not they are submitted by government-sponsored authors. As with all other costs, NIH expects its investigators to be careful stewards of Federal funds and to manage these resources appropriately. Grantees may rebudget funds to support these costs, but NIH will consider all other options to ensure that budgets are not affected unduly which should be achievable given the voluntary nature of this request.

M. PMC's Capacity and Functionality

Comments supporting the proposed policy noted that online access was desirable because it was centralized, cheaper than accessing a print version, and easier to access. Some comments expressed limited confidence in PMC's ability to keep pace with the current volume of publications, or to handle a large influx of additional manuscripts. Several comments requested that PMC add more functionality to address the increased amount of content.

NLM's National Center for Biotechnology Information supports many large production services, including GenBank, PubMed, and PMC, handling over 3 million queries daily from more than 1.2 million unique users. Since PMC went live in 2000, there have been no delays for any active production PMC journal due to production lags or technical problems at PMC. In addition to incorporating content provided by publishers, the PMC back-scanning project has generated and tagged electronic versions of more than 200,000 printed articles in the last year. The roughly 60,000 manuscripts a year for the new NIH Policy will be tagged in a similar manner and incorporated into PMC using a single, consistent digital format.

A commercial service monitors PMC's Web site performance and reliability. Based on over 22,000 measurements in a recent two-week period, articles were successfully returned for 98.5 percent of the requests to PMC. This compared during the same two-week period to a 92 percent average success rate for 40 of the largest commercial Web sites monitored by the same service. The average response time to download a PMC article has been 2.8 seconds.

Another key advantage of PMC is that the articles returned by a PMC search are automatically linked to a variety of research-related resources in other NLM databases, such as DNA and protein sequences, protein structures, clinical trials, small molecules (PubChem), and taxonomy. These databases also provide linkage to a broad collection of other biological and health-related information resources. Investigators applying for new and competing renewal support from the NIH can also utilize this resource by providing links in the applications to their PMC-archived information.

N. Domestic and International Coordination

A number of commenters urged the NIH to coordinate with other scientific agencies in the United States and internationally, while others countered that providing unrestricted access to non-U.S. individuals would represent a subsidization of scientific knowledge outside the United States that disadvantages American scientists.

We believe that American scientists and global health will benefit from greater access to research publications leading to increased collaborative efforts worldwide. In an increasingly interdependent world, the United States and nations around the globe not only share the risk of diseases, but also the challenge to respond. This can best be accomplished in an environment in which rapid communication is possible, wherein scientific knowledge is readily available to all, and where research is conducted based on partnership. This environment will also foster continued U.S. leadership in science.

O. Timing of the Policy's Implementation

Many commenters sought to delay the Policy's implementation, expressing strong concerns that the proposed policy had not been adequately analyzed for short- and long-term impacts. Commenters called for more dialogue and consideration. Others called for more formal studies before Policy implementation.

The request for investigators to submit the authors' final manuscripts to PMC is not a requirement. The NIH instead is providing guidance to conform to a long-standing NIH policy that the results and accomplishments of NIH-funded research activities should be made available to the public. The Policy encourages voluntary cooperation of investigators, and it does not penalize investigators who choose not to use PMC to submit pre-print hard copy versions of their manuscripts as part of their progress reporting requirements.

Timely implementation of the Policy will allow NIH to manage more efficiently and to understand better its research portfolio, monitor scientific productivity, and ultimately, help set research priorities. Also, because many commenters highlighted the public's desire for enhanced access to scientific publications in a timely manner, NIH is confident that this Policy will not only advance science but will benefit the scientific community, the public, and the NIH.

This Policy is subject to periodic review based upon lessons learned in the course of its implementation. Issuance of this Policy is the beginning of a process that will include refinement as experience develops, outcomes are evaluated, and public dialogue among all the stakeholders is continued.

A NIH Public Access Advisory Working Group of the NLM Board of Regents [12] will be established. The Working Group will be composed of stakeholders that will advise NIH/NLM on implementation and assess progress in meeting the goals of the NIH Public Access Policy. Once the system is operational, modifications and enhancements will be made as needed with the Working Group, or a permanent subcommittee of the Board, providing ongoing advice on improvements.

P. Legal Issues

NIH received several comments and objections of a legal nature.

1. *Request vs. Required:* Some commenters argued that the proposal is mandatory, even though the proposal requests, rather than requires, submission of final manuscripts to NIH. As evidence, they note that NIH plans to monitor submissions as part of the grants close-out process and that the proposal states that the submission will fulfill the current requirement to submit one copy of each publication in the annual or final progress reports. One commenter also asserted that reading the proposal as a requirement would be consistent with House Appropriations

Committee Report language in H.R. Rep. No. 108–636.

The final Policy reiterates that submission of the electronic final manuscript is voluntary and that it can serve as an alternate means for meeting current progress reporting requirements as well as application and close-out submissions in the future. The monitoring referred to in the proposed policy referred to determining whether the final manuscripts had already been submitted electronically. We have removed that language from the final Policy to avoid any confusion. The House Appropriations Report did propose requiring submission; however, the NIH Policy requesting, rather than requiring, submission is consistent with the final report language found on page 1177 of the Joint Explanatory Statement in H.R. Rep. No. 108–792.[13]

2. *Copyright:* NIH received comments that the proposal infringes on copyright interests of Federal grantees. These commenters argued that copyright interests are well-established under Federal law, that NIH has no authority to alter them, and that the proposal is not consistent with controlling Department of Health and Human Services (HHS) regulations. They believe the proposal fails to recognize the need for copyright permission from authors and/or publishers. They argue that neither the principle of fair use, nor the Federal purpose license, can be used by NIH to implement the proposal. Finally, they argue that the PMC open access submission agreement constitutes a forced license and undermines copyright.

The Policy explicitly recognizes and upholds the principles of copyright. First, submission of final manuscripts is voluntary rather than mandatory; the voluntary submission to NIH by authors and institutions under the Policy constitutes permission to post the manuscripts on PMC and release to the public after the submitter's specified post-publication delay time. The fair use exemption to copyright infringement does not apply to the government's request for the manuscripts. It applies to the public use of the manuscripts as posted on PMC and provides a limitation on such use consistent with the terms of that exemption.

NIH does not need to seek permission from journals who may acquire copyrights from authors or institutions because any copyright transfer or assignment is currently subject to the government purpose license pursuant to 45 CFR 74.36. Although the NIH is relying on permission, rather than the government purpose license, as the basis for its Policy, the government purpose license is fully available as a legal authority under which manuscripts could be reproduced, published, or otherwise used for Federal purposes. The comment that the proposal is not consistent with controlling HHS regulations granting copyright is not persuasive, since those same regulations grant the agency its government purpose license.

Finally, authors can indicate what copyright restrictions, if any, apply to their manuscripts when submitting them to PMC and can choose an appropriate PMC submission agreement that recognizes those rights.

3. *Government Purpose Copyright License:* NIH received a comment that the government purpose license of 45 CFR 74.36 cannot be used by the government as a basis to post final manuscripts on PMC.

Although the NIH, at this time, is not relying on the government purpose license, it is an available means for NIH to reproduce, publish or otherwise use copyrighted works resulting from NIH funding for Federal purposes, as well as to authorize others to do so. Arguments put forth and cases cited by the commenter as support for the premise that the government purpose license could not be used as a basis for PMC to post the manuscripts are not persuasive. None of the cases address circumstances where a government agency is acting to fulfill its own statutory purposes with regard to publications resulting from its own research funding. Creation of a publicly accessible, permanent archive of NIH-funded research publications is squarely within the statutory authorities of the NIH and the NLM and clearly constitutes a Federal purpose.[14]

4. *Other Intellectual Property Concerns:* One commenter suggested that the proposed policy undermines other aspects of intellectual property because problems would result if the principle that ''the taxpayers have already paid for the research'' were also applied to patents, pharmaceuticals, and other products of government-funded research.

The NIH Public Access Policy is not based on the principle of delivering a product to the taxpayer in return for research support. The Policy calls for the voluntary submission of final author manuscripts; it does not affect the ability to copyright. Funding recipients may continue to assert copyright in works arising from NIH-funded research, and they may assign these rights to journals as is the current practice. Copyright holders may enforce these copyrights as before. A member of the public viewing or downloading a copyrighted document from PMC is subject to the same rights and restrictions as when copying an article from the library. For example, making a copy of an article for personal use is generally considered to be a ''fair use'' under copyright law. For uses that fall outside of the fair use principle, permission to reproduce copyrighted materials must be obtained directly from the copyright holders. PMC currently includes a copyright notice alerting the public to the rights of copyright holders and will continue to post this notice as it has done in the past.

5. *Bayh-Dole Act:* NIH received a comment that the proposal undercuts the Bayh-Dole Act by interfering with technology transfer, because scientific publications are an important component of technology transfer, and the proposal weakens that component. This commenter also suggested the proposal undermines the Bayh-Dole principle that the private sector is the preferable vehicle to move research to the marketplace.

The NIH Public Access Policy serves to establish a permanent archive of NIH-funded research publications. It is not expected to supersede any private sector publication activity or create competition with publishers. Manuscripts that are submitted by authors will be available to the public through PMC after the time specified by the author post-publication. As such, we do not believe that the Policy will interfere with publications as a technology transfer vehicle, or that it will supersede the private sector as a vehicle to move research to the marketplace.

6. *Patent Application Filing Concerns:* NIH received comments that because final manuscripts as submitted to NIH will be subject to Freedom of Information Act (FOIA) disclosure, they will likely be considered printed publications for purposes of the timing of filing patent applications. Commenters suggested this would be a change from current practice, which relies on the date of journal publication.

The NIH Policy requests authors to submit final manuscripts after the peer review process has been completed. Although each research institution must determine the timing of the filing of any patent applications arising from their NIH-funded work, NIH does not believe that submission to PMC under the Public Access Policy will constitute a printed publication, nor otherwise interfere with the timing of filing of patent applications. The manuscripts will not have the indicia of ''public accessibility'' that are generally relied upon as criteria by which prior art references have been judged. Until the

interested public has access to the document, it would not be considered to be available as a printed publication within the meaning of 35 U.S.C. 102(a) or (b). The primary journal publication constitutes the date of publication for patent filing purposes, as it has traditionally served.

Courts have found it helpful to rely on distribution and indexing as proxies for public accessibility, and one commenter argued that the final manuscripts will be indexed by PMC prior to journal publication. However, even if indexed in preparation for posting, the publication itself will not be available to the public. Once final manuscripts are posted in the archive, indexing and search capabilities will assist user access.

Other aspects of the process of scientific publication do not establish statutory bars to patentability. For example, processes such as oral presentations at scientific meetings and submission of manuscripts and information to peer reviewers or to a journal for review have not been considered to establish a publication date for patent purposes, because these activities have not been considered to result in public availability. Similarly, there is no reason to believe submission to NIH with the expectation of confidentiality until after publication will be treated differently by the U.S. Patent and Trademark Office.

7. *Freedom of Information Act (FOIA):* Some commenters expressed concern that the final manuscripts would be subject to disclosure to the public under FOIA prior to journal publication.

NIH believes the manuscript information is protected from release under FOIA by Exemption 4.[15] In accordance with HHS FOIA regulations, if NIH receives a FOIA request for such a document, it will notify the submitter of the manuscript of the FOIA request in order to provide an opportunity for the manuscript submitter to object to any potential disclosure of the record. If the final publication is requested after the journal publication date but prior to the posting date on PMC, NIH believes that these publications are not agency records subject to FOIA. See 45 CFR 5.5, stating that definition of record for purposes of the HHS FOIA regulation does not include ''books, magazines, pamphlets, or other reference material in formally organized and officially designated HHS libraries where such materials are available under the rules of the particular library.''

8. *Administrative Procedures Act (APA) Rule-Making:* Some have commented that the proposed policy constitutes a rule-making under the Administrative Procedures Act (APA) and that NIH lacks legislative authority to adopt this policy because it is without rule-making power. They also argue that the notice and comment opportunity for the proposal was insufficient to meet rule-making requirements.

NIH agrees that authority to adopt new regulations is retained by the Secretary, Health and Human Services, and has not been delegated to NIH. However, the proposed policy is not a rule-making for which APA notice and comment, and other procedural requirements for final agency actions, attach. The APA defines a rule as the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy describing the organization, procedure, or practice requirements of an agency. 5 U.S.C. 551. Exempt from the formal rule-making requirements of the law are matters relating to agency management* * * and matters concerning interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice. 5 U.S.C. 553.

The Policy does not require investigators to do anything other than what the current rules require. While funding recipients may follow the Policy to fulfill some of their existing reporting requirements they need not do so and may continue to provide hard copies of publications. The Policy will allow the agency to manage better its research award process and will also enable it to advance further its public health mission to support high-quality biomedical, behavioral, and clinical research and improve public health. In order to help it develop the Policy, the agency provided public notice and sought public comment on a draft policy. This notice and comment procedure were not undertaken to comply with the APA rule-making requirements; the agency does not believe that they apply because the Policy is not a rule.

9. *Regulatory Flexibility Act:* Some commenters asserted that the NIH must comply with the Regulatory Flexibility Act before it implements the proposed policy. The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, was enacted to ensure that when adopting regulations, Federal agencies seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public. In particular, in accordance with the RFA, Federal agency regulations should not disproportionately affect small entities. Under the RFA, Federal agencies must determine the impact of their regulations on small entities and consider alternatives to alleviate burdens while achieving the agency's policy goals. By definition, the RFA applies when a Federal agency publishes a general notice of proposed rule-making under 5 U.S.C. 553(b); in other words, it is triggered when an agency engages in rule-making under the APA. As noted above, this Policy is not a rule-making. Accordingly, the RFA does not apply.

10. *Paperwork Reduction Act:* Some commenters suggested that NIH must comply with the Paperwork Reduction Act (PRA) and cannot penalize investigators until Office of Management and Budget (OMB) clearance under the law is completed.

The PRA requires OMB review before an agency undertakes a collection of information, regardless of whether the collection is mandatory or voluntary. Under the regulations implementing the law, a collection of information includes obtaining...information by or for an agency by means of * * * identical reporting * * * or disclosure requirements imposed on ten or more people or entities in any given year. 5 CFR 1320.3. While the request to provide copies of manuscripts or publications may not fall within this definition, even if the definition is met, we need not obtain any new OMB clearance because the Policy falls within the existing, approved information collection activities concerning applications, progress and final reporting, (OMB NO. 0925–0001, Expires 9/2007 and 0925–0002, Expires 6/2005). Furthermore, while some commenters focused their PRA criticism on the fact that the agency would be unable to penalize investigators if PRA review is not conducted, we note that the Policy serves as an alternative to compliance with existing reporting activities and, therefore, a discussion of any new penalties is misplaced.

The PRA also requires that agencies ensure the public has timely and equitable access to agency public information. The final manuscripts will be submitted under confidentiality agreements and will be posted on PMC only with the permission of submitting authors. Therefore, NIH does not believe that the final manuscripts submitted by authors constitute agency public information within the meaning of the PRA until the terms of the confidentiality agreement are met and an author permits posting on PMC. At that time, NIH expects to ensure timely and equitable access. As discussed above, submission is not expected to constitute a publication for purposes of

filing patent applications, nor are the documents expected to be available to the public under FOIA. Thus, the absence of public availability prior to author permission does not constitute an improperly restrictive agency arrangement.

11. OMB Circular A–76: Some commenters argued that the agency must undertake a cost-comparison under OMB Circular A–76 to determine that the cost of the plan is less expensive than the cost of the present system of scientific publishing before implementing the Policy.

This criticism is based on the assumption, in the words of one commenter, that NIH wants PMC to become an in-house electronic publisher of these final manuscripts. This conclusion misstates the Policy and NIH's goals. The NIH Policy is to maintain copies of final manuscripts in a permanent, public archive so that the published results of NIH-funded research are permanently and readily accessible to NIH and others. This archive will be contained in the NIH's existing, electronic archive for scientific publications, PMC. The PMC archive has provided this service for the agency and others when articles are voluntarily provided to it. Electronic copies of publications are available through PMC in the same way that hard copies of publications are available from the NIH's National Library of Medicine.

The NIH Policy does not create any new obligations under OMB Circular A–76. Insofar as the activities of PMC are subject to the requirements of the Circular and related laws, those activities will continue to be reviewed and all applicable requirements will be met.

The NIH Public Access Policy is to establish a permanent archive of NIH-funded research publications. It is not expected to supersede any private sector publication activity or create competition with publishers.

12. *Constitutional concerns/Executive Order (E.O.) 12630:* One commenter suggested that the proposal implicates Executive Order 12630, which requires government officials to review actions that may have takings implications and to be sensitive to, anticipate, and account for, the obligations imposed by the Just Compensation Clause of the Fifth Amendment in planning out and carrying out governmental actions .* * *

The purpose of E.O. 12630 is to ensure that government officials do not unintentionally exercise the government's power of eminent domain, resulting in an unanticipated or undue drain on the government treasury. NIH believes that its Policy is consistent with E.O. 12630 and that no additional review is required. The private property at issue is the funding recipient's ability to assert copyright pursuant to 45 CFR 74.36. The NIH Policy does not interfere with that right, as authors and institutions will be voluntarily submitting copies of final manuscripts to NIH, and copyright may be asserted and enforced as it has been traditionally. Further, the same regulation that allows the funding recipient to assert copyright grants the government corresponding rights to reproduce, publish, or otherwise use the work for Federal purposes and to authorize others to do so. A voluntary request for the same use already allowed to the government by regulation is consistent with E.O. 12630 and does not trigger additional review.

13. *Information Quality Act:* One commenter asked whether the Federal Information Quality Act (IQA), 44 U.S.C. 3516 note, applies to documents contained in the electronic archive of publications created through the NIH Public Access Policy.

The NIH Public Access Policy calls for the centralized storage of NIH-funded scientific publications in PMC, an electronic archive of scientific publications operated by the National Library of Medicine. The NIH will include in its electronic archive a statement explaining that the views contained in the archived publications and manuscripts are those of the authors, and do not necessarily reflect the views of the government. Thus, publication in PMC does not make an article/scientific manuscript subject to the NIH Information Quality Guidelines.

III. Text of Final Policy Statement

The NIH Public Access Policy (the Policy) on enhancing public access to archived publications resulting from NIH-funded research follows:

Beginning May 2, 2005, NIH-funded investigators are requested to submit an electronic version of the author's final manuscript upon acceptance for publication, resulting from research supported, in whole or in part, with direct costs from NIH. The author's final manuscript is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process.

This Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies. The Policy applies to peer-reviewed research publications, resulting from research supported in whole or in part with direct costs from NIH, but it does not apply to book chapters, editorials, reviews, or conference proceedings.

Under this Policy, electronic submission will be made directly to the NIH National Library of Medicine's (NLM) PubMed Central (PMC): *http://www.pubmedcentral.nih.gov*. PMC is the NIH digital repository of full-text, peer-reviewed biomedical, behavioral, and clinical research journals. It is a publicly-accessible, stable, permanent, and searchable electronic archive.

At the time of submission, the author will specify the timing of the posting of his or her final manuscript for public accessibility through PMC. Posting for public accessibility through PMC is requested and strongly encouraged as soon as possible (and within twelve months of the publisher's official date of final publication).

The publisher may choose to furnish PMC with the publisher's final version, which will supersede the author's final version. Also, if the publisher agrees, public access to the publisher's final version in PMC can occur sooner than the timing originally specified by the author for the author's final version.

Effective with progress reports submitted for Fiscal Year 2006 funding, this Policy provides an alternative means, via PMC, for NIH-supported investigators to fulfill the existing requirement to provide publications as part of progress reports. Though the NIH anticipates that investigators will use this opportunity to submit their manuscripts, sending electronic copies is voluntary and will not be a factor in the review of scientific progress.

By creating an archive of peer-reviewed, NIH-funded research publications, NIH is helping health care providers, educators, and scientists to more readily exchange research results and the public to have greater access to health-related research publications. As the archive grows, the public will be more readily able to access an increasing number of these publications.

Once the system is operational, modifications and enhancements will be made as needed. An NIH Public Access Advisory Working Group will be established to advise NIH/NLM on implementation and assess progress in meeting the goals of the NIH Public Access Policy.

This Policy is intended to improve the internal management of the Federal government, and is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, its officers, or any person.

Additional details for the public and for submitting authors pertaining to the implementation of this Policy are available at: *http://www.nih.gov/about/publicaccess/index.htm*.

Footnotes

[1] Costs that can be specifically identified with a particular project or activity. NIH Grants Policy Statement, Rev. 12/2003; *http://grants.nih.gov/grants/policy/nihgpslowbar;2003/NIHGPS_Part2.htm#_Toc54600040*.

[2] NIH Grants Policy Statement, Rev. 12/2003; *http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part7.htm*.

[3] These figures are derived from searching the PubMed database for citations with 2003 publication dates that include a reference to a specific NIH grant number. The data provide useful estimates of articles funded by NIH, although individual journal counts may vary slightly if calculations are performed using other sources or search strategies.

[4] PubMed includes links to full-text articles in PMC and to several thousand journal websites. PMC is an electronic archive for full-text journal articles, offering unrestricted access to its contents. Every full-text article in PMC has a corresponding entry in PubMed.

[5] Internet Health Resources, Pew Internet and American Life Project, Washington, DC 2003: *http://www.pewinternet.org/pdfs/PIP_Healthlowbar;Report_July_2003.pdf*.

[6] Cybercitizen Health 3.0 Survey, Table 10 (Manhattan Research, New York, 2003).

[7] These data are derived from searching the PubMed database for citations with 2003 publication dates that acknowledge funding from either NIH specifically or from an agency of the Public Health Service (PHS). Because some journal citations do not include a reference to the specific NIH grant number, a broader search was done for citations where the Public Health Service (PHS) is identified as the sponsor of the research. These data provide useful estimates of articles funded by NIH/PHS, although individual journal counts may vary slightly if calculations are based on other sources.

[8] The estimated $30 million is a conservative figure based on amounts spent on page charges and other publication costs on a sample of R01 grant application budgets, scaled up to provide an estimate of direct costs paid on all research grants.

[9] Established pursuant to 42 U.S.C. 286a, section 466 of the Public Health Service Act, as amended. The Board is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

[10] *http://opcit.eprints.org/oacitation-biblio.html*.

[11] *http://romeo.eprints.org/stats.php*.

[12] Established pursuant to 42 U.S.C. 286a, section 466 of the Public Health Service Act, as amended. The Board is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

[13] *http://thomas.loc.gov/home/omni2005/index.htm*.

[14] See, e.g., 42 U.S.C. 241(a)(1); 42 U.S.C. 286.

[15] HHS FOIA Regulations, 45 CFR 5.65(b); available at: *http://www.hhs.gov/foia/45cfr5.html#Subf*.

Notice Number: NOT–OD–08–033—(See Notice NOT–OD–08–057).

Key Dates

Release Date: January 11, 2008.
Effective Date: April 7, 2008.

Issued By

National Institutes of Health (NIH), (*http://www.nih.gov/*) .

Department of Health and Human Services Action

Notice; Revised Policy Statement.

Summary

In accordance with Division G, Title II, section 218 of Public Law 110–161 (Consolidated Appropriations Act, 2008), the NIH voluntary Public Access Policy (*NOT–OD–05–022*) is now mandatory. The law states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

Specifics

1. The NIH Public Access Policy applies to all peer-reviewed articles that arise, in whole or in part, from direct costs 1 funded by NIH, or from NIH staff, that are accepted for publication on or after April 7, 2008.

2. Institutions and investigators are responsible for ensuring that any publishing or copyright agreements concerning submitted articles fully comply with this Policy.

3. PubMed Central (PMC) is the NIH digital archive of full-text, peer-reviewed journal articles. Its content is publicly accessible and integrated with other databases (see: *http://www.pubmedcentral.nih.gov/*).

4. The final, peer-reviewed manuscript includes all graphics and supplemental materials that are associated with the article.

5. Beginning May 25, 2008, anyone submitting an application, proposal or progress report to the NIH must include the PMC or NIH Manuscript Submission reference number when citing applicable articles that arise from their NIH funded research. This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

Compliance

Compliance with this Policy is a statutory requirement and a term and condition of the grant award and cooperative agreement, in accordance with the *NIH Grants Policy Statement* For contracts, NIH includes this requirement in all R&D solicitations and awards under Section H, Special Contract Requirements, in accordance with the Uniform Contract Format.

Inquiries

Send questions concerning this Notice or other aspects of the NIH Public Access Policy to: Office of Extramural Research, National Institutes of Health, 1 Center Drive, Room 144, Bethesda, MD 20892–0152, E-mail: *PublicAccess@nih.gov*, Web site: *http://publicaccess.nih.gov*.

[1] Costs that can be specifically identified with a particular project or activity. NIH Grants Policy Statement, Rev. 12/2003; *http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm#_Toc54600040*.

Public Access Frequently Asked Questions

Posted: January 11, 2008

General Information

A. General Information

1. *What is the NIH Public Access Policy?*
2. *What is PubMed Central?*
3. *Where can I get information about a medical or health related topic?*

For Investigators, Awardees, and NIH Staff

B. Scope of the Policy

1. *Does the NIH Public Access Policy apply to me?*
2. *To what types of articles does the NIH Public Access Policy apply?*
3. *My article is based on research only partially funded by NIH. Is the article required to be submitted?*
4. *My article is based on research funded by a grant or cooperative agreement that expired before Fiscal Year 2008. Is the article required to be submitted?*
5. *My article is based on research funded by a contract awarded before April 7, 2008. Is the article required to be submitted?*
6. *Can I submit articles accepted for publication prior to April 7, 2008?*
7. *Am I responsible for articles that arise from my NIH funded project for which I am not an author?*
8. *Is the NIH Public Access Policy a condition of award?*
9. *Will compliance with the NIH Public Access Policy affect the outcome of the application review?*

C. How to Comply With the Policy

1. *What do I have to do to comply with the NIH Public Access Policy?*
2. *Whose approval do I need to submit my article to PubMed Central?*
3. *Can NIH provide language that could be used in a copyright agreement between an author or institution and a publisher?*
4. *A publisher says that an NIH-funded article cannot be deposited under the NIH Public Access Policy. What should I do?*
5. *What is the difference between a final peer-reviewed manuscript and final published article?*
6. *How do I include the PubMed Central reference number in my citations?*

D. What Needs to Be Submitted

1. *The journal that published my work routinely deposits its articles in PubMed Central. Do I have to submit my article myself?*
2. *I plan to publish in an open access journal. Do I have to submit my article?*
3. *My article is already listed in PubMed. Do I have to submit my article?*
4. *My article is available on the publisher's web site. Do I have to submit my article?*

E. How to Submit Articles to NIH/PubMed Central

1. *How do I submit an article to NIH/PubMed Central?*
2. *What is the relationship between PubMed Central and the NIH Manuscript Submission system?*
3. *Will NIH pay for publication costs?*
4. *My article has multiple authors and/or is funded from multiple NIH sources. Who should submit the article?*

Policy Background

F. Policy Background

1. *Can authors and publishers continue to assert copyright in scientific publications resulting from NIH funding?*
2. *What is the difference between the NIH Public Access Policy and Open Access?*
3. *How does the NIH Public Access Policy differ from the 2003 NIH Data Sharing Policy?*
4. *How many publications arise from NIH funds each year?*

A. General Information

1. What is the NIH Public Access Policy?

The Policy implements Division G, Title II, section 218 of Public Law 110–161 (Consolidated Appropriations Act, 2008) which states:

SEC. 218. The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

The Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit journal articles that arise from NIH funds to the digital archive PubMed Central (*http://www.pubmedcentral.nih.gov/*). The Policy requires that these articles be accessible to the public on PubMed Central to help advance science and improve human health.

2. What is PubMed Central?

PubMed Central is an archive of full-text biomedical journal articles available online without a fee. Articles on PubMed Central contain links to other scientific databases such as GenBank (*http://www.ncbi.nlm.nih.gov/Genbank/*) and PubChem (*http://pubchem.ncbi.nlm.nih.gov/*). Articles collected under the Public Access Policy are archived on PubMed Central. More information about PubMed Central is available at *http://www.pubmedcentral.nih.gov/about/faq.html.*

3. Where can I get information about a medical or health related topic?

NIH provides information on health topics at http://health.nih.gov/.

B. Scope of the Policy

1. Does the NIH Public Access Policy apply to me?

The Policy applies to you if your peer-reviewed article is based on work in one or more of the following categories:

1. Directly [1] funded by an NIH grant or cooperative agreement active in Fiscal Year 2008 (October 1, 2007–September 30, 2008) or beyond;

2. Directly [1] funded by a contract signed on or after April 7, 2008;

3. Directly funded by the NIH Intramural Program.

4. If NIH pays your salary.

2. To what types of articles does the NIH Public Access Policy apply?

The Policy applies to all peer-reviewed journal articles, including research reports and reviews. The Policy does not apply to non-peer-reviewed materials such as correspondence, book chapters, and editorials.

3. My article is based on research only partially funded by NIH. Is the article required to be submitted?

Yes. The NIH Public Access Policy applies to all peer-reviewed journal articles that arise from the NIH intramural program or any amount of direct costs1 funded by NIH, regardless of the source or amount of other funding.

4. My article is based on research funded by a grant or cooperative agreement that expired before Fiscal Year 2008. Is the article required to be submitted?

No, submission is not required. But you may submit your article if you want to and have appropriate copyright permission.

5. My article is based on research funded by a contract awarded before April 7, 2008. Is the article required to be submitted?

No, submission is not required. But you may submit your article if you want to and have appropriate copyright permission.

6. Can I submit articles accepted for publication prior to April 7, 2008?

Yes. You may submit your article if you want to and have appropriate copyright permission.

7. Am I responsible for articles that arise from my NIH funded project for which I am not an author?

Principal Investigators and their Institutions are responsible for ensuring all terms and conditions of awards are met. This includes the submission of articles that arise directly from their awards, even if they are not an author or co-author of the publication. Principal Investigators and their Institutions should ensure that the authors are aware of and comply with the NIH Public Access Policy.

8. Is the NIH Public Access Policy a condition of award?

The NIH Public Access Policy is a Term and Condition of Award for all grants and cooperative agreements active in Fiscal Year 2008 (October 1, 2007–September 30, 2008) or beyond, and for all contracts awarded after April 7, 2008.

9. Will compliance with the NIH Public Access Policy affect the outcome of the application review?

Compliance with the Public Access Policy is not a factor in the evaluation of grant applications. Non-compliance will be addressed administratively, and may delay or prevent awarding of funds.

C. How to Comply With the Policy

1. What do I have to do to comply with the NIH Public Access Policy?

Compliance is a three-step process.

(1) Address Copyright. Before you sign a publication agreement or similar copyright transfer agreement, make sure that the agreement allows the article to be submitted to NIH in accordance with the Public Access Policy. *See FAQ on approval for submitting articles.*

(2) Submit the article to NIH. This can be done in a number of ways:

a. You or someone in your organization (e.g., an assistant or your library) may deposit a copy of the peer reviewed manuscript in the NIH Manuscript Submission (NIHMS) system (*http://www.nihms.nih.gov/*).

b. Your publisher may send the peer-reviewed manuscript files to the NIH Manuscript Submission system for you.

In both cases above (a and b), you still will have to verify and approve the manuscript personally via the NIH Manuscript Submission system, which will send you an email message requesting this action. *See FAQ on using NIHMS.*

c. Some publishers have agreed to make the final published article of every NIH-funded article publicly available in PubMed Central within 12 months of publication (*see FAQ on journals that deposit articles*). For these journals, you do not need to do anything to fulfill the submission requirement of the NIH Public Access Policy. See *http://publicaccess.nih.gov/submit_process_journals.htm* for a list of these journals.

3) Cite. As of May 25, 2008, when citing an article in NIH applications, proposals, and progress reports that falls under the Policy, and was authored or co-authored by you or arose from your NIH award, you must include the PubMed Central reference number (PMCID). This policy includes applications submitted to the NIH for the May 25, 2008 due date and subsequent due dates.

Intramural researchers must ensure a PubMed Central reference number is included in the Institute's Annual Report for any publication they have authored or co-authored. *See FAQ on how to cite articles.*

2. Whose approval do I need to submit my article to PubMed Central?

Authors own the original copyrights to materials they write. Consistent with individual arrangements with authors' employing institutions, authors often transfer some or all of these rights to the publisher when the journal agrees to publish their article. Some publishers may ask authors to transfer copyrights for a manuscript when it is first submitted to a journal for review.

Authors should work with the publisher before any rights are transferred to ensure that all conditions of the NIH Public Access Policy can be met. Authors should avoid signing any agreements with publishers that do not allow the author to comply with the NIH Public Access Policy.

Federal employees always may submit their final peer-reviewed manuscript to PubMed Central, because government works are not subject to copyright protection in the United States.

3. Can NIH provide language that could be used in a copyright agreement between an author or institution and a publisher?

NIH can provide an example. Individual copyright arrangements can take many forms, and authors and their institutions should continue to manage such arrangements as they have in the past. However, in order to comply with the NIH Public Access Policy, you must make sure that the agreement allows the accepted peer-reviewed manuscript to be deposited with the NIH upon acceptance of publication and made available for public posting on PubMed Central no later than 12 months after journal publication.

Institutions and investigators may wish to develop particular copyright agreement terms in consultation with their own legal counsel or other applicable official at their institution, as appropriate. As an example, the kind of language that an author or institution might add to a copyright agreement includes the following:

''Journal acknowledges that Author retains the right to provide a copy of the final manuscript to the NIH upon acceptance for Journal publication, for public archiving in PubMed Central as soon as possible but no later than 12 months after publication by Journal.''

Your institution or professional society may have developed specific model language for this purpose, as well.

4. A publisher says that an NIH-funded article cannot be deposited under the NIH Public Access Policy. What should I do?

Publishers may ask authors to transfer copyrights for a manuscript when it is first submitted to a journal for review, and/or at the time it is accepted for publication. Authors should work with the publisher before any rights are transferred, to ensure that all conditions of the NIH Public Access Policy can be met. You should check with your institutional official, who may wish to consult with your institution's legal counsel, to determine how the copyright transfer agreement that the publisher proposes you sign impacts your ability to comply with the Policy.

5. What is the difference between a final peer-reviewed manuscript and final published article?

Final peer-reviewed manuscript: The Investigator's final manuscript of a peer-reviewed article accepted for journal publication, including all modifications from the peer review process.

Final published article: The journal's authoritative copy of the article, including all modifications from the publishing peer review process, copyediting and stylistic edits, and formatting changes.

6. How do I include the PubMed Central reference number in my citations?

List the PubMed Central reference number (PMCID) at the end of the already-required full journal citation for the article. If a PubMed Central reference number is not yet available, include the NIH Manuscript Submission system reference number (NIHMS ID) instead.

Examples:

Varmus H, Klausner R, Zerhouni E, Acharya T, Daar A, Singer P. 2003. PUBLIC HEALTH: Grand Challenges in Global Health. Science 302(5644): 398–399. PMCID: 243493

Zerhouni, EA. (2003) A New Vision for the National Institutes of Health. *Journal of Biomedicine and Biotechnology* (3), 159–160. PMCID: 400215

D. What Needs To Be Submitted?

1. The journal that published my work routinely deposits its articles in PubMed Central. Do I have to submit my article myself?

It depends on which version of the article the journal is depositing—the final published article or the final peer reviewed manuscript—and on the terms of any agreement that the journal may have with NIH. There are three possible cases, described below. In the first case you do not have to take any action. In the other two, you do have to take certain actions.

(a) Journal deposits final published article and makes it available within 12 months: If your journal deposits the final published article in PubMed Central and allows NIH to make it available to the public within 12 months of publication, you do not have to do anything to fulfill the submission requirement of the NIH Public Access Policy.

(b) Journal deposits final published article but does not make it available within 12 months: If the journal deposits the final published article in PubMed Central, but delays its release to the public for more than 12 months after publication, you will have to deposit a copy of your manuscript yourself.

(c) Journal deposits final peer-reviewed manuscript: If the journal is only depositing a copy of your final peer-reviewed manuscript files via the NIH Manuscript Submission system, you will still have to sign on to the NIH Manuscript Submission system *(http://www.nihms.nih.gov/)* to review and approve release of the article to PubMed Central. *Also see FAQ on submit an article to NIH/ PubMed Central.*

Check *http://publicaccess.nih.gov/submit_process_journals.htm* for a list of the journals that deposit the final published article in PMC with an embargo of 12 months or less, relieving you of the need to do anything further.

2. I plan to publish in an open access journal. Do I have to submit my article?

Yes, unless the journal has an agreement to deposit its articles in PubMed Central. Not all open-access journals have agreements with PubMed Central. Check (*http://publicaccess.nih.gov/submit_process_journals.htm*) to see which journals do.

3. My article is already listed in PubMed. Do I have to submit my article?

Yes, you must submit the article to PubMed Central. PubMed includes only citations and abstracts of articles, while PubMed Central carries the entire article.

4. My article is available on the publisher's Web site. Do I have to submit my article?

Yes, you must submit the article to PubMed Central. Articles available through publishers' Web sites do not fulfill the authors' obligations under the NIH Public Access Policy.

E. How To Submit Articles to PubMed Central

1. How do I submit an article to NIH/ PubMed Central?

You must use the NIH Manuscript Submission (NIHMS) system to submit an article.

You deposit the manuscript files (e.g., Microsoft Word document and figures) in the NIHMS.

You indicate the NIH award(s) to which the article is related.

After the NIHMS converts your deposited files to a standard PubMed Central (PMC) format, NIHMS will email you to review the PMC formatted article to approve its release.

Some journals will deposit the manuscript files for you. In that case, you still have to provide the associated award information, and review and approve the article. The NIHMS will notify you via e-mail when these actions are needed and include a link to the NIHMS web site.

For more information about the NIHMS, go to *http://www.nihms.nih.gov/.* There is an online tutorial at *http://www.nihms.nih.gov/web-help/index.html.*

2. What is the relationship between PubMed Central and the NIH Manuscript Submission system?

PubMed Central (PMC) is NIH's digital journal archive, which gives the public access to its articles at no cost.

The NIH Manuscript Submission system (NIHMS) takes in manuscripts covered by the NIH Public Access Policy and formats them for inclusion into PMC. You deposit the files for a manuscript (e.g., Microsoft Word document and figures) into the NIHMS. The files are converted to a standard PMC format, and then reviewed by you to confirm that the converted article is faithful to the original. The NIHMS transfers the article to PMC when it is ready to be made available publicly.

3. Will NIH pay for publication costs?

Yes. The NIH will reimburse publication costs, including author fees, for grants and contracts on three conditions: (1) Such costs incurred are actual, allowable, and reasonable to advance the objectives of the award; (2) costs are charged consistently regardless of the source of support; (3) all other applicable rules on allowability of costs are met.

4. My article has multiple authors and/ or is funded from multiple NIH sources. Who should submit the article?

Any author may submit the article, but each Principal Investigator and Institution is responsible for ensuring that the terms and conditions of their award are met. An article need only be submitted once to the NIH Manuscript Submission system. Authors will be notified during the submission process if they try to submit an article that has already been submitted.

Articles can be assigned multiple NIH award numbers during submission. They can also be linked to an award electronically via the Commons when completing an electronic Progress Report, or listed as arising from any NIH award in writing when submitting an application, proposal or progress report.

F. Policy Background

1. Can authors and publishers continue to assert copyright in scientific publications resulting from NIH funding?

Yes. The NIH Public Access Policy does not affect the ability of the author, the author's institution, or the publisher to assert ownership in the work's copyright. Authors, consistent with their employment arrangements, may assign these rights to journals (as is the current practice), subject to the limited right that must be retained by the funding recipient to post the works in accordance with the Policy, or the provision that the journal submits the works in accordance with the Policy on the author's behalf.

2. What is the difference between the NIH Public Access Policy and Open Access?

The Public Access Policy ensures that the public has access to the peer reviewed and published results of all NIH funded research through PubMed Central (PMC). United States and/or foreign copyright laws protect most of the articles in PMC; PMC provides access to them at no cost, much like a library does, under the principles of Fair Use.

Generally, Open Access involves the use of a copyrighted document under a Creative Commons or similar license-type agreement that allows more liberal use (including redistribution) than the traditional principles of Fair Use. Only a subset of the articles in PMC are available under such Open Access provisions. See the PMC Copyright page, *http://www.pubmedcentral.nih.gov/about/copyright.html,* for more information.

3. How does the NIH Public Access Policy differ from the 2003 NIH Data Sharing Policy?

The NIH Public Access Policy covers only peer-reviewed articles arising from NIH funds. The 2003 NIH policy on data sharing applies to certain NIH-funded research and is not focused on access to peer-reviewed articles. The 2003 NIH policy on data sharing is available at *http://grants.nih.gov/grants/policy/data_sharing/.*

4. How many publications arise from NIH funds each year?

We estimate that there are approximately 80,000 articles published each year that arise from NIH funds.

1. Costs that can be specifically identified with a particular project or

activity. NIH Grants Policy Statement, Rev. 12/2003; *http://grants.nih.gov/grants/policy/nihgps_2003/NIHGPS_Part2.htm#_Toc54600040*

Dated: March 25, 2008.

Sally J. Rockey,

Deputy Director, Office of Extramural Research, National Institutes of Health.

[FR Doc. E8–6579 Filed 3–28–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

Agency Information Collection Activities: Form I–508, Extension of a Currently Approved Information Collection; Comment Request

ACTION: 60-Day Notice of Information Collection Under Review: Form I–508, Waiver of Rights, Privileges, Exemptions and Immunities; OMB Control No. 1615–0025.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection is published to obtain comments from the public and affected agencies. Comments are encouraged and will be accepted for sixty days until May 30, 2008.

Written comments and suggestions regarding items contained in this notice, and especially with regard to the estimated public burden and associated response time should be directed to the Department of Homeland Security (DHS), USCIS, Chief, Regulatory Management Division, Clearance Office, 111 Massachusetts Avenue, NW., Suite 3008, Washington, DC 20529. Comments may also be submitted to DHS via facsimile to 202–272–8352, or via e-mail at *rfs.regs@dhs.gov.* When submitting comments by email please add the OMB Control Number 1615–0025 in the subject box.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate 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;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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:* Waiver of Rights, Privileges, Exemptions, and Immunities.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form I–508. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. This form is used by the USCIS to determine eligibility of an applicant to retain the status of an alien lawfully admitted to the United States for permanent residence.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,800 responses at 5 minutes (.083) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 149 annual burden hours.

If you have additional comments, suggestions, or need a copy of the information collection instrument, please visit the USCIS Web site at : *http://www.regulations.gov/.*

We may also be contacted at: USCIS, Regulatory Management Division, 111 Massachusetts Avenue, NW., Suite 3008, Washington, DC 20529, telephone number 202–272–8377.

Dated: March 24, 2008.

Stephen Tarragon,

Acting Chief, Regulatory Management Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. E8–6570 Filed 3–28–08; 8:45 am]

BILLING CODE 4410–10–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of Federal Housing Enterprise Oversight

Examination Guidance

AGENCY: Office of Federal Housing Enterprise Oversight, HUD.

ACTION: Notice of Final Examination Guidance—Conforming Loan Limit Calculations; Response to Comments.

SUMMARY: The Office of Federal Housing Enterprise Oversight is publishing today an Examination Guidance, ''Conforming Loan Limit Calculations,'' following two requests for public comment on a proposed examination guidance. Material in the guidance does not constitute a regulation.

DATES: March 31, 2008.

FOR FURTHER INFORMATION CONTACT: If you have any questions regarding OFHEO's Examination Guidance—Conforming Loan Limit Calculations, you may contact Alfred M. Pollard, General Counsel, at (202) 414–3800 (not a toll free number). The telephone number for the Telecommunications Device for the Deaf is: (800) 877–8339 (TDD *Only*).

SUPPLEMENTARY INFORMATION: OFHEO's Examination Guidance on Conforming Loan Limit Calculations is posted on the Internet at *http://www.ofheo.gov.* This document, as well as all others mentioned in the preamble can also be accessed on business days between the hours of 10 a.m. and 3 p.m., at the Office of Federal Housing Enterprise Oversight, Fourth Floor, 1700 G Street, NW., Washington, DC 20552. To make an appointment to inspect documents, please call the Office of General Counsel at (202) 414–6924.

I. Background and Statement on the Conforming Loan Limit for 2008

On November 15, 2006, OFHEO announced that any decline in the house price index used to establish the conforming loan limit would not result in a decline in that limit for 2007. OFHEO also committed at that time, to providing updated guidance on how future reductions in the relevant house price index would affect the conforming loan limit.

On June 20, 2007, OFHEO released on its Web site for public comment, a proposed revision to its existing Examination Guidance entitled ''Conforming Loan Limit Calculations'' (the original proposal). Subsequently, on October 22, 2007, OFHEO published in the **Federal Register** for public comment a revised version of that

proposed guidance (the revised proposal). Today, OFHEO is issuing the final Examination Guidance.

II. Comments Received on revised Examination Guidance—Conforming Loan Limit Calculations

Calculations for the conforming loan limit establish the maximum size of loans that Fannie Mae and Freddie Mac may purchase, as provided in their charters. The conforming loan limit is adjusted annually through a calculation of year over year changes to the existing level of home prices based on data from the Federal Housing Finance Board's Monthly Interest Rate Survey (MIRS).

A. *Guidance Proposals.* OFHEO provided for public comment on the proposed examination guidance through OFHEO's Web site on June 20, 2007, and at the end of a thirty day comment period, some 23 comments from 25 organizations (representing over 2 million individuals and businesses) and individual comments were received. OFHEO took these comments into consideration, altered its proposed draft guidance and reissued it for further public comment on October 22, 2007. Central to OFHEO's consideration was assuring clarity in the process of calculating loan limits, providing for smooth market operations and affording certainty to those involved in making and securing mortgages-Fannie Mae and Freddie Mac, mortgage originators, and homebuyers.

The proposed guidances and the guidance made final today elaborate on, revise and supersede an existing guidance—Supervisory Guidance *Conforming Loan Limit Calculations,* SG–04–01 (February 20, 2004) that delineated OFHEO's role in calculating and announcing the conforming loan limit. In 2006, after a decline in housing price numbers, OFHEO announced that, while the conforming loan level had decreased, the resulting decline in the limit would be deferred a year. OFHEO also indicated it would revise and update the existing guidance and address how the decline would be implemented. OFHEO sought comment on all aspects of the guidance, noting certain key provisions addressing (1) whether and how existing conforming loans should be grandfathered; (2) a number of procedural matters, including rounding down announced loan limits to the nearest $100; and (3) needed clarity on treatment of declines in the conforming loan limit. As proposed, the calculated declines of less than one or, alternatively, three percent in the loan limit (currently $417,000) would be deferred. Once cumulative deferrals reached one or, alternatively, three percent, then the total decline would be subtracted one year later from the calculated conforming loan limit after adjusting for any subsequent price increase that had occurred. Additional information on OFHEO's original and revised guidance proposals remain on OFHEO's Web site.

B. *Comments Received.* OFHEO received comments from seven commentators to its Revised Draft Examination Guidance for calculating the conforming loan limit (CLL), proposed on October 22, 2007. Four housing and mortgage industry trade associations commented, specifically, the National Association of Realtors (NAR), the Mortgage Bankers Association of America (MBA), the National Association of Homebuilders (NAHB), and a joint comment letter from the American Bankers Association and America's Community Bankers (ABA/ACB). Jeff Butchko, a private citizen, submitted a comment letter. Both Freddie Mac and Fannie Mae submitted comment letters.

1. *Industry Trade Associations.* The NAHB, the NAR, and the MBA reiterated that OFHEO does not have statutory power to reduce the conforming loan limit. The NAHB, NAR, and the MBA asserted that the draft guidance was bad public policy and introduced a complicated calculation method that would distort markets. Additionally, both the MBA and NAHB repeated concerns that the proposed guidance was a regulation under the Administrative Procedure Act and it must be issued in accordance with the requirements of that Act, whereby the APA promulgation would be subject to judicial review. Central to their argument was that, for operational and other reasons, the conforming loan limit should not decline.

The MBA requested further expansion of the ''grandfathering'' provision due to a decline in the loan limit post-commitment but prior to closing. The NAR, however, stated that despite their statutory authority and public policy concerns, they would support the 3 percent *de minimis* threshold, the deferral of reductions for at least one year, and the grandfathering of mortgages approved under higher conforming loan limits. Both the MBA and NAHB resubmitted their previous comment letters to support their criticism of the draft Guidance.

The ABA/ACB, in a joint comment, expressed support of OFHEO's proposed guidance. They stated that the revised guidance addressed their general concern on ''grandfathering'' issues, and they welcomed the *de minimis* change from one percent to three percent in the revised guidance.

Mr. Jeff Butchko's comment letter (e-mail) stated that the conforming loan limit is too low for many areas of the country and requested that OFHEO raise this limit.

2. *Enterprise Comments.* Fannie Mae offered comments on the grandfather rule, questioning whether language in the draft guidance grandfathering loans that were conforming at origination matched the language in the preamble. They expressed a concern that this difference in language could be disruptive to the market. Fannie Mae further argued that the mechanism to provide for decreases in the conforming loan limit had no long-term significance and ''potential harmful'' short-term effects. They stated that the ''question for OFHEO may be not whether it has statutory authority to enforce a 'negative increase' in the CLL but whether the statute *requires* this result; not whether it *can* reduce the CLL temporarily but whether it *should.*''

Freddie Mac had specific comments to multiple elements of the revised guidance. Freddie Mac recommended that any decrease in the MIRS should be offset against future increases, rather than reducing the CLL. If OFHEO decided to require a *de minimis* threshold for a decrease, the proposed three percent threshold should be raised to five percent. Like Fannie Mae, Freddie Mac recommended that the grandfathering language in the preamble be adopted in the body of the guidance. Finally, Freddie Mac recommended removing the rounding provision altogether. If OFHEO chose to retain the rounding provision, Freddie requested that OFHEO retain its current practice of rounding down to the nearest $50.

The final examination guidance on conforming loan limit calculations, which OFHEO has determined to revise and issue, is set forth below.

OFHEO

Office of Federal Housing Enterprise Oversight

Examination Guidance

Issuance Date: March 31, 2008. Doc. #: EG–08–001
Subject: Conforming Loan Limit Calculations
To: OFHEO Examiners
OFHEO Associate Directors

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I. Introduction

a. Scope

This guidance addresses the annual establishment of the conforming loan limit amount for mortgages purchased by Fannie Mae and Freddie Mac (''the Enterprises'') and OFHEO supervisory procedures related to such activity.

This guidance replaces Supervisory Guidance SG–04–01.

(1) OFHEO Supervisory Authority

OFHEO oversees two housing government sponsored enterprises—Fannie Mae and Freddie Mac—to assure they operate in a safe and sound manner and maintain adequate capital; 12 U.S.C. 4501, 4511, 4513. OFHEO's responsibilities include avoiding situations that would present safety and soundness problems; 12 CFR part 1720, Appendices A and B and 12 CFR part 1777. In addressing areas where such problems could arise, OFHEO has highlighted corporate governance and financial disclosures; 12 CFR parts 1730 and 1710. In its regulation on disclosure, OFHEO noted key areas of concern—access to markets and potential damages to the firms from incurring reputation risk. Therefore, OFHEO has set forth this guidance to ensure that the conforming loan limit is established in a manner consistent with safe and sound operations and with statutory requirements.

For twenty-five years of practice, the Enterprises announced a conforming loan limit. However, in seven of those years adjustments or decisions were made that raised safety and soundness concerns about the annual adjustment to the conforming loan limit. OFHEO believes that the situation may be addressed through appropriate guidance, setting a more regularized process of oversight and control for this matter of national significance. That is the intent of this guidance.

(2) Conforming Loan Limit (CLL)

The Enterprises are authorized by their charters to purchase mortgages up to a specified limit as adjusted annually; 12 U.S.C. 302(b)(2) and 305(a)(2). This limit is referred to as the conforming loan limit (CLL).

The Enterprises make this adjustment based on a survey conducted by the Federal Housing Finance Board (FHFB). The FHFB monthly conducts and publishes the results of a survey of mortgage interest rates, the Monthly Interest Rate Survey (MIRS). Under the Enterprise charters, the change in the national average one-family house price during the twelve-month period ending with the previous October as determined by the FHFB in its survey is the basis for changes to the conforming loan limit. The Enterprises apply the percentage change to the current year's conforming loan limit to establish the next year's limit. This number constitutes part of the determinations of the eligibility of loans for Enterprise purchases.

OFHEO as safety and soundness regulator has responsibility to oversee safe and sound operations and may act to redress violations of law by the Enterprises. In the case of the conforming loan limits, OFHEO determined in 2004, following a problem in technical matters relating to the limits, that a more formalized process for establishing the conforming loan limit was needed.

(3) Background to Conforming Loan Limit Determinations

Since 1981, the Enterprises have adjusted the conforming loan limit as allowed under the Housing and Community Development Act of 1980. During this time frame, two types of occurrences have transpired that raise the need for a more formal process: (1) The Enterprises on some occasions adjusted their loan limits in a manner that was different from the survey results and (2) the Federal Housing Finance Board has made technical changes to its methodology for determining housing prices that the Enterprises have not reflected in their adjustments.

On three occasions prior to 2006, the average house price declined from October to October (in 1989, 1993, and 1994). In November 1989, the Enterprises reduced the 1990 conforming loan limit by $150 from the 1989 level based on a house price decline of 0.07 percent. In November 1993 and November 1994, however, the Enterprises announced that the conforming loan limit would remain constant at $203,150, despite declines in house prices of 2.96 percent in 1993 and 1.46 percent in 1994. After housing prices increased from October 1994 to October 1995, the Enterprises raised the limit for 1996 without any adjustment for the previous declines.

Additionally, in November 1997, the Enterprises took another course, setting a lower number than the adjustment produced. They determined that the 1998 conforming loan limit would increase by only 3.67 percent, even though the percentage change in house prices using FHFB data for 1996–1997 was 8.44 percent. The practical effect of this action was to adjust retroactively for the 1993 and 1994 price declines.

There have been three occasions—in 1992, 1998 and 2003—when the Federal Housing Finance Board made methodological changes to the Monthly Mortgage Interest Rate Survey that required an adjustment to one or both of the reference years, that is, the prior or current year's October calculation (in 1992, 1998, and 2003). In December 1992, the Enterprises determined that the 1993 conforming loan limit would increase 0.42 percent based on adjusted FHFB numbers for October 1991 and October 1992 national average one-family house price. In November 1998, the Enterprises determined that the 1999 conforming mortgage loan limit would increase by 5.66 percent based on an adjusted October 1997 house price survey. Therefore, in 1992 and again in 1998, the Enterprises used the adjusted national average one-family house price(s) provided by the FHFB.

In 2003, however, the Enterprises adopted a conforming loan limit that disregarded communications from the FHFB staff regarding a change in the methodology for estimating house prices. The Enterprises determined that the 2004 conforming loan limit would increase by 3.41 percent based on unadjusted national average house prices for October 2002 and October 2003. However, FHFB staff had indicated that the October 2003 national average house price should be adjusted downward by $1,647, resulting in a net increase of 2.71 percent.

Due to this inconsistent application of procedures for price declines and methodology changes, OFHEO issued a conforming loan limit guidance in 2004. To clarify elements of the existing guidance and to address the concerns around possible declines in the national average house price average, OFHEO announced in late 2006 that it would issue a new guidance to replace the 2004 issuance.

In 2006, the October national house price average declined by 0.16 percent from the previous October, which by the standard calculation would have reduced the maximum single family conforming loan limit from $417,000 to $416,300. OFHEO had previously indicated, however, that the effect of any decrease in the house price average

would be deferred until the Fall 2007 calculation of the limits for the following year. OFHEO also stated that for the 2008 calculation, the decrease of 0.16 percent would be deducted from any increase in the average house price in the year ended October 2007 or, if the average price decreased, the loan limit would decrease by that 0.16 percent amount. OFHEO subsequently announced that in line with its approach in proposed guidances, the conforming loan limit would not decrease in 2008. Left to be determined was how a further decline in 2008, if it occurred, would be treated and whether any existing loans would be grandfathered. The purpose of this guidance, which was subject to public notice and comment on two occasions is to address these and related issues.

b. Preservation of Existing Authority

Nothing contained in this guidance prevents OFHEO from undertaking such supervisory or enforcement actions as may be necessary to meet its statutory obligations to oversee maintenance of safety and soundness and adequate capital.

II. Calculation of Conforming Loan Limit

a. General Procedures

(i) Consistent with statute, OFHEO will utilize the Federal Housing Finance Board's annual October-to-October Monthly Interest Rate Survey (MIRS) data (routinely released in November) to calculate the conforming loan limit for the following calendar year.

(ii) Under the terms of an inter-agency agreement, the FHFB will provide OFHEO with the confidential October survey data prior to its public release.

(iii) OFHEO will calculate the percentage change in the average house price, make any adjustment needed to reflect FHFB methodological changes and determine the new maximum conforming loan limit for the following year. The result of the calculation will be rounded downward, in line with existing practice, to the nearest $100, for marketplace convenience and administrative simplicity.

(iv) Immediately following the FHFB's October MIRS announcement, OFHEO will announce the maximum level of the new conforming loan limit and simultaneously issue a letter with its determination to each Enterprise.

(v) Each Enterprise under its charter then determines whether to set the conforming loan limit at its institution at or below that level.

(vi) The purchase of any mortgage above the limit by Fannie Mae or Freddie Mac will be considered an unsafe and unsound practice, running contrary to statute.

b. Procedures for Years in Which the House Price Level Declines

(i) If the October MIRS survey data indicate a decline from the previous October, no decrease in the loan limit for the next year will be required.

(ii) The next increase in the conforming loan limit will take into account prior decline(s) in the MIRS so that an increase in the loan limit will reflect the net change in the MIRS average price since the last loan limit increase. Declines will be accumulated and then reduce increases until increases exceed such prior declines.

c. Procedures for Adjustments and Technical Changes

(i) At any time during the year after a calculation has been made and the conforming loan limit set, if the FHFB revises the MIRS or any calculation, the Enterprises may provide comments to the FHFB for its consideration. Copies of any Enterprise comments should be provided contemporaneously to OFHEO.

(ii) Once the FHFB has determined the nature, scope and timing of technical changes or adjustments, OFHEO will make adjustments to the next year's conforming loan limit based upon the procedures set forth in this Guidance.

III. Changes to the Conforming Loan Limit Guidance

After careful consideration of comments received and seeking to meet the goals of clarity, ease of implementation, providing market certainty and in light of the temporary increase in the conforming loan limit contained in the *Recovery Rebates and Economic Stimulus for the American People Act of 2008,* OFHEO has revised and is issuing a final Examination Guidance—Conforming Loan Limit Calculations. Regarding the central topic of most comments and for which differing comments were received, OFHEO has determined that any October-to-October decrease in the national average house price, as reported by the Federal Housing Finance Board's MIRS, will not require a decrease in the loan limit but will be charged against the next increase or increases, as necessary. Any percentage increase in the loan limit will not exceed the net percentage increase in the MIRS average price since October of the year preceding the last increase in the loan limit. In sum, the loan limit will not decline from the present $417,000 level; however, calculated decreases will be accumulated and offset increases until all of the accumulated amounts have been offset. This will ensure that the conforming loan limit remains, as contemplated, a measure tied to housing prices. Over time, both increases and decreases will be reflected in the limit. This also means that the *de minimis* and grandfathering proposals are no longer relevant.

Other elements of the draft guidance have been adopted as proposed. OFHEO reconsidered whether it should round the maximum permitted loan limit to the nearest $100, as proposed, or whether it should retain the current practice of rounding to the nearest $50. In view of the quadrupling of house prices generally since adoption of the $50 figure, OFHEO determined to adopt the $100 rounding factor as proposed. Below is a summary of key provisions and additions or deletions made in the guidance issued today.

A. Loan Limit Declines and Statute

Some comments received agreed with OFHEO's determination to address declines in home price levels, while others disagreed. OFHEO's view remains the same—that declines fit within the statutory language as ''negative increases.'' In the alternative, where statutory language is silent, as is the case here, regulators routinely fill gaps in statutes with rational solutions in line with available statutory intent. Since loan limit calculations are tied to annual home price surveys, increases and declines reasonably may be considered in line with that statutory structure.

B. Loan Limit Declines—Deferrals

In line with a streamlined approach adopted herein, OFHEO has extended the deferral period. Decreases will be accumulated and then applied to the next following increase in the loan level. They are not deferred for a set period but accumulated until an increase occurs and are then applied to offset increases until increases exceed accumulated decreases.

C. Loan Limit Declines—De Minimis Declines

In line with a streamlined approach adopted herein, OFHEO has dropped language regarding *de minimis* declines. Since the conforming loan limit does not decline, but rather increases in the limit may be reduced by prior declines, there are no operational concerns, as were identified in the comment period, regarding offsetting increases with reductions or not making increases

where deferred amounts offset any increase.

D. Grandfathering Issues

In line with the streamlined approach adopted herein, OFHEO has dropped language on grandfathering. Since the conforming loan limit does not decline, no concerns exist about loans made prior to a decline in the loan limit.

E. Rounding Down

Comments received regarding a rounding down to the lowest $100 as opposed to the current OFHEO practice of rounding down to the lowest $50 were mixed with some opposing and others indicating either no objection to or no opinion on OFHEO's proposal. The final guidance adopts the approach of rounding down to the nearest $100 as having value as to market and consumer simplicity and understanding. Also, it would represent a doubling of this rounding standard, a much smaller percentage change than the four-fold increase in the loan limits since the $50 standard was adopted.

Accordingly, as stated in the Preamble, OFHEO hereby publishes the text of its Final Examination Guidance on Conforming Loan Limit Calculations.

Dated: March 25, 2008.

James B. Lockhart, III,

Director, Office of Federal Housing Enterprise Oversight.

[FR Doc. E8–6560 Filed 3–28–08; 8:45 am]

BILLING CODE 4220–01–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Agency Information Collection Activities: Submitted for Office of Management and Budget (OMB) Review; Comment Request

AGENCY: U.S. Geological Survey (USGS), Interior.

ACTION: Notice of an extension of an information collection (1028–0078).

SUMMARY: To comply with the Paperwork Reduction Act of 1995 (PRA), we are notifying the public that we have submitted to OMB an information collection request (ICR) to renew approval of the paperwork requirements for ''North American Amphibian Monitoring Program.'' This notice also provides the public a second opportunity to comment on the paperwork burden of this form.

DATES: Submit written comments by April 30, 2008.

ADDRESSES: Please submit comments on this information collection directly to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs, Attention: Desk Officer for the Department of the Interior via OMB e-mail: (*OIRA_DOCKET@omb.eop.gov*); or by fax (202) 395–6566; and identify your submission with #1028–0078.

Please also submit a copy of your comments to the Department of the Interior, USGS, via:

- E-mail: *atravnic@usgs.gov.* Use Information Collection Number 1028–0078 in the subject line.
- FAX: (703) 648–7069. Use Information Collection Number 1028–0078 in the subject line.
- Mail or hand-carry comments to the Department of the Interior; USGS Clearance Officer, U.S. Geological Survey, 807 National Center, Reston, VA 20192. Please reference Information Collection 1028–0078 in your comments.

FOR FURTHER INFORMATION CONTACT: Linda Weir at (301) 497–5932. Copies of the full Information Collection Request and the forms can be obtained at no cost at *http://www.reginfo.gov* or by contacting the USGS clearance officer at the phone number listed below.

SUPPLEMENTARY INFORMATION:

Title: North American Amphibian Monitoring Program (NAAMP).

OMB Control Number: 1028–0078.

Abstract: The North American Amphibian Monitoring Program (NAAMP) is a long-term, large-scale anuran monitoring program to track the status and trends of eastern and central North American frogs and toads. Volunteers conduct calling surveys three times per year, depending on the regional species assemblage. Volunteers listen for 5 minutes at 10 stops along the route. Data are submitted electronically via the Internet or on hard copy. These data will be used to estimate population trends at various geographic scales and assist with documenting species distribution.

Frequency: 3 times per year.

Estimated Number and Description of Respondents: Approximately 500 volunteer respondents per year.

Estimated Number of Responses: 1,500.

Annual burden hours: 4,500 hours.

Estimated Annual Reporting and Recordkeeping ''Hour'' Burden: We estimate the public reporting burden averages 3 hours per response. This includes the time for driving to/from the survey route locations, 5-minute listening period per sampling station (10 sampling stations per route) and data entry time to submit data to the NAAMP Web site.

Estimated Reporting and Recordkeeping ''Non-Hour Cost'' Burden: We estimate the total ''non-hour'' cost burden to be $11,500. This total includes a one-time cost per respondent for the purchase of a thermometer to record air temperature during the survey, plus the operational costs of mileage for conducting the surveys.

Public Disclosure Statement: The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a currently valid OMB control number. Until OMB approves a collection of information, you are not obligated to respond.

Comments: Before submitting an ICR to OMB, PRA section 3506(c)(2)(A) (44 U.S.C. 3501, *et seq.*) requires each agency ''* * * to provide notice * * * and otherwise consult with members of the public and affected agencies concerning each proposed collection of information * * *'' Agencies must specifically solicit comments to: (a) Evaluate whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) enhance the quality, usefulness, and clarity of the information to be collected; and (d) minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

To comply with the public consultation process, on January 25, 2008, we published a **Federal Register** notice (73 FR 4620) announcing that we would submit this ICR to OMB for approval. The notice provided the required 60-day public comment period. We have received two comments in support of the survey. The comments had no effect on the burden.

USGS Information Collection Clearance Officer: Alfred Travnicek, 703–648–7231.

Dated: March 17, 2008.

Susan D. Haseltine,

Associate Director for Biology.

[FR Doc. E8–6612 Filed 3–28–08; 8:45 am]

BILLING CODE 4311–AM–P

DEPARTMENT OF THE INTERIOR

Geological Survey

Announcement of National Geospatial Advisory Committee Meeting

AGENCY: U. S. Geological Survey, Interior.

ACTION: Notice of meeting.

SUMMARY: The National Geospatial Advisory Committee (NGAC) will meet on April 15–16, 2008 in the 2nd Floor Boardroom of the American Institute of Architects Building, 1735 New York Avenue, NW., Washington, DC 20006. The NGAC, which is comprised of representatives from governmental, private sector, non-profit, and academic organizations, has been established to advise the Chair of the Federal Geographic Data Committee on management of Federal geospatial programs, the development of the National Spatial Data Infrastructure, and the implementation of Office of Management and Budget (OMB) Circular A–16. Topics to be addressed at the meeting include:

—Briefings on current Federal geospatial activities

—Review and discussion of NGAC study topics

—Review and discussion of NGAC subcommittee assignments

The meeting will include an opportunity for public comment during the morning of April 16. Comments may also be submitted to the NGAC in writing. While the meeting will be open to the public, seating may be limited due to room capacity.

DATES: The meeting will be held on April 15–16, from 1 p.m. to 5 p.m. on April 15, and from 8:30 a.m. to 5 p.m. on April 16.

FOR FURTHER INFORMATION CONTACT: John Mahoney, U.S. Geological Survey (206–220–4621).

SUPPLEMENTARY INFORMATION: Meetings of the National Geospatial Advisory Committee are open to the public. Additional information about the NGAC and the meeting are available at *http://www.fgdc.gov/ngac.*

Dated: March 25, 2008.

Ivan DeLoatch,

Staff Director, Federal Geographic Data Committee.

[FR Doc. E8–6437 Filed 3–28–08; 8:45am]

BILLING CODE 4311–AM–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UTU 85338]

Public Land Order No. 7697; Transfer of Public Land for the Crescent Junction Uranium Mill Tailings Repository; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order permanently transfers 500 acres of public land to the Department of Energy in accordance with the terms of the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7916 (2000)), as amended.

EFFECTIVE DATE: March 31, 2008.

FOR FURTHER INFORMATION CONTACT: Mary von Koch, Realty Specialist, BLM Moab Field Office, 82 East Dogwood Avenue, Moab, Utah 84532, 435–259–2128.

Order

By virtue of the authority vested in the Secretary of the Interior by the Uranium Mill Tailings Radiation Control Act of 1978 (42 U.S.C. 7916 (2000)), as amended, it is ordered as follows:

1. Subject to valid existing rights, the following described public land is hereby permanently transferred to the Department of Energy, and as a result of this transfer, except for oil and gas leasing, the land is no longer subject to the general land laws, including the United States mining laws, other mineral or geothermal leasing, and mineral material sales, for the Crescent Junction Uranium Mill Tailings Repository:

T. 21 S., R. 19 E.
Sec. 22, SE¼SE¼SW¼; NE¼SW¼SE¼, S½SW¼SE¼, and SE¼SE¼;
Sec. 23, S½NE¼SW¼, S½NW¼SW¼, and S½SW¼;
Sec. 26, N½NW¼, N½SW¼NW¼, and NW¼SE¼NW¼;
Sec. 27, N½NE¼, SW¼NE¼, N½SE¼NE¼, SW¼SE¼NE¼, E½NE¼NW¼, and E½SE¼NW¼.

The area described contains 500 acres in Grand County.

2. The transfer of the above-described land to the Department of Energy vests in that Department full management, jurisdiction, authority, responsibility, and liability for such land and all activities conducted therein, except as provided in Paragraphs 3 and 4.

3. The authority to administer any existing claims, rights, and interests in this land established before the effective date of the transfer is reserved to the Secretary of the Interior.

4. Authority to administer any future oil and gas leasing is reserved to the Secretary of the Interior.

Dated: March 20, 2008.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

[FR Doc. E8–6598 Filed 3–28–08; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[UTU 42911 and UTU 42915]

Public Land Order No. 7698; Modification of Secretarial Orders Dated July 6, 1925 and April 1, 1941; Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Public land order.

SUMMARY: This order establishes a 20-year term for two Secretarial Orders which withdrew lands from surface entry and mining and reserved them on behalf of the Bureau of Reclamation for the Salt Lake Basin and Gooseberry Projects. The lands, which currently aggregate approximately 6,768 acres after a previous partial revocation, are still needed for the purpose for which they were withdrawn. The lands will remain withdrawn from surface entry and mining but not from mineral and geothermal leasing or mineral material sales.

EFFECTIVE DATE: *March 31, 2008.*

FOR FURTHER INFORMATION CONTACT: Rhonda Flynn, BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101–1345, 801–539–4132.

SUPPLEMENTARY INFORMATION: The Bureau of Reclamation has determined that the lands are still needed for reclamation purposes. The lands will remain withdrawn from surface entry and mining but not from mineral and geothermal leasing or mineral material sales. The April 1, 1941 Secretarial Order was partially revoked by Public Land Order No. 5040. A copy of the pertinent orders containing legal descriptions of the lands involved is available from the Bureau of Land Management, Utah State Office at the address above.

Order

By virtue of the authority vested in the Secretary of the Interior by section 204 of the Federal Land Policy and

Management Act of 1976, 43 U.S.C. 1714 (2000), it is ordered as follows:

The Secretarial Orders dated July 6, 1925 and April 1, 1941, which withdrew lands from surface entry and mining and reserved them on behalf of the Bureau of Reclamation for the Salt Lake Basin and Gooseberry Projects, are hereby modified to expire 20 years from the effective date of this order unless, as a result of a review conducted before the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(f) (2000), the Secretary determines that the withdrawals shall be extended.

Dated: March 20, 2008.

C. Stephen Allred,

Assistant Secretary—Land and Minerals Management.

[FR Doc. E8–6583 Filed 3–28–08; 8:45 am]

BILLING CODE 4310–MN–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: Amerind Foundation Museum, Amerind Foundation, Inc., Dragoon, AZ; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of the Amerind Foundation Museum, Amerind Foundation, Inc., Dragoon, AZ, that meet the definition of ''objects of cultural patrimony'' and ''sacred objects'' under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in this notice.

This notice replaces a previously published Notice of Intent to Repatriate in the **Federal Register** of December 19, 2007, (FR Doc E7–24645, page 71964), by identifying the cultural items as both ''objects of cultural patrimony'' and as ''sacred objects.'' The cultural items were originally only identified as ''sacred objects.''

The 140 objects include 38 painted wooden hoops; 17 painted wooden wands; 17 miscellaneous mask-making raw materials (sticks, feathers, leather); 16 ''bowed crosses;'' 16 ceremonial Gaan masks; 9 painted wooden crosses; 7 plant stem bundles (sage, fir, bear grass); 5 painted wooden staves; 5 wooden drumsticks; 4 painted ''headed'' sticks; 3 wooden bullroars; 1 metal tulapai strainer; 1 metal bread cooker; and 1 eagle feather bundle. The cultural items are from the William Neil Smith Apache Collection. The collection is well documented by photographs and journals, and supplemented by interviews conducted with Mr. Smith by the staff of the Arizona State Museum in Tucson.

In the spring of 1942, the 140 cultural items were removed from caves in the vicinity of Canyon Day on the Fort Apache Reservation in eastern Arizona by William Neil Smith, a collector from Tucson, AZ. In October 1942, the collection was loaned by Mr. Smith to the Arizona State Museum on the condition that it would be returned when Mr. Smith was released from active duty in the military. From 1944 to 1945, letters were exchanged between the director of the Arizona State Museum, superintendent of the Fort Apache Reservation, and Chair of the Fort Apache Tribal Council, and it was determined at that time that the collections were removed illegally. On October 1, 1945, the Fort Apache Tribal Council voted unanimously to donate the entire collection to the Arizona State Museum, to use them as the museum saw fit. Accordingly, the collection was accessioned into the permanent collection of the Arizona State Museum, and there are no further entries on the collection in the Arizona State Museum files until 1959.

In November 1959, in response to a request from Mr. Smith to reclaim his 1942 loan from the Arizona State Museum, museum staff informed Mr. Smith that the Apache ceremonial objects had been donated to the museum by the Apache Tribal Council and, therefore, would not be returned. However, the collection was returned to Mr. Smith. On November 11, 1963, the collection was sold in its entirety to a member of the Amerind Foundation Board of Directors. The member donated the materials to the Amerind Foundation where it was accessioned into the foundation's permanent collection (Accession Nos. 4499–4583). In April 1966, the Arizona State Museum provided the Amerind with copies of photographs, catalog cards, and other records pertaining to the cultural items.

In June 2005, the Amerind Foundation consulted with tribal representatives of the San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and Yavapai–Apache Nation of the Camp Verde Indian Reservation, Arizona. Tribal representatives identified the cultural items as culturally affiliated with Western Apache Indian tribes.

In August 2005, the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona formally requested the return of all materials in the collection as sacred objects for the practice of traditional Native American religion by their present–day adherents. The cultural items were originally made and used by Western Apache religious leaders during the annual ceremonial cycle. These ceremonial activities remain an important part of White Mountain Apache daily life. According to White Mountain Apache cultural tradition, once the objects were used they were to be curated according to traditional religious practices and never used or seen again by humans.

According to the traditional cultural authorities, the cultural items also have ongoing historical, traditional, and cultural importance to the Western Apache, and today, must be returned to the tribes representing the Western Apache to fully complete the ceremonial cycle into which they were introduced; as such, the cultural items are objects of cultural patrimony.

In 2006, the Amerind Foundation Board of Directors voted unanimously to treat the William Neil Smith Collection as stolen property and to return all 140 cultural items to the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona.

Officials of the Amerind Foundation Museum have determined that, pursuant to 25 U.S.C. 3001 (3)(C), the 140 cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents. Officials of the Amerind Foundation Museum have determined that, pursuant to 25 U.S.C. 3001 (3)(D), the 140 cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual. Lastly, officials of the Amerind Foundation Museum also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the sacred objects/objects of cultural patrimony and the White Mountain

Apache Tribe of the Fort Apache Reservation, Arizona.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the sacred objects/objects of cultural patrimony should contact Dr. John A. Ware, Executive Director, Amerind Foundation Museum, Amerind Foundation, Inc., P.O. Box 400, 2100 North Amerind Road, Dragoon, AZ 85609, telephone (520) 586–3666, before April 30, 2008. Repatriation of the sacred objects/objects of cultural patrimony to the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona may proceed after that date if no additional claimants come forward.

The Amerind Foundation is responsible for notifying the San Carlos Apache Tribe of the San Carlos Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and Yavapai–Apache Nation of the Camp Verde Indian Reservation, Arizona that this notice has been published.

Dated: February 20, 2008.

Sherry Hutt,

Manger, National NAGPRA Program.

[FR Doc. E8–6571 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: Maryhill Museum of Art, Goldendale, WA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of the Maryhill Museum of Art, Goldendale, WA, that meet the definition of ''unassociated funerary objects'' under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in this notice.

In 1943, Native American items were loaned to the Maryhill Museum of Art by Harvey T. and Bessie Day Harding of Wenatchee, WA. In 1979, their children, Ethel L. Harding, Helen Harding Schmidt, and Charles L. Harding gifted the collection to the museum (Maryhill Accession, 1979.02). Most of the cultural items in the collection were gathered by H.T. Harding and his associates between 1920 and 1928 along the Columbia River in Oregon and Washington. Mr. Harding's documentation of his collection recorded four cedar burial markers, probably found at three different sites along the Columbia River. However, there are only two cedar burial markers presently in the possession of Maryhill Museum. It is unknown which two of the original four were donated to the museum. The two cedar burial markers are four feet long.

According to Mr. Harding's documentation, he received two cedar burial markers in September of 1923 from Mrs. S. Bowman. The two burial markers from Mrs. Bowman were collected by S. Bowman ''about 15 years ago from a party near Coal Springs, Oregon, about 10 miles from Wallula. These being in duplicate,'' Mr.Harding reported, he then donated one to Adam H. East ''to pay for one that he gave me about 2 years ago.'' Although Mr. East often accompanied Mr. Harding, it is reported that most of Mr. East's collection came from the area near Moses Lake, WA, where it still resides in the Moses Lake Art Center. At Wahluke Ferry, approximately 15 miles south east of Priest Rapids, Mr. Harding reported receiving the following from H. Glauzman, ''One Totem, an older specimen than those described above.'' It is believed that this is also a cedar burial marker.

During consultation, representatives of the Confederated Tribes of the Umatilla Reservation, Oregon, provided historical evidence that the Imatalamlama had a spring and summer camp between Umatilla and Cold Springs Junction (also known as Coal Springs) called Tk'uyipa, or ''at tule place.'' They have also identified several other nearby sites that were important fishing, camping, and burial areas to the Imatalamlama and Weyiiletpuu and are located within the area from which the cultural items were removed. The Imatalamlama are members of the Confederated Tribes of the Umatilla Reservation, Oregon and the Wanapum Band, a non-federally recognized Indian group. However, since it is unknown which of the sites the two burial markers were removed from and many of the sites are the traditional and aboriginal use lands common to the Umatilla, Yakama, and Wanapum, officials of the Maryhill Museum of Art reasonably believe that there is a possible shared group relationship between the burial markers and the Umatilla, Yakama, and Wanapum. Descendants of the Umatilla are members of the Confederated Tribes of the Umatilla Reservation, Oregon. Descendants of the Yakama are members of the Confederated Tribes and Bands of the Yakama Nation, Washington. Descendants of the Wanapum are members of the Wanapum Band, a non-federally recognized Indian group.

Officials of the Maryhill Museum of Art have determined that, pursuant to 25 U.S.C. 3001 (3)(B), the two cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of an Native American individual. Officials of the Maryhill Museum of Art also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the unassociated funerary objects and the Confederated Tribes of the Umatilla Reservation, Oregon and possibly the Confederated Tribes and Bands of the Yakama Nation, Washington. Furthermore, officials of the Maryhill Museum of Art have determined that there may be a cultural relationship between the unassociated funerary objects and the Wanapum Band, a non-federally recognized Indian group.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the unassociated funerary objects should contact, Colleen Schafroth, Executive Director, Maryhill Museum of Art, 35 Maryhill Museum Drive, Goldendale, WA 98620, telephone (509) 773–3733, before April 30, 2008. Repatriation of the unassociated funerary objects to the Confederated Tribes of the Umatilla Reservation, Oregon may proceed after that date if no additional claimants come forward.

Maryhill Museum of Art is responsible for notifying the Confederated Tribes of the Umatilla Reservation, Oregon; Confederated Tribes and Bands of the Yakama Nation, Washington; and Wanapum Band, a non-federally recognized Indian group that this notice has been published.

Dated: March 15, 2008.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. E8–6561 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: Science Museum of Minnesota, St. Paul, MN

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, of the intent to repatriate cultural items in the possession of the Science Museum of Minnesota, St. Paul, MN, that meet the definition of ''sacred objects'' under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the cultural items. The National Park Service is not responsible for the determinations in this notice.

In August of 1961, Mrs. Sidney A. Peterson purchased five objects relating to the Midewiwin religion from Jack Chicag of Nett Lake, MN. The five cultural items are two beaded panels with human designs (61–1420 and 61–1419), one bear paw bag (61–1439), one cat paw bag (61–1438), and one tin can with pine residue (61–1410).

Museum accession, catalogue, collector notes and purchase records, as well as consultation with representatives of the Bois Forte Band (Nett Lake) of the Minnesota Chippewa Tribe, Minnesota, indicate that the five cultural objects are Chippewa and are from the Nett Lake Reservation, and are sacred objects. The sacred objects are derived from the Midewiwin Society, also known as the Medicine Lodge Society, and needed by Midewiwin Society members to conduct ceremonies and religious leaders of the Minnesota Chippewa Tribe, Minnesota for the practice of traditional Native American religious ceremonies.

Officials of the Science Museum of Minnesota have determined that, pursuant to 25 U.S.C. 3001 (3)(C), the five cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present–day adherents. Officials of The Science Museum of Minnesota also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the sacred objects and the Bois Forte Band (Nett Lake) of the Minnesota Chippewa Tribe, Minnesota.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the sacred objects should contact Tilly Laskey, Curator of Ethnology, Science Museum of Minnesota, St. Paul, MN 55102, telephone (651) 221–9432 before April 30, 2008. Repatriation of the sacred objects to the Bois Forte Band (Nett Lake) of the Minnesota Chippewa Tribe Minnesota may proceed after that date if no additional claimants come forward.

The Science Museum of Minnesota is responsible for notifying the Bois Forte Band (Nett Lake) of the Minnesota Chippewa Tribe, Minnesota that this notice has been published.

Dated: February 18, 2008.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. E8–6573 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: Oregon State University Department of Anthropology, Corvallis, OR

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the control of Oregon State University Department of Anthropology, Corvallis, OR. The human remains were removed from Skagit County, WA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by Oregon State University Department of Anthropology professional staff in consultation with representatives of Jamestown S'Klallam Tribe of Washington; Muckleshoot Indian Tribe of the Muckleshoot Reservation, Washington; Samish Indian Tribe, Washington; and Swinomish Indians of the Swinomish Reservation, Washington.

On unknown dates, human remains representing a minimum of two individuals were removed from Similk Bay and LaConner Flats, Skagit County, WA. The human remains were donated to the Department of Anthropology by Dr. T. Tillman of the Oregon State University Physical Education Department upon his retirement. Dr. Tillman received the human remains from the widow of an unknown collector between 1940 and 1978. No known individuals were identified. No associated funerary objects are present.

The collection records state that both individuals are ''Indian,'' and the Department of Anthropology's physical anthropology faculty confirms that both skulls have cranial modification consistent with Native American cultural practices. According to collection records and tribal consultants, the human remains were removed from locations in the traditional and current territory of the Swinhomish Indians of the Swinhomish Reservation, Washington.

Officials of the Oregon State University Department of Anthropology have determined that, pursuant to 25 U.S.C. 3001 (9–10), the human remains described above represent the physical remains of two individuals of Native American ancestry. Officials of the Oregon State University Department of Anthropology have also determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Swinomish Indians of the Swinomish Reservation, Washington.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Dr. David McMurray, Oregon State University Department of Anthropology, 238 Waldo Hall, Corvallis, OR 97331, telephone (541) 737–4515, before April 30, 2008. Repatriation of the human remains to the Swinomish Indians of the Swinomish Reservation, Washington may proceed after that date if no additional claimants come forward.

Oregon State University Department of Anthropology is responsible for notifying the Confederated Tribes of the Chehalis Reservation, Washington; Confederated Tribes of the Colville Reservation, Washington; Confederated Tribes and Bands of the Yakama Nation, Washington; Cowlitz Indian Tribe, Washington; Hoh Indian Tribe of the Hoh Indian Reservation, Washington; Kalispel Indian Community of the

Kalispel Reservation, Washington; Lower Elwha Tribal Community of the Lower Elwha Reservation, Washington; Lummi Tribe of the Lummi Reservation, Washington; Makah Indian Tribe of the Makah Indian Reservation, Washington; Muckleshoot Indian Tribe of the Muckleshoot Reservation, Washington; Nisqually Indian Tribe of the Nisqually Reservation, Washington; Nooksack Indian Tribe of Washington; Port Gamble Indian Community of the Port Gamble Reservation, Washington; Puyallup Tribe of the Puyallup Reservation, Washington; Quileute Tribe of the Quileute Reservation, Washington; Quinault Tribe of the Quinault Reservation, Washington; Samish Indian Tribe, Washington; Sauk-Suiattle Indian Tribe of Washington; Shoalwater Bay Tribe of the Shoalwater Bay Indian Reservation, Washington; Skokomish Indian Tribe of the Skokomish Reservation, Washington; Snoqualmie Tribe, Washington; Spokane Tribe of the Spokane Reservation, Washington; Squaxin Island Tribe of the Squaxin Island Reservation, Washington; Stillaguamish Tribe of Washington; Suquamish Indian Tribe of the Port Madison Reservation, Washington; Swinomish Indians of the Swinomish Reservation, Washington; Tulalip Tribes of the Tulalip Reservation, Washington; and Upper Skagit Indian Tribe of Washington that this notice has been published.

Dated: March 5, 2008.

David Tarler,

Acting Manager, National NAGPRA Program.

[FR Doc. E8–6559 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: U.S. Department of Defense, Army, Installation Management Agency–Army Reserve Office, Arlington, VA, and University of Utah, Utah Museum of Natural History, Salt Lake City, UT

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the control of the U.S. Department of Defense, Army, Installation Management Agency–Army Reserve Office, Arlington, VA, and in the physical custody of the University of Utah, Utah Museum of Natural History, Salt Lake City, UT. The human remains were removed from Fort Douglas, Salt Lake County, UT.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by U.S. Department of Defense, Army professional staff in consultation with representatives of the Great Basin Inter–Tribal NAGPRA Coalition, representing the Big Pine Band of Owens Valley Paiute Shoshone Indians of the Big Pine Reservation, California; Bridgeport Paiute Indian Colony of California; Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada; Ely Shoshone Tribe of Nevada; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; Northwestern Band of Shoshoni Nation of Utah (Washakie); Paiute–Shoshone Indians of the Bishop Community of the Bishop Colony, California; Paiute–Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California; Paiute–Shoshone Tribe of the Fallon Reservation and Colony, Nevada; Reno–Sparks Indian Colony, Nevada; Shoshone Tribe of the Wind River Reservation, Wyoming; Shoshone–Bannock Tribes of the Fort Hall Reservation of Idaho; Shoshone–Paiute Tribes of the Duck Valley Reservation, Nevada; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Susanville Indian Rancheria, California; Te–Moak Tribe of Western Shoshone Indians of Nevada (Four constituent bands: Battle Mountain Band; Elko Band; South Fork Band and Wells Band); Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Steward Community, & Washoe Ranches); and Yomba Shoshone Tribe of the Yomba Reservation, Nevada. Representatives of the Death Valley Timbi–Sha Shoshone Band of California were also consulted, but are not members of the Great–Basin Inter–Tribal NAGPRA Coalition. The Ute Indian Tribe of the Uintah & Ouray Reservation, Utah and Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah were contacted, but declined to participate in the consultation.

On March 16, 1939, human remains representing a minimum of one individual were removed from the basement of an officer's quarters on Fort Douglas in Salt Lake County, UT, during excavations conducted to enlarge the basement area of a ''Sgt. Pooles'' house. The human remains were transferred for curation to the University of Utah, Utah Museum of Natural History, Salt Lake City, UT, on March 19, 1939. No known individual was identified. No associated funerary objects are present.

Information obtained during the inventory conducted by University of Utah, Utah Museum of Natural History staff indicates that this burial is believed to date to the Archaic period (circa 7,000 B.C. to A.D. 800). Since the Archaic period is a continent–wide archeological culture period with no known distinctly identifiable ties to any one modern tribe, it is unlikely that a specific tribal affiliation can be assigned to the Native American human remains. However, a review of the available literature demonstrates ethnographically, linguistically, and/or archeologically, that the present–day Northern Shoshone, Western Shoshone, Eastern Shoshone, and Ute bands and tribes have both historic and prehistoric ties to the general geographical area of Fort Douglas. Furthermore, Northern Shoshone, Western Shoshone, Eastern Shoshone, and Ute bands and tribes have aboriginal ancestral territories that fall within the Great Basin culture area encompassing Fort Douglas. The present–day descendants of the Northern Shoshone, Western Shoshone, Eastern Shoshone, and Ute band and tribes are members of the Big Pine Band of Owens Valley Paiute Shoshone Indians of the Big Pine Reservation, California; Bridgeport Paiute Indian Colony of California; Death Valley Timbi–Sha Shoshone Band of California; Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada; Ely Shoshone Tribe of Nevada; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; Northwestern Band of Shoshoni Nation of Utah (Washakie); Paiute–Shoshone Indians of the Bishop Community of the Bishop Colony, California; Paiute–Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California; Paiute–Shoshone Tribe of the Fallon Reservation and Colony, Nevada; Reno–Sparks Indian Colony, Nevada;

Shoshone Tribe of the Wind River Reservation, Wyoming; Shoshone–Bannock Tribes of the Fort Hall Reservation of Idaho; Shoshone–Paiute Tribes of the Duck Valley Reservation, Nevada; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Te–Moak Tribe of Western Shoshone Indians of Nevada; Susanville Indian Rancheria, California; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah; Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Steward Community, & Washoe Ranches); and Yomba Shoshone Tribe of the Yomba Reservation, Nevada.

Officials of the Army, Installation Management Agency–Army Reserve Office have determined that, pursuant to 25 U.S.C. 3001 (9–10), the human remains described above represent the physical remains of one individual of Native American ancestry. Officials of the Army, Installation Management Agency–Army Reserve Office have also determined that, pursuant to 25 U.S.C. 3001 (2), a relationship of shared group identity cannot reasonably be traced between the Native American human remains and any present–day Indian tribe. Lastly, officials of the Army, Installation Management Agency–Army Reserve Office determined that the physical remains of the one individual of Native American ancestry are culturally unidentifiable.

The Native American Graves Protection and Repatriation Review Committee (Review Committee) is responsible for recommending specific actions for disposition of culturally unidentifiable human remains. In 1997, the Army, Installation Management Agency–Army Reserve determined that there was not sufficient evidence of a shared group identity (cultural affiliation) between the human remains and a particular Indian Tribe or Tribes and the human remains were ''culturally unidentifiable.'' Officials of the Army, Installation Management Agency–Army Reserve requested that the Review Committee recommend disposition of the culturally unidentifiable human remains from Fort Douglas to the 20 federally recognized tribes that represent the Great Basin Inter–Tribal NAGPRA Coalition. The Great Basin Inter–Tribal NAGPRA Coalition has adopted a resolution for a joint claim for the human remains from Fort Douglas (Great Basin Inter–Tribal NAGPRA Coalition Resolution No. 04–001).

In 2005, a letter from the Review Committee's Designated Federal Officer, writing on behalf of the Secretary of the Interior, recommended disposition by the Army, Installation Management Agency–Army Reserve of the physical remains of one individual to the 20 federally recognized bands and tribes that are members of the Great Basin Inter–Tribal NAGPRA Coalition contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills this requirement.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Mr. Richard White, Conservation Chief, ATTN: IMAR–E, 2511 Jefferson Davis Highway, 10th Floor, Arlington, VA 22202–3926, telephone (703) 602–2848, before April 30, 2008. Repatriation of the human remains to the Great Basin Inter–Tribal NAGPRA Coalition, on behalf of the Big Pine Band of Owens Valley Paiute Shoshone Indians of the Big Pine Reservation, California; Bridgeport Paiute Indian Colony of California; Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada; Ely Shoshone Tribe of Nevada; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; Northwestern Band of Shoshoni Nation of Utah (Washakie); Paiute–Shoshone Indians of the Bishop Community of the Bishop Colony, California; Paiute–Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California; Paiute–Shoshone Tribe of the Fallon Reservation and Colony, Nevada; Reno–Sparks Indian Colony, Nevada; Shoshone Tribe of the Wind River Reservation, Wyoming; Shoshone–Bannock Tribes of the Fort Hall Reservation of Idaho; Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Susanville Indian Rancheria, California; Te–Moak Tribe of Western Shoshone Indians of Nevada; Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Steward Community, & Washoe Ranches); and Yomba Shoshone Tribe of the Yomba Reservation, Nevada, may proceed after that date if no additional claimants come forward.

The U.S. Department of Defense, Army, Installation Management Agency–Army Reserve Office is responsible for notifying the Big Pine Band of Owens Valley Paiute Shoshone Indians of the Big Pine Reservation, California; Bridgeport Paiute Indian Colony of California; Death Valley Timbi-Sha Shoshone Band of California; Duckwater Shoshone Tribe of the Duckwater Reservation, Nevada; Ely Shoshone Tribe of Nevada; Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Lovelock Paiute Tribe of the Lovelock Indian Colony, Nevada; Northwestern Band of Shoshoni Nation of Utah (Washakie); Paiute–Shoshone Indians of the Bishop Community of the Bishop Colony, California; Paiute–Shoshone Indians of the Lone Pine Community of the Lone Pine Reservation, California; Paiute–Shoshone Tribe of the Fallon Reservation and Colony, Nevada; Reno-Sparks Indian Colony, Nevada; Shoshone Tribe of the Wind River Reservation, Wyoming; Shoshone-Bannock Tribes of the Fort Hall Reservation of Idaho; Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Susanville Indian Rancheria, California; Te–Moak Tribe of Western Shoshone Indians of Nevada; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah; Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Steward Community, & Washoe Ranches); and Yomba Shoshone Tribe of the Yomba Reservation, Nevada that this notice has been published.

Dated: February 28, 2008.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. E8–6557 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: Paul H. Karshner Memorial Museum, Puyallup, WA; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains in the possession of the Paul H. Karshner Memorial Museum, Puyallup,

WA. The human remains were removed from an unknown area of Western Oregon.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

This notice increases the minimum number of individuals from one to two in a Notice of Inventory Completion published in the **Federal Register** of January 15, 2008 (FR Doc E8–563, Pages 2525–2526).

The Notice of Inventory Completion in the **Federal Register** of January 15, 2008, paragraph number 4 is corrected by substituting the following paragraph:

In the 1930s, human remains representing a minimum of two individuals were removed from an unknown area in Western Oregon. The human remains were donated to the museum by Dr. Warner M. Karshner in the 1930s. No known individuals were identified. No associated funerary objects are present.

Paragraph number 7 is corrected by substituting the following paragraph:

Officials of the Paul H. Karshner Memorial Museum have determined that, pursuant to 25 U.S.C. 3001 (9–10), the human remains described above represent the physical remains of two individuals of Native American ancestry. Officials of the Paul H. Karshner Memorial Museum also have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and the Confederated Tribes of the Grand Ronde Community of Oregon.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Dr. Jay Reifel, Assistant Superintendent, telephone (253) 840–8971 or Ms. Beth Bestrom, Museum Curator, Paul H. Karsnher Memorial Museum, 309 4th St. NE, Puyallup, WA 98372, telephone (253) 841–8748, before April 30, 2008. Repatriation of the human remains to the Confederated Tribes of the Grand Ronde Community of Oregon may proceed after that date if no additional claimants come forward.

Paul H. Karshner Memorial Museum is responsible for notifying the Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians of Oregon; Confederated Tribes of the Grand Ronde Community of Oregon; Confederated Tribes of the Siletz Reservation, Oregon; and Coquille Tribe of Oregon that this notice has been published.

Dated: February 4, 2008.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. E8–6558 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, and The University Museum, University of Arkansas, Fayetteville, AR

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the control of the U.S. Department of the Interior, Bureau of Indian Affairs, Washington, DC, and in the physical custody of The University Museum, University of Arkansas, Fayetteville, AR. The human remains and associated funerary objects were removed from the Gila River Indian Community near Sacaton, AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by The University Museum professional staff, on behalf of the U.S. Department of the Interior, Bureau of Indian Affairs, in consultation with representatives of the Gila River Indian Community of the Gila River Indian Reservation, Arizona.

Sometime between 1931 and 1934, human remains representing a minimum of two individuals were removed from a cremation feature at an unknown site in the vicinity of Sacaton (AZ U:14), Gila River Reservation, Pinal County, AZ, by Carl Moosberg. In 1935, the human remains were donated to the Arizona State Museum by Mr. Moosberg. In 1954, the human remains were transferred to The University Museum in an exchange with the Arizona State Museum. No known individuals were identified. The two associated funerary objects are one red–on–buff jar and one Gila redware jar.

Based on characteristics of the mortuary pattern and the attributes of the ceramic style, this burial has been identified as being associated with the Sedentary Phase of the Hohokam archeological tradition, which spanned the years circa A.D. 950–1150.

Continuities of mortuary practices, ethnographic materials, and technology indicate affiliation of Hohokam settlements with present–day O'odham (Piman), Pee Posh (Maricopa), and Puebloan cultures. Oral traditions documented for the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima–Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico support cultural affiliation with Hohokam sites in central Arizona. Descendants of the Hohokam are members of the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima–Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico.

Officials of the Bureau of Indian Affairs and The University Museum have determined that, pursuant to 25 U.S.C. 3001 (9–10), the human remains described above represent the physical remains of two individuals of Native American ancestry. Officials of the Bureau of Indian Affairs and The University Museum also have determined that, pursuant to 25 U.S.C. 3001 (3)(A), the two objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Indian Affairs and The University Museum have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt

River Pima–Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Mary Suter, Curator of Collections, The University Museum, University of Arkansas, Fayetteville, AR 72701, telephone (479) 575–3481, before April 30, 2008. Repatriation of the human remains and associated funerary objects to the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima–Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico, may proceed after that date if no additional claimants come forward.

The University Museum is responsible for notifying the Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona; Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima–Maricopa Indian Community of the Salt River Reservation, Arizona; Tohono O'odham Nation of Arizona; and Zuni Tribe of the Zuni Reservation, New Mexico that this notice has been published.

Dated: February 28, 2008.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. E8–6569 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: University of Wisconsin–Stevens Point, Stevens Point, WI

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects in the possession of the University of Wisconsin–Stevens Point, Stevens Point, WI. The human remains and associated funerary objects were removed from Portage County, WI.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003 (d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

A detailed assessment of the human remains was made by University of Wisconsin–Stevens Point professional staff in consultation with representatives of the Ho–Chunk Nation of Wisconsin and Menominee Indian Tribe of Wisconsin.

In the late 1950s, human remains were removed from the Bigelow–Hamilton site (47–Pr–29), Portage County, WI, by George Dixon. Mr. Dixon subsequently donated the human remains and associated funerary objects to the University of Wisconsin–Stevens Point. No known individuals were identified. Most of the human remains and associated funerary objects were reinterred in 1986 and 1987 at the request of the Wisconsin Winnebago Tribe, now called the Ho–Chunk Nation of Wisconsin. In 1994, 1995, and 2001, additional human remains representing a minimum of two individuals and associated funerary objects from the Bigelow–Hamilton site were discovered in the University of Wisconsin–Stevens Point collections. The 71 associated funerary objects are 1 fragment of mink or otter fur, 2 textile fragments, 9 shell fragments, 6 stone tools, 48 stone flakes, 3 Madison Plain sherds, and 2 cord–impressed sherds.

The Bigelow–Hamilton site consists of mounds, several large village areas, and a possible storage precinct. Archival research, literature review, and artifact analysis indicate sequential occupations of the site from 400 to 200 B.C., A.D. 0 to 200, A.D. 200 to 400, A.D. 500 to 1200, and during the 19th century. The human remains are believed to be associated with a Menominee sugar camp at the site that was used between A.D. 1839 and 1840. The Bigelow–Hamilton site is located with the area ceded by the Menominee to the United States under the Treaty of September 3, 1836 (7 Stat. 506). Other historic records indicate that the ancestors of the Ho–Chunk Nation of Wisconsin and Menominee Indian Tribe of Wisconsin occupied the Portage County area during the 1830s and 1840s. The Ho–Chunk Nation of Wisconsin and Menominee Indian Tribe of Wisconsin have agreed that the Ho–Chunk Nation of Wisconsin will assume repatriation for the human remains and associated funerary objects from the area of the Bigelow–Hamilton site.

Officials of the University of Wisconsin–Stevens Point have determined that, pursuant to 25 U.S.C. 3001 (9–10), the human remains described above represent the physical remains of two individuals of Native American ancestry. Officials of the University of Wisconsin–Stevens Point also have determined that, pursuant to 25 U.S.C. 3001 (3)(A), the 71 objects described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the University of Wisconsin–Stevens Point have determined that, pursuant to 25 U.S.C. 3001 (2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Ho–Chunk Nation of Wisconsin and/or Menominee Tribe of Indians of Wisconsin.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains should contact Sharon Cloud, University of Wisconsin–Stevens Point, Stevens Point, WI 54481–3897, telephone (715) 346–3576, before April 30, 2008. Pursuant to 25 U.S.C. 3009 (2), the human remains and associated funerary objects were repatriated to the Ho-Chunk Nation of Wisconsin in 2003 to complete the repatriation that was pending at the time of NAGPRA's enactment.

The University of Wisconsin–Stevens Point is responsible for notifying the Ho–Chunk Nation of Wisconsin and Menominee Indian Tribe of Wisconsin that this notice has been published.

Dated: March 15, 2008.

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. E8–6575 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations and Related Actions

Nominations for the following properties being considered for listing or related actions in the National Register were received by the National Park Service before March 14, 2008. Pursuant to section 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 April 15, 2008.

J. Paul Loether,

Chief, National Register of Historic Places/ National Historic Landmarks Program.

GEORGIA

Fulton County

Peachtree Highlands—Peachtree Park Historic District, Roughly bounded by Piedmont & Peachtree Rds., GA 400 & MARTA N–S line., Atlanta, 08000325.

ILLINOIS

Du Page County

Schiller, Alfred A., House, 734 Lenox Rd., Glen Ellyn, 08000326.

McLean County

Sprague's Super Service, (Route 66 through Illinois MPS) 305 E. Pine St., Normal, 08000327.

IOWA

Dubuque County

Interstate Power Company Building, (Dubuque, Iowa MPS) 1000 Main; 131 W. 10th St., Dubuque, 08000328.

Plymouth County

Foster Park Historic District, 500–900 blks. Central Ave. S. & blocks around Foster Park, Le Mars, 08000329.

Polk County

Grocers Wholesale Company Building, 22 W. 9th St., Des Moines, 08000330.

Scott County

Community Building, 428 S. River Dr., Princeton, 08000331.

Woodbury County

Simmons Hardware Company Warehouse, 323 Water St., Sioux City, 08000332.

MISSOURI

Taney County

Parnell, Samuel T. and Mary B., House, 220 Angels Trail, Branson, 08000333.

MONTANA

Glacier County

Logan Pass Visitor Center, Going-to-the-Sun Rd., 18 mi. W. of U.S. 89, Saint Mary, 08000334.

Saint Mary Visitor Center, Entrance Station and Checking Stations, Going-to-the-Sun Rd., 5 mi. E. of U.S. 89, Saint Mary, 08000335.

NEW JERSEY

Monmouth County

Brielle Road Bridge over the Glimmer Glass, Brielle Rd. over The Glimmer Glass, Manasquan, 08000336.

OREGON

Jackson County

Putnam—Neff House, 227 N. Berkeley Wy., Medford, 08000337.

SOUTH CAROLINA

Greenville County

Woodson, Azariah and Henry F., Farmstead, 840 & 856 Beech Springs Rd., Pelzer, 08000338.

TEXAS

Chambers County

Chambers County Courthouse, 404 Washington St., Anahuac, 08000339.

VIRGINIA

Albemarle County

Carr's Hill, 1910 Carr's Hill Rd., Charlottesville, 08000340.

Richmond Independent City

United Daughters of the Confederacy Memorial Building, 328 North Blvd., Richmond (Independent City), 08000341.

[FR Doc. E8–6505 Filed 3–28–08; 8:45 am]

BILLING CODE 4312–51–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0083

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed authority for 30 CFR part 955 and the Form OSM–74, Certification of Blasters in Federal program States and on Indian lands.

DATES: Comments on the proposed information collection must be received by May 30, 2008, to be assured of consideration.

ADDRESSES: Comments may be mailed to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave, NW., Room 202—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov*.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request, explanatory information and related form, contact John Trelease, at (202) 208–2783.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies an information collection that OSM will be submitting to OMB for approval. This collection is contained in Form OSM–74 which incorporates the requirements of 30 CFR 955. OSM will request a 3-year term of approval for each information collection activity.

Comments are Invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

The following information is provided for the information collection: (1) Title of the information collection; (2) OMB control number; (3) summary of the information collection activity; and (4) frequency of collection, description of the respondents, estimated total annual responses, and the total annual reporting and recordkeeping burden for the collection of information.

Title: Certification of blasters in Federal program States and on Indian lands, 30 CFR 955.

OMB Control Number: 1029–0083.

Summary: This information is being collected to ensure that the applicants for blaster certification are qualified. This information, with blasting tests, will be used to determine the eligibility of the applicant.

Bureau Form Number: OSM–74.

Frequency of Collection: On occasion.

Description of Respondents: Individuals intent on being certified as blasters in Federal program States and on Indian lands.

Total Annual Responses: 8.

Total Annual Burden Hours: 18.

Total Annual Non-Wage Burden Cost: $549.

Dated: March 24, 2008.

John R. Craynon,

Chief, Division of Regulatory Support.

[FR Doc. E8–6373 Filed 3–28–08; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–497]

Advice Concerning Possible Modifications to the U.S. Generalized System of Preferences, 2007 Review of Competitive Need Limit Waivers

AGENCY: United States International Trade Commission.

ACTION: Change in scope of investigation.

SUMMARY: Following receipt of a letter on March 13, 2008, from the United States Trade Representative (USTR) advising of the withdrawal of petitions requesting the waiver of the competitive need limit for the following two articles under the Generalized System of Preferences (GSP) program, the Commission has terminated its investigation with respect to those two articles and will not provide probable economic effect advice with respect to those articles:

Polyethylene terephthalate (PET) resin (HTS subheading 3907.60.00) from Indonesia, USTR accepted case 2007–13); and

Full grain, unsplit, fancy leather (HTS subheading 4107.91.80) from Argentina, USTR accepted case 2007–15).

The Commission expects to transmit its report to the USTR providing its advice with respect to the remaining articles that are the subject of the USTR's request for advice by April 17, 2008.

ADDRESSES: All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street, SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street, SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://www.usitc.gov/secretary/edis.htm*.

FOR FURTHER INFORMATION CONTACT: Information may be obtained from Cynthia B. Foreso, Project Leader, Office of Industries (202–205–3348 or *cynthia.foreso@usitc.gov*) or Eric Land, Deputy Project Leader, Office of Industries (202–205–3349 or *eric.land@usitc.gov*). For more information on legal aspects of the investigation, contact William Gearhart of the Commission's Office of the General Counsel (202–205–3091 or *william.gearhart@usitc.gov*). The media should contact Margaret O'Laughlin, Office of External Relations (202–205–1819 or *margaret.olaughlin@usitc.gov*). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS–ONLINE) at *http://www.usitc.gov/secretary/edis.htm*. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

Background: The Commission instituted the investigation on January 29, 2008, following receipt of a letter from the USTR on January 18, 2008. Notice of institution of the investigation and the scheduling of a public hearing was published in the **Federal Register** of February 4, 2008 (73 FR 6526); notice of cancellation of the public hearing, following the withdrawal of requests to appear by all scheduled witnesses, was published in the **Federal Register** of February 28, 2008 (73 FR10807). The deadline for filing written submissions in this investigation was March 7, 2008.

By order of the Commission.

Issued: March 25, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–6498 Filed 3–28–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–620]

In the Matter of Certain Low Antimony Phosphoric Acid; Notice of Commission Decision Not To Review an Initial Determination Terminating the Investigation on the Basis of a Settlement Agreement

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to not to review the initial determination (''ID'') (Order No. 3) of the presiding administrative law judge (''ALJ'') terminating the above-captioned investigation on the basis of a settlement agreement.

FOR FURTHER INFORMATION CONTACT: James A. Worth, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–3065. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On December 18, 2007, the Commission instituted an investigation titled *Certain Low Antimony Phosphoric Acid,* Inv. No. 337–TA–620, based upon a complaint filed November 8, 2007 on behalf of ICL Performance Products, LP (St. Louis, Missouri) (''ICL''). 72 FR 71,698 (December 18, 2007). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain low antimony phosphoric acid by reason of infringement of certain claims of U.S. Patent No. 5,989,509. The complaint named as respondents Maruzen Chemicals Co., Ltd. (Osaka, Japan) (''Maruzen'') and Rasa Industries, Ltd. (Tokyo, Japan) (''Rasa''). The complaint was accompanied by a motion for temporary relief, which was later withdrawn.

ICL, Maruzen, and Rasa subsequently filed a joint motion, dated January 16, 2008, to terminate the above-captioned investigation on the basis of a settlement agreement. The Commission investigative attorney filed a response in support of the joint motion.

The ALJ issued the subject ID on February 25, 2008, granting the joint motion to terminate the investigation. No petitions for review have been filed. The Commission has determined not to

review the subject ID. The investigation is hereby terminated. This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and sections 210.41(a) and 210.42(h)(3) of the Commission's Rules of Practice and Procedure (19 CFR 210.41(a), 210.42(h)(3)).

By order of the Commission.

Issued: March 25, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–6436 Filed 3–28–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Inv. No. 337–TA–641]

In the Matter of Certain Variable Speed Wind Turbines and Components Thereof; Notice of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on February 27, 2008, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of General Electric Company of Fairfield, Connecticut. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain variable speed wind turbines and components thereof that infringe certain claims of U.S. Patent Nos. 5,083,039 and 6,921,985. The complaint further alleges that an industry in the United States exists as required by subsection (a)(2) of section 337.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a permanent exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street, SW., Room 112, Washington, DC 20436, telephone 202–205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov*. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov*.

FOR FURTHER INFORMATION CONTACT: Thomas S. Fusco, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2571.

AUTHORITY: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2007).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on March 25, 2008, ordered that—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain variable speed wind turbines and components thereof that infringe one or more of claims 104 and 121–125 of U.S. Patent No. 5,083,039 and claims 1–12, 15–18, and 21–28 of U.S. Patent No. 6,921,985, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—General Electric Company, 3135 Easton Turnpike, Fairfield, Connecticut 06828–0001.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served: Mitsubishi Heavy Industries, Ltd., 16–5 Konan 2–Chome, Minato-ku, Tokyo 1088215, Japan; Mitsubishi Heavy Industries America, Inc., Headquarters, 630 Fifth Avenue, Suite 3155, New York, New York 10111; Mitsubishi Power Systems, Inc., 100 Colonial Center Parkway, Lake Mary, Florida 32746.

(c) The Commission investigative attorney, party to this investigation, is Thomas S. Fusco, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street, SW., Room 401Q, Washington, DC 20436; and

(3) For the investigation so instituted, the Honorable Carl C. Charneski is designated as the presiding administrative law judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(d) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of the respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or cease and desist orders or both directed against the respondent.

By order of the Commission.

Issued: March 25, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–6496 Filed 3–28–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1092 and 1093 (Final) (Remand)]

Diamond Sawblades and Parts Thereof From China and Korea

AGENCY: United States International Trade Commission.

ACTION: Notice of remand proceedings.

SUMMARY: The U.S. International Trade Commission (''Commission'') hereby gives notice of the court-ordered remand of its final determinations in the antidumping investigation Nos.731–TA–1092–1093 concerning diamond sawblades and parts thereof from China and Korea. For further information concerning the conduct of this

proceeding and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subpart A (19 CFR part 207).

DATES: *Effective Date:* March 24, 2008.

FOR FURTHER INFORMATION CONTACT: Douglas Corkran, Office of Investigations, telephone 202–205–3057, or Charles St. Charles, Office of General Counsel, telephone 202–205–2782, U.S. International Trade Commission, 500 E Street, SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record of investigation Nos. 731–TA–1092 and 1093 may be viewed on the Commission's electronic docket (''EDIS'') at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—In July 2006, the Commission determined that an industry in the United States was not materially injured or threatened with material injury by reason of imports of diamond sawblades and parts thereof from China and Korea that are sold in the United States at less than fair value. The Commission's determinations were appealed to the Court of International Trade (''CIT'' or ''Court''). On February 6, 2008, the Court issued a decision remanding the matter to the Commission for further proceedings consistent with that opinion. *Diamond Sawblade Manufacturers* v. *United States,* Slip Op. 08–18 (Ct. Int'l Trade, Feb. 6, 2008). In its opinion, the Court found that the Commission had not provided adequate explanation or substantial evidentiary support for certain of its findings. The Court instructed the Commission to provide further explanation of its finding that there was limited competition between the subject imports from China and Korea and the domestic like product during the period of investigation, and to provide further explanation of its volume, price, impact, and threat findings, to the extent they were based on the Commission's limited competition finding. The Court also instructed the Commission to provide further explanation of certain aspects of its finding that there was not a correlation between domestic producers' price movements and prices for the subject imports.

Participation in the proceeding.—Only those persons who were interested parties and parties to the proceeding in the investigations and were also parties to the action before the CIT may participate in the remand proceeding. Such persons need not make any additional filings with the Commission to participate in the remand proceeding. Business proprietary information (''BPI'') referred to during the remand proceeding will be governed, as appropriate, by the administrative protective order issued in the investigations.

Written submissions.—The Commission is reopening the record for the limited purpose of collecting data pertinent to its analysis of the extent to which competition between subject diamond sawblade imports and the domestic like product was or was not limited during the period of investigation by differences in product and customer types. The Commission will permit the parties to file comments addressing the new information obtained by the Commission on remand and the specific issues that are the subject of the CIT's remand instructions. The parties may not submit any new factual information in their comments; nor may they raise issues that are not the subject of the remand instructions. Any such comments must be filed with the Commission no later than April 18, 2008, and must be no more than twenty (20) double-spaced, single-sided pages of textual material. The Commission will not hold a hearing on remand.

All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 FR 68036 (Nov. 8, 2002).

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Parties are also advised to consult with the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR Part 201), and part 207, subpart A (19 CFR Part 207) for provisions of general applicability concerning written submissions to the Commission.

By order of the Commission.

Issued: March 24, 2008.

William R. Bishop,

Acting Secretary to the Commission.

[FR Doc. E8–6302 Filed 3–28–08; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–454; 731–TA–1144 (Preliminary)]

Welded Stainless Steel Pressure Pipe From China

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (Commission) determines, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 19 U.S.C. 1673b(a)) (the Act), that there is a reasonable indication that an industry in the United States is materially injured,[2] or threatened with material injury [3] by reason of imports from China of welded stainless steel pressure pipe, provided for in subheading 7306.40 of the Harmonized Tariff Schedule of the United States, that are alleged to be subsidized by the Government of China and sold in the United States at less than fair value (LTFV).

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the Department of Commerce (Commerce) of affirmative preliminary determinations in these investigations under sections 703(b) and 733(b) of the Act, or, if the preliminary

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR § 207.2(f)).

[2] Commissioner Charlotte R. Lane, Commissioner Irving A. Williamson, and Commissioner Dean A. Pinkert determine that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of welded stainless steel pressure pipe from China.

[3] Chairman Daniel R. Pearson, Vice Chairman Shara L. Aranoff, and Commissioner Deanna Tanner Okun determine that there is a reasonable indication that an industry in the United States is threatened with material injury by reason of imports of welded stainless steel pressure pipe from China.

determinations are negative, upon notice of affirmative final determinations in those investigations under sections 705(a) and 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Background

On January 30, 2008, a petition was filed with the Commission and Commerce by Bristol Metals (Bristol, TN), Felker Brothers Corp. (Marshfield, WI), Marcegaglia USA Inc. (Munhall, PA), Outoukumpu Stainless Pipe, Inc. (Schaumburg, IL), and the United Steel Workers of America (Pittsburgh, PA), alleging that an industry in the United States is materially injured or threatened with material injury by reason of subsidized and LTFV imports of welded stainless steel pressure pipe from China. Accordingly, effective January 30, 2008, the Commission instituted countervailing duty investigation No. 701–TA–454 (Preliminary) and antidumping duty investigation No. 731–TA–1144 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of February 5, 2008 (73 FR 6741). The conference was held in Washington, DC, on February 21, 2008, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on March 17, 2008. The views of the Commission are contained in USITC Publication 3986 (March 2008), entitled *Welded Stainless Steel Pressure Pipe from China: Investigation Nos. 701–TA–454 and 731–TA–1144 (Preliminary).*

By order of the Commission.

Issued: March 25, 2008.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. E8–6497 Filed 3–28–08; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Office of the Secretary

Submission for OMB Review: Comment Request

March 25, 2008.

The Department of Labor (DOL) hereby announces the submission of the following public information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chapter 35). A copy of this ICR, with applicable supporting documentation; including among other things a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAMain* or by contacting Darrin King on 202–693–4129 (this is not a toll-free number) / e-mail: *king.darrin@dol.gov.*

Interested parties are encouraged to send comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Employment and Training Administration (ETA), Office of Management and Budget, Room 10235, Washington, DC 20503, Telephone: 202–395–7316 / Fax: 202–395–6974 (these are not a toll-free numbers), e-mail: *OIRA_submission@omb.eop.gov* within 30 days from the date of this publication in the **Federal Register**. In order to ensure the appropriate consideration, comments should reference the OMB Control Number (see below).

The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Agency: Employment and Training Administration.

Type of Review: Revision of a currently approved collection.

Title: Application for Permanent Employment Certification.

OMB Control Number: 1205–0451.

Form Number: ETA–9089.

Affected Public: Business or other for-profits.

Estimated Number of Respondents: 120,000.

Estimated Total Annual Burden Hours: 340,585.

Estimated Total Annual Costs Burden: $2,500,000.

Description: The application Form 9089 and other information requirements are necessary to the collection of information from U.S. employers wishing to sponsor foreign labor for permanent residency through the Labor Certification process. The information collected is used by the Secretary of Labor to make the necessary certification in compliance with the Immigration and Nationality Act as amended. The applicable regulations are located at Title 20 CFR Part 656 and Tile 8 CFR 204.5. For additional information, see related notice published at 72 FR 48689 on August 24, 2007.

Darrin A. King,

Acting Departmental Clearance Officer.

[FR Doc. E8–6467 Filed 3–28–08; 8:45 am]

BILLING CODE 4510–FP–P

DEPARTMENT OF LABOR

Proposed Information Collection for Workforce Innovation in Regional Economic Development (WIRED) Initiative Evaluation; Comment Request

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden conducts a preclearance consultation program to provide the general public and federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested

data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Employment and Training Administration is soliciting comments on a new data collection for the Workforce Innovation in Regional Economic Development (WIRED) Initiative Evaluation.

A copy of the proposed information collection request (ICR) can be obtained by contacting the office listed below in the **ADDRESSEE** section of this notice or by accessing: *http://www.doleta.gov/OMBCN/OMBControlNumber.cfm.*

DATES: Written comments must be submitted to the office listed in the **ADDRESSEE'S** section below on or before May 30, 2008.

ADDRESSES: Submit written comments to the Employment and Training Administration, Room N–5641, 200 Constitution Avenue, NW., Washington, DC 20210, Attention: Eileen Pederson Telephone number: 202–693–3647 (this is not a toll-free number). Fax: 202–693–2766. E-mail: *Pederson.eileen@dol.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In February 2006, under authority of section 414 of the American Competitiveness and Workforce Improvement Act of 1998, the Employment and Training Administration (ETA) awarded grants to 13 regions across the United States to support community efforts to link their varied knowledge resources with their business and innovation assets, and to ensure that their workforces have the skills and knowledge required to work effectively in new and emerging industries. In addition to grant funds, each of these grantees, collectively known as Generation I regions, is also eligible to receive access to ongoing technical assistance provided directly and indirectly from ETA. At the same time that these grants were awarded, ETA selected another 13 regions to receive $100,000 to support their participation in peer-to-peer grantee conferences (known as WIRED Academies) and other learning opportunities. In early 2007, ETA increased the funds awarded to these regions, at which time they became known as the Generation II regions. Finally, in June 2007, ETA awarded grants to 13 more regions, known as the Generation III regions.

The WIRED Initiative focuses on labor market areas that are comprised of multiple jurisdictions within states or across state borders. It supports innovative approaches to workforce development, training and education that go beyond traditional strategies for preparing workers to compete and succeed both within the United States and globally. Through the initiative and with support and guidance from their state Governors, WIRED regions have a unique opportunity to design and implement strategic approaches for coordinated regional economic development and job growth. For the grant awards, ETA selected regions that demonstrated the presence of labor market elements (unemployment, low-wages, low levels of new job creation) and economic conditions (such as industries that are declining or industries targeted for growth) that are driving the need for transformation. In addition, each grant recipient described how the region will: Implement new strategic efforts designed to drive integration among workforce, economic development and education systems; promote innovation in addressing challenges; and utilize and build upon existing structures, resources and legislatively-funded programs. Finally, each region outlined the presence of a strategic partnership that is representative of the entire economic region and is comprised of a strong team of regional leaders which will lead the regional transformation.

This data collection covers qualitative information to be obtained through on-site, unstructured interviews with representatives in each WIRED region. Data to be collected includes information regarding the regional context, goals, planning, structure, partnerships, collaboration, activities, funding, challenges, innovations, approaches for measuring success, and sustainability.

II. Review Focus

The Department of Labor is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions

Type of Review: New.

Agency: Employment and Training Administration.

Title: Workforce Innovation in Regional Economic Development (WIRED) Initiative Evaluation.

OMB Number: 1205–0NEW.

Record Keeping: NA.

Affected Public: State, local, or tribal government; business or other for-profit; and not-for-profit institutions.

Total Respondents: Approximately 2,400.

Frequency: The unstructured interviews will be conducted annually, for two years, per Generation of regions, per following table.

Year	Group of regions	Number of respondents	Total responses	Average time per response (min)	Annual burden (hrs)
2008 ..	Generation 1	800	800	45	600
2009 ..	Generation 1	800	800	45	1,800
	Generation 2	800	800	45	.....
	Generation 3	800	800	45	.....
2010 ..	Generation 2	800	800	45	1,200
	Generation 3	800	800	45	
3 year Total		4,800	4,800	.....	3,600

Total Annual Responses: An average of approximately 1,600.

Average Time per Response: 45 minutes per interview.

Estimated Total Burden Hours: The total annual burden hours is estimated to be 1,200 hours.

Total Burden Cost: Varies per year, per following table.

Year	Group of regions	Annual burden (hrs)	Average cost per hour	Annual burden cost
2008	Generation 1	600	$36	$21,600
2009	Generation 1	600	36	64,800
	Generation 2	600	36	
	Generation 3	600	36	
2010	Generation 2	600	36	43,200
	Generation 3	600	36	
Total		3,600		129,600

The cost to regional representatives to participate in the unstructured interviews, based on an annual average salary of $75,000 per representative, is approximately $129,600.

Comments submitted in response to this comment request 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: March 26, 2008.

Thomas M. Dowd,

Administrator, Office of Policy Development and Research, Employment and Training Administration.

[FR Doc. E8–6549 Filed 3–28–08; 8:45 am]

BILLING CODE 4510–FN–P

NUCLEAR REGULATORY COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The NRC is preparing a submittal to OMB for review of continued approval of information collections under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* NRC Form 354, ''Data Report on Spouse.''

2. *Current OMB approval number:* 3150–0026.

3. *How often the collection is required:* On occasion.

4. *Who is required or asked to report:* NRC contractors, licensees, applicants and others (e.g. intervenor's) who marry or cohabitate after completing the Personnel Security Forms, or after having been granted an NRC access authorization or employment clearance.

5. *The number of annual respondents:* 60.

6. *The number of hours needed annually to complete the requirement or request:* 12 hours (0.2 hours per response).

7. *Abstract:* NRC Form 354 must be completed by NRC contractors, licensees, and applicants who marry or cohabitate after completing the Personnel Security Forms, or after having been granted an NRC access authorization or employment clearance. Form 354 identifies the respondent, the marriage, and data on the spouse and spouse's parents. This information permits the NRC to make initial security determinations and to assure there is no increased risk to the common defense and security.

Submit, by May 30, 2008, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the draft supporting statement may be viewed free of charge at the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O–1 F21, Rockville, MD 20852. OMB clearance requests are available at the NRC worldwide Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/index.html.* The document will be available on the NRC home page site for 60 days after the signature date of this notice.

Comments and questions about the information collection requirements may be directed to the NRC Clearance Officer, Margaret A. Janney (T–5 F52), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–7245, or by e-mail to *INFOCOLLECTS@NRC.GOV.*

Dated at Rockville, Maryland, this 25th day of March 2008.

For the Nuclear Regulatory Commission.

Gregory Trussell,

Acting NRC Clearance Officer, Office of Information Services.

[FR Doc. E8–6518 Filed 3–28–08; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57550; File No. SR–ISE–2008–30]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Regarding Responses to Special Orders

March 24, 2008.

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 March 19, 2008, the International Securities Exchange, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Items I and II below, which Items have been substantially prepared by ISE. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder,[4] which renders it effective upon filing with the Commission.[5] The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE proposes to amend its rules regarding responses to special orders. The text of the proposed rule change is available at ISE, the Commission's Public Reference Room, and *http://www.iseoptions.com*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the ISE included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The ISE has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposed rule change is to amend the Exchange's rules regarding responses to special orders. Currently, when members enter orders into the options trading system's Block Mechanism, Facilitation Mechanism, and Solicited Order Mechanism, the orders are exposed to all market participants for three seconds. However, the Exchange's rules restrict on whose behalf a member may respond. In the case of the Block, Facilitation and Solicited Order Mechanisms, members may not enter responses on behalf of options market makers on other exchanges.

Many of ISE's members operate as market makers on other exchanges that do not have this same type of restrictions in their rules. Accordingly, the Exchange proposes to eliminate the restriction on the entry of orders for the account of market makers of another options exchange. The Exchange does not believe that this proposed rule change will have a material effect on the current participation in trades entered into the mechanisms. Further, this proposed rule change will bring ISE's rules into conformance with those of the other exchanges who, as noted above, do not have this restriction in their rules.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations under the Act applicable to a national securities exchange and, in particular, the requirements of section 6(b) of the Act.[6] Specifically, the Exchange believes the proposed rule change is consistent with section 6(b)(5) of the Act [7] requirements that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts and, in general, to protect investors and the public interest. In particular, the proposed rule change will strengthen the Exchange's competitive position while allowing a greater number of market participants to respond to special orders on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change does not 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

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (1) significantly affect the protection of investors or the public interest; (2) impose any significant burden on competition; and (3) become operative for thirty days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to section 19(b)(3)(A) of the Act [8] and Rule 19b–4(f)(6) [9] thereunder.[10]

A proposed rule change filed under Commission Rule 19b–4(f)(6) [11] normally does not become operative prior to thirty days after the date of filing. The Exchange requests that the Commission waive the 30-day operative delay, as specified in Rule 19b–4(f)(6)(iii), and designate the proposed rule change to become operative immediately. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver will enable a greater number of market participants to respond to special orders on the Exchange. For these reasons, the Commission designates the proposed rule change as effective upon filing.[12]

At any time within 60 days of the filing of such proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, 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 Number SR–ISE–2008–30 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary,

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The Exchange has asked the Commission to waive the 30-day operative delay required by Rule 19b–4(f)(6)(iii), 17 CFR 240.19b–4(f)(6)(iii). See discussion *infra* Section III.

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

[10] Pursuant to Rule 19b–4(f)(6)(iii), the Exchange gave the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date on which the Exchange filed the proposed rule change. *See* 17 CFR 240.19b–4(f)(6)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] For the purposes only of waiving the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2008–30. 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 Room, 100 F Street, NE., Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the ISE. All comments 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 Number SR–ISE–2008–30 and should be submitted on or before April 21, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–6476 Filed 3–28–08; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57553; File No. SR–ISE–2007–76]

Self-Regulatory Organizations; International Securities Exchange, LLC; Order Approving a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2 Thereto, Relating to Voluntary Professionals

March 25, 2008.

I. Introduction

On August 24, 2007, the International Securities Exchange, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder[2] to allow Public Customers to elect to become ''Voluntary Professionals,'' and thereby to have their orders treated like Non-Customer Orders with respect to the Exchange's priority rules and transaction fees.[3] On January 25, 2008, ISE filed Amendment No. 1 to the proposed rule change. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on February 7, 2008.[4] The Commission received one comment letter on the proposal.[5] On March 24, 2008, ISE filed Amendment No. 2 to the proposed rule change.[6] This order approves the proposed rule change, as modified by Amendment Nos. 1 and 2.

II. Description of the Proposal

Currently, ISE grants certain advantages to Public Customer Orders[7] over Non-Customer Orders. In particular, Public Customer Orders receive priority over Non-Customer Orders and market maker quotes at the same price. In addition, subject to certain exceptions,[8] Public Customer Orders do not incur transaction fees, but may incur cancellation fees.[9] Non-Customer Orders incur transaction fees, but are not subject to cancellation fees.

ISE proposes to add a new term, ''Voluntary Professional,'' to the list of definitions in Exchange Rule 100. A Voluntary Professional would be defined as ''any Public Customer that elects, in writing, to be treated in the same manner as a broker or dealer in securities for purposes of Rules 713, 716, 722, and 723 as well as the Exchange's schedule of fees.''[10] ISE proposes further to amend its definition of Non-Customer to include Voluntary Professionals.[11] Thus, the orders of Voluntary Professionals would be Non-Customer Orders. Public Customers would be required to instruct Electronic Access Members (''EAMs'') in writing to designate their orders as Non-Customer Orders.

As a result of ISE's proposal, the orders of Voluntary Professionals would be treated in ISE's allocation process on equal terms with the orders of broker-dealers, and the orders of other Public Customers would have priority over the orders of Voluntary Professionals. The orders of Voluntary Professionals, when executed, also would incur the same transaction fees that are charged to broker-dealers.

In explaining the purpose of the proposal, the Exchange states that its members have indicated that certain of their non-broker-dealer customers, who employ sophisticated trading strategies that involve cancelling a large percentage of their orders before the orders are executed, would prefer to have their orders categorized as Non-Customer Orders. By electing to become Voluntary Professionals, such customers would not be subject to the Exchange's cancellation fees.[12]

ISE further states that the Voluntary Professional designation otherwise would not affect non-broker-dealer individuals and entities with respect to all other ISE rules. For example, ISE

[13] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A ''Public Customer'' is defined in ISE's rules as ''a person that is not a broker or dealer in securities.'' ISE Rule 100(a)(38). A ''Non-Customer'' is defined as ''a person or entity that is a broker or dealer in securities,'' and a ''Non-Customer Order'' is ''an order for the account of a Non-Customer.'' ISE Rules 100(a)(27) and (28).

[4] *See* Securities Exchange Act Release No. 57255 (February 1, 2008), 73 FR 7348.

[5] *See* letter from Rachel J. Rich, St. Paul, MN, to Nancy M. Morris, Secretary, Commission, dated February 7, 2008 (''Rich Letter'').

[6] In Amendment No. 2, ISE stated that it would issue a circular informing members of the process to properly mark the orders of Voluntary Professionals. The Commission considers Amendment No. 2 a technical amendment not subject to notice and comment.

[7] A ''Public Customer Order'' is defined as ''an order for the account of a Public Customer.'' ISE Rule 100(a)(39). For the definition of ''Public Customer,'' *see supra* note 3.

[8] For example, Public Customer Orders currently incur fees for certain transactions in ''Premium Products'' (defined in the ISE Schedule of Fees) and Complex Orders that take liquidity on the Exchange's complex order book. In addition, transaction fees are charged for Public Customer Orders entered in response to special order broadcasts, such as Facilitation orders, Solicitation orders, Block orders, and orders entered in the Exchange's Price Improvement Mechanism. *See* ISE Schedule of Fees.

[9] The Exchange imposes a cancellation fee, currently $1.75 per cancellation, on a clearing EAM that cancelled at least 500 Public Customer orders in a month for itself or for an introducing broker, for each order cancellation in excess of the total number of orders executed for itself or for such introducing broker that month. The cancellation fee does not apply to the cancellation of Public Customer Orders that improve ISE's disseminated quote at the time the orders were entered.

[10] ISE Rules 713 (Priority of Quotes and Orders), 716 (Block Trades), 722 (Complex Orders), and 723 (Price Improvement Mechanism for Crossing Transactions) contain provisions concerning priority in the allocation of orders. The Commission notes that the orders of Voluntary Professionals would still be treated as Public Customer Orders with respect to the rules governing Customer Participation Orders as set forth in ISE Rule 715 (Types of Orders).

[11] ISE Rule 100(a)(21) would be amended to state: ''The term 'Non-Customer' means a person or entity that is a broker or dealer in securities and Voluntary Professionals.''

[12] *See supra* note 9 and accompanying text.

rules relating to the Intermarket Linkage [13] would continue to apply to all customers who are not broker-dealers—even those customers whose orders are identified as Non-Customer Orders because they are Voluntary Professionals. Similarly, rules regarding customer suitability and other protections for customers would continue to apply with respect to all customers who are not broker-dealers.[14]

III. Discussion and Commission Findings

After careful consideration of the proposed rule change, the Commission finds that the proposed rule change is consistent with Section 6(b) [15] of the Act and the rules thereunder.[16] In particular, the Commission believes that the proposed rule change is consistent with Section 6(b)(5) of the Act,[17] which requires that the rules of a national securities exchange, among other things, be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest; and not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The proposed rule change would allow Public Customers to elect to become Voluntary Professionals by choosing to instruct EAMs to designate their orders as Non-Customer Orders. Through such an election, the orders of such customers no longer would be subject to cancellation fees. The Commission believes that, in view of this result, the ability to become a Voluntary Professional could represent significant savings for a Public Customer whose trading strategy involves placing, and then cancelling, orders frequently.

By electing to become a Voluntary Professional, a Public Customer would cede the priority rights normally granted to the orders of Public Customers, and fees would be incurred on a Voluntary Professional's transactions. The Commission notes, however, that this result is determined solely by the choice of the customer. Thus, the proposed rule change would not introduce any rule that would alter the preferential treatment accorded to the orders of a Public Customer against that Public Customer's will.

The Commission believes that the proposed rule change would not limit or restrict Public Customers in any way. On the contrary, it would give Public Customers more flexibility and expand their ability to participate cost-effectively in ISE's marketplace. The Commission notes that the one commenter who expressed a view to the Commission regarding the proposal favored the proposed rule change as ''fair and just'' and believed that it would promote increased trading activity.[18]

The Commission notes further that Voluntary Professionals would continue to benefit from all the protections afforded to Public Customers under the rules of the Exchange (other than the advantages Public Customers have with respect to priority and transaction fees). In addition, the advantages with respect to priority and fees would be restored when a Public Customer rescinded its election to be a Voluntary Professional.

In sum, the Commission believes that the proposed rule change appropriately would accommodate Public Customers who employ trading strategies that involve numerous order cancellations by allowing them to assess and determine for themselves the most beneficial status and fee structure for their orders, and to choose accordingly.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[19] that the proposed rule change (SR–ISE–2007–76), as modified by Amendment Nos. 1 and 2, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–6545 Filed 3–28–08; 8:45 am]

BILLING CODE 8011–01–P

[13] *See* Chapter 19 of the ISE Rules.

[14] *See* Chapter 6 of the ISE Rules. Telephone conversation between Ira Brandriss and Ronesha Butler, Special Counsels, Division of Trading Markets, Commission, and Katherine Simmons, Deputy General Counsel, ISE, on March 11, 2008.

[15] 15 U.S.C. 78f(b).

[16] In approving the proposed rule change, the Commission notes that it has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Rich Letter *supra* note 5.

[19] 15 U.S.C. 78s(b)(2).

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–57551; File No. SR–ISE–2008–28]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing of Proposed Rule Change Relating to the Exposure of Public Customer Orders

March 25, 2008.

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 March 18, 2008, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE''), 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 substantially prepared by ISE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE is proposing to expose public customer orders that are not executable on the Exchange before sending an order through the intermarket linkage system (a ''Linkage Order'') on behalf of the public customer. The text of the proposed rule change is available on the Exchange's Web site (*http://www.iseoptions.com*), at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ISE 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. ISE has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The ISE will not automatically execute a customer's options order

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

when the ISE's best bid or offer (''BBO'') is inferior to the national best bid or offer (''NBBO'').[3] Under ISE Rule 803(c)(2)(ii), the primary market maker (''PMM'') is obligated to address public customer orders that are not automatically executed because there is a better price on another exchange. Rule 803(c) specifies that the PMM can either execute the order or send a Linkage Order to any other exchange displaying the best price in an attempt to get the better price for the public customer.[4]

Under the current procedure, if the PMM does not execute the public customer order, it sends a Linkage Order(s) to a competing exchange(s) even though there may be other ISE market makers who would be willing to execute the public customer order at the better price. Additionally, when a PMM sends a Linkage Order to another exchange, it is charged the other exchange's execution fee. Therefore, the cost to the PMM of sending the Linkage Order can be substantial, particularly with respect to other options exchanges that have adopted a maker-taker fee schedule. To retain as much order flow as possible on the ISE and to help reduce PMM costs by reducing the number of Linkage Orders they need to send to other exchanges, we propose to expose public customer orders to all ISE market makers before the PMM sends a Linkage Order to another exchange to give all ISE market makers an opportunity to provide the public customer with the best price.[5]

Specifically, under the proposal, before the PMM sends a Linkage Order on behalf of a public customer, the public customer order will be exposed at the NBBO price for a period established by the Exchange not to exceed one second.[6] During the exposure period, Exchange market makers may enter responses up to the size of the order being exposed in the regular trading increment applicable to the option. If at the end of the exposure period, the order is executable at the then-current NBBO and the ISE is not at the then-current NBBO, the order will be executed against responses that equal or better the then-current NBBO.[7] The exposure period will be terminated if the exposed order becomes executable on the ISE at the prevailing NBBO or if the Exchange receives an unrelated order that could trade against the exposed order at the prevailing NBBO price.[8] If, after an order is exposed, the order cannot be executed in full on the Exchange at the then-current NBBO or better, and it is marketable against the then-current NBBO, the PMM will send a Linkage Order on the customer's behalf for the balance of the order as provided in Rule 803(c)(2)(ii). If the balance of the order is not marketable against the then-current NBBO, it will be placed on the ISE book.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with section 6(b) of the Act[9] in general and furthers the objectives of section 6(b)(5) of the Act[10] in particular in that it should promote just and equitable principles of trade, serve to remove impediments to and perfect the mechanism of a free and open market and a national market system, and protect investors and the public interest. Exposing public customer orders before the PMM sends a Linkage Order on the public customer's behalf will give additional ISE participants an opportunity to provide the orders an execution at the NBBO on the ISE and reduce PMM costs by reducing the number of Linkage Orders sent to other exchanges.

B. Self-Regulatory Organization's Statement on Burden on Competition

This proposed rule change does not 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

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding, or (ii) as to which ISE consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. 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 Number SR–ISE–2008–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Nancy M. Morris, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2008–28. 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 Room on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for

[3] *See* ISE Rule 714.

[4] ISE Rules, Chapter 19 (Intermarket Linkage Rules).

[5] Immediate-or-cancel orders are cancelled if they cannot be executed on the ISE upon entry. Therefore, such orders are not handled by the PMM under Rule 803(c)(2)(ii) and will not be exposed under this proposal.

[6] The Exchange will issue a Circular to inform members of the time period.

[7] Executions will be allocated pro-rata based on size (*i.e.*, the percentage of the total number of contracts available at the same price that is represented by the size of a market maker's response).

[8] The order will be executed against orders and quotes on the book and responses received during the exposure period in price priority. At the same price, customer orders will be executed first in time priority and then all other interest (orders, quotes and responses) will be allocated pro-rata based on size.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

inspection and copying at the principal office of ISE. All comments 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 Number SR–ISE–2008–28 and should be submitted on or before April 21, 2008.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. E8–6546 Filed 3–28–08; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

CommunityExpress Pilot Program

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of Pilot Program extension.

SUMMARY: This notice announces SBA's extension of the CommunityExpress Pilot Program until June 30, 2008. This extension will allow SBA to complete and implement a restructuring of the CommunityExpress program.

DATES: The CommunityExpress Pilot Program is extended under this notice until June 30, 2008.

FOR FURTHER INFORMATION CONTACT: Charles Thomas, Office of Financial Assistance, U.S. Small Business Administration, 409 Third Street, SW., Washington, DC 20416; Telephone (202) 205–6490; *charles.thomas@sba.gov*.

SUPPLEMENTARY INFORMATION: The CommunityExpress Pilot Program was established in 1999 based on the Agency's SBAExpress Program. Lenders approved for participation in CommunityExpress are authorized to use the expedited loan processing procedures in place for the SBAExpress Program, but the loans approved under this Program must be to distressed or underserved markets. To encourage lenders to make these loans, SBA provides its standard 75–85 percent guaranty, which contrasts to the 50 percent guaranty the Agency provides under SBAExpress. However, under CommunityExpress, participating lenders must arrange and, when necessary, pay for appropriate technical assistance for their borrowers under the program. Maximum loan amounts under this Program are limited to $250,000. SBA previously extended CommunityExpress until March 30, 2008 (72 FR 73415) to discuss and develop possible changes and enhancements to the Program.

The further extension of this Program until June 30, 2008, will allow SBA to evaluate several program concepts and features designed to improve the potential effectiveness and efficiency of the program and enhance the prospects of success for the small business borrowers under it.

(Authority: 13 CFR 120.3)

Eric R. Zarnikow,

Associate Administrator for Capital Access.

[FR Doc. E8–6550 Filed 3–28–08; 8:45 am]

BILLING CODE 8025–01–P

[11] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 11196 and # 11197]

Georgia Disaster Number GA–00012

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 1.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for the State of Georgia (FEMA–1750–DR), dated 03/20/2008.

Incident: Severe Storms and Tornadoes.

Incident Period: 03/14/2008 through 03/16/2008.

EFFECTIVE DATE: 03/22/2008.

Physical Loan Application Deadline Date: 05/19/2008.

EIDL Loan Application Deadline Date: 12/22/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: The notice of the Presidential disaster declaration for the State of Georgia, dated 03/20/2008 is hereby amended to include the following areas as adversely affected by the disaster:

Primary Counties: Bartow, Burke, Dekalb, Floyd, Jefferson, Polk.

Contiguous Counties:

Georgia: Chattooga, Emanuel, Glascock, Gordon, Haralson, Henry, Jenkins, Johnson, Mcduffie, Paulding, Pickens, Richmond, Rockdale, Screven, Walker, Warren, Washington.

Alabama: Cherokee, Cleburne.

South Carolina: Aiken, Allendale, Barnwell.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–6552 Filed 3–28–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 11198]

Kentucky Disaster # KY–00014

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Commonwealth of Kentucky (FEMA–1746–DR), dated 02/21/2008.

Incident: Severe Storms, Tornadoes, Straight-line Winds, and Flooding.

Incident Period: 02/05/2008 through 02/06/2008.

EFFECTIVE DATE: 02/21/2008.

Physical Loan Application Deadline Date: 04/21/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 02/21/2008, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Adair, Allen, Bath, Carlisle, Casey, Estill, Franklin, Grayson, Hardin, Meade, Mercer, Metcalfe, Monroe, Morgan, Muhlenberg, Shelby.

The Interest Rates are:

Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11198.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–6554 Filed 3–28–08; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 11199]

Missouri Disaster # MO–00024

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Missouri (FEMA–1749–DR), dated 03/19/2008.

Incident: Severe Storms and Flooding.

Incident Period: 03/17/2008 and continuing.

DATES: Effective Date: 3/19/2008.

Physical Loan Application Deadline Date: 05/19/2008.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT:

A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW., Suite 6050, Washington, DC 20416.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 03/19/2008, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Audrain, Barry, Barton, Bollinger, Butler, Callaway, Camden, Cape Girardeau, Carter, Cedar, Christian, Cole, Cooper, Crawford, Dade, Dallas, Dent, Douglas, Dunklin, Franklin, Gasconade, Greene, Hickory, Howard, Howell, Iron, Jasper, Jefferson, Laclede, Lawrence, Lincoln, Madison, Maries, McDonald, Miller, Mississippi, Moniteau, Montgomery, Morgan, New Madrid, Newton, Oregon, Osage, Ozark, Pemiscot, Perry, Phelps, Pike, Polk, Pulaski, Reynolds, Ripley, Saint Charles, Saint Clair, Saint Louis, Saint Louis City, Sainte Genevieve, Scott, Shannon, St. Francois, Stoddard, Stone, Taney, Texas, Vernon, Warren, Washington, Wayne, Webster, Wright.

The Interest Rates are:

	Percent
Other (Including Non-Profit Organizations) With Credit Available Elsewhere	5.250
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 11199.

(Catalog of Federal Domestic Assistance Number 59008)

Herbert L. Mitchell,

Associate Administrator for Disaster Assistance.

[FR Doc. E8–6553 Filed 3–28–08; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF STATE

[Public Notice 6161]

Notice of Intent To Prepare an Environmental Impact Statement and Notice of Floodplain and Wetland Involvement; Enbridge Energy, Limited Partnership (''Alberta Clipper Project'')

AGENCY: Department of State.

ACTION: Notice of Intent to Prepare an Environmental Impact Statement and Notice of Floodplain and Wetland Involvement; Enbridge Energy, Limited Partnership (''Alberta Clipper Project'').

Enbridge Energy, Limited Partnership (''EELP'') has applied to the Department of State for a Presidential Permit, pursuant to Executive Order 13337 of April 30, 2004, to construct, connect, operate, and maintain a 36-inch diameter crude oil and liquid hydrocarbon pipeline at the U.S.-Canadian border near Neche, Pembina County, North Dakota, for the purpose of transporting liquid hydrocarbons and other petroleum products between the United States and Canada. EELP seeks this authorization in connection with its Alberta Clipper Pipeline Project (''Alberta Clipper Project''), which is designed to transport Canadian crude oil from the Western Canadian Sedimentary Basin (''WCSB'') to existing refinery markets in the Midwest region of the United States.

On July 27, 2007, the Department of State published notice of intent to prepare an environmental assessment and to conduct scoping hearings for the Alberta Clipper Project (72 FR 41381). Based on public comments received during twelve public hearings conducted along the proposed pipeline route in August 2007, comments received by the Department during the 45-day public comment period, and on consultations with other federal agencies, the Department of State has concluded that the issuance of the Presidential Permit to EELP for the Alberta Clipper Project would constitute a major federal action that may have a significant impact upon the environment within the meaning of the National Environmental Policy Act (NEPA). For this reason, the Department of State intends to prepare an environmental impact statement (EIS) to address reasonably foreseeable impacts from the proposed action and alternatives to the proposed action. The Department will comply with section 106 of the Historic Preservation Act and section 7 of the Endangered Species Act.

The U.S. Army Corps of Engineers (Corps) is a cooperating agency in the preparation of the EIS by the Department. The Corps is also independently reviewing the Albert Clipper proposal in connection with its own decision on EELP's application for a Department of the Army section 404 Clean Water Act and section 10 Rivers and Harbors Act permit. Any questions or concerns regarding the aquatic environment along the proposed pipeline route can be forwarded to: U.S. Army Corps of Engineers, St. Paul District, CE MVP–OP–R, Attn: Leo Grabowski, Brainerd Field Office, 10867 East Gull Lake Drive NW., Brainerd, MN 56401–9051.

The purpose of this Notice of Intent is to inform the public about the proposed action. As the proposed project may involve an action in a floodplain or wetland, the EIS will include a floodplain and wetlands assessment and floodplain statement of findings.

FOR FURTHER INFORMATION CONTACT: For information on the proposed project or to receive a copy of the Draft Alberta Clipper EIS when it is issued, contact Elizabeth Orlando at OES/ENV Room

2657, U.S. Department of State, Washington, DC 20520, or by telephone (202) 647–4284, or by fax at (202) 647–5947, or by e-mail at: *albertaclipper@state.gov.* More information on the EELP Alberta Clipper Project, including associated maps and drawings, is available in its entirety from an Enbridge-hosted project Web site: *http://www.enbridgeUS.com/publicinfo.* This Web site will NOT accept public comments for the record. All public documents related to EELP's permit application, including EELP's permit application and the draft EIS when produced, can be viewed and downloaded at: *http://albertaclipper.state.gov.*

SUPPLEMENTARY INFORMATION: In the U.S., the Alberta Clipper Project would consist of approximately 326 miles of new 36-inch-diameter pipeline from the United States-Canada border near Neche, North Dakota to the existing EELP tank farm in Superior, Wisconsin. EELP proposes to construct the pipeline generally along its existing pipeline right-of-way. EELP proposes to begin construction of the project in November 2008. Construction would occur over approximately 14 months, with an in-service date on or before December 31, 2009. U.S. counties that could possibly be affected by construction of the proposed pipeline are:

North Dakota: Pembina.

Minnesota: Kittson, Marshall, Pennington, Red Lake, Polk, Clearwater, Beltrami, Hubbard, Cass, Itasca, Aitkin, St. Louis, Carlton.

Wisconsin: Douglas.

Construction of the proposed pipeline would generally require a 140-foot-wide construction right-of-way to allow temporary storage of topsoil and spoil and to accommodate safe operation of construction equipment. EELP would retain a portion of the construction right-of-way in order to maintain a 75-feet right-of-way from the current outermost pipeline.

Issued in Washington, DC on March 25, 2008.

Stephen J. Gallogly,

Director, International Energy and Commodity Policy, Department of State.

[FR Doc. E8–6565 Filed 3–28–08; 8:45 am]

BILLING CODE 4710–07–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2005–20331]

RIN 2105–AD48

Request for Public Comments and Office of Management and Budget (OMB) Approval of an Existing Information Collection (2105–0552)

AGENCY: Office of the Secretary (OST), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) described below has been forwarded to OMB for extension of the currently approved collection. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** notice with a 60-day comment period soliciting comments on the following collection of information was published on October 10, 2007 (72 FR 57631). The purpose of this notice is to allow the public an additional 30 days from the date of this notice to submit comments on our application to renew ICR 2105–0552, Reports by Carriers on Incidents Involving Animals During Air Transport. The current information collection request approved by OMB expires on March 31, 2008.

DATES: Comments on this notice must be received by April 30, 2008.

ADDRESSES: You may file comments identified by the docket number DOT–OST–2005–20331 by any of the following methods:

- Federal eRulemaking Portal: Go to *http://www.regulations.gov* and follow the online instructions for submitting comments.
- Mail: Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave., SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- Hand Delivery or Courier: West Building Ground Floor, Room W12–140, 1200 New Jersey Ave., SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- Fax: (202) 493–2251.

Instructions: You must include the agency name and docket number DOT–OST–2005–20331 or the Regulatory Identification Number (RIN) for the rulemaking at the beginning of your comment. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in 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 (65 FR 19477–78), or you may visit *http://DocketsInfo.dot.gov*.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Blane A. Workie, Office of the Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation, 1200 New Jersey Ave., SE., Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *blane.workie@dot.gov* (e-mail).

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law No. 104–13, Sec. 2, 109 Stat. 163 (1995) (codified as revised at 44 U.S.C. 3501–3520), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), 1320.12. On October 10, 2007, OST published a 60-day notice in the **Federal Register** soliciting comment on ICRs for which the agency was seeking OMB approval. 72 FR 57631. OST received no comments after issuing this notice. Accordingly, DOT announces that these information collection activities have been re-evaluated and certified under 5 CFR 1320.5(a) and forwarded to OMB for review and approval pursuant to 5 CFR 1320.12(c).

Before OMB decides whether to approve these proposed collections of information, it must provide 30 days for public comment. 44 U.S.C. 3507(b); 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.12(d); see also 60 FR 44978, 44983, Aug. 29, 1995. OMB believes that the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44978, 44983, Aug. 29, 1995. Therefore, respondents should submit their respective

comments to OMB within 30 days of publication of this notice to best ensure their having full effect. 5 CFR 1320.12(c); see also 60 FR 44978, 44983, Aug. 29, 1995.

The summary below describes the nature of the information collection requirement (ICR) and the expected burden.

Title: Reports by Carriers on Incidents Involving Animals During Air Transport.

OMB Control Number: 2105–0552.

Type of Request: Extension without change of a previously approved collection.

Abstract: The requested extension of the approved control number covers the information collection request (ICR) OMB No. 2105–0552, ''Reports by Carriers on Incidents Involving Animals During Air Transport,'' which the Department of Transportation codified at 14 CFR 234.13. Section 234.13, which implements Section 710 of the Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR–21) [i.e., Public Law 106–810], requires U.S. air carriers that provide scheduled service to submit a monthly report on any incidents involving the loss, injury or death of an animal during air transport to the Department's Aviation Consumer Protection Division (ACPD). ''Animal'' is defined in the rule as any warm or cold blooded animal which, at the time of transportation, is being kept as a pet in a family household in the United States. The information gathered from the airline reports is published in DOT's Air Travel Consumer Report to provide the public with a valuable tool to use in choosing which air carrier to travel with when traveling with a pet.

Respondents: Air carriers that transport pets.

Estimated Number of Respondents: 30.

Frequency: 12 reports per year for each respondent

Estimated Annual Burden on Each Respondent: 12 hours a year for each respondent [time to prepare and submit each report (1 hour) multiplied by frequency (12)].

Estimated Total Burden on Respondents: 360 hours [Respondents (30) × Estimated Annual Burden on Each Respondent (12 hours per year)].

Comments are Invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department'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 automated collection techniques or other forms of information technology. As noted earlier, OST published a **Federal Register** notice with a 60-day comment period for this ICR on Wednesday, October 10, 2007. The purpose of this notice is to allow the public an additional 30 days from the date of this notice to submit comments. A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

Issued in Washington, DC, on March 25, 2008.

Samuel Podberesky,

Assistant General Counsel for Aviation Enforcement and Proceedings, U.S. Department of Transportation.

[FR Doc. E8–6591 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Request Revision From the Office of Management and Budget of a Currently Approved Information Collection Activity, Request for Comments; Implementation to the Equal Access to Justice Act

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FAA invites public comments about our intention to request the Office of Management and Budget (OMB) to approve a current information collection. The information is needed to determine an applicant's eligibility for an award of attorney's fees and other expenses under the Equal Access to Justice Act.

DATES: Please submit comments by May 30, 2008.

FOR FURTHER INFORMATION CONTACT: Carla Mauney on (202) 267–9895, or by e-mail at: *Carla.Mauney@faa.gov*.

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Implementation to the Equal Access to Justice Act.

Type of Request: Extension of an approved collection.

OMB Control Number: 2120–0539.

Form(s): There are no FAA forms associated with this collection.

Affected Public: A total of 17 Respondents.

Frequency: The information is collected on occasion.

Estimated Average Burden Per Response: Approximately 40 hours per response.

Estimated Annual Burden Hours: An estimated 680 hours annually.

Abstract: The information is needed to determine an applicant's eligibility for an award of attorney's fees and other expenses under the Equal Access to Justice Act.

ADDRESSES: Send comments to the FAA at the following address: Ms. Carla Mauney, Room 712, Federal Aviation Administration, IT Enterprises Business Services Division, AES–200, 800 Independence Ave., SW., Washington, DC 20591.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on March 20, 2008.

Carla Mauney,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. E8–6333 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Agency Information Collection Activity Seeking OMB Approval

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice.

SUMMARY: The FAA invites public comments about our intention to request the Office of Management and Budget's (OMB) revision of a current information collection. The **Federal Register** Notice with a 60-day comment period soliciting comments on the following collection of information was published on December 6, 2007, vol. 72, no. 234, page 68949. This rule revised the airport certification regulations and establishes certification requirements for airports serving scheduled air carrier operations in aircraft with 10–30 seats.

DATES: Please submit comments by April 30, 2008

FOR FURTHER INFORMATION CONTACT: Carla Mauney at *Carla.Mauney@faa.gov.*

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Certification of Airports, 14 CFR part 139.

Type of Request: Extension without change of a currently approved collection.

OMB Control Number: 2120–0675.

Form(s): 5280–1.

Affected Public: An estimated 600 Respondents.

Frequency: This information is collected on occasion.

Estimated Average Burden per Response: Approximately 22 hours per response.

Estimated Annual Burden Hours: An estimated 52,993 hours annually.

Abstract: This rule revised the airport certification regulations and establishes certification requirements for airports serving scheduled air carrier operations in aircraft with 10–30 seats. The changes to 14 CFR Part 139 result in additional information collections from respondents.

ADDRESSES: Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to Nathan Lesser, Desk Officer, Department of Transportation/FAA, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–6974.

Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on March 21, 2008.

Carla Mauney,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. E8–6339 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Request Revision From the Office of Management and Budget of a Currently Approved Information Collection Activity, Request for Comments; Federal Aviation Administration, SWIFT Customer Satisfaction Survey

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FAA invites public comments about our intention to request the Office of Management and Budget (OMB) to approve a current information collection. This collection of information is necessary to determine how satisfied applicants are with the automated staffing solution.

DATES: Please submit comments by May 30, 2008.

FOR FURTHER INFORMATION CONTACT: Carla Mauney on (202) 267–9895, or by e-mail at: *Carla.Mauney@faa.gov.*

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Federal Aviation Administration, SWIFT Customer Satisfaction Survey.

Type of Request: Extension of an approved collection.

OMB Control Number: 2120–0699.

Forms(s): There are no FAA forms associated with this collection.

Affected Public: A total of 50,000 Respondents.

Frequency: The information is collected on occasion.

Estimated Average Burden Per Response: Approximately 3 minutes per response.

Estimated Annual Burden Hours: An estimated 2,500 hours annually.

Abstract: This collection of information is necessary to determine how satisfied applicants are with the automated staffing solution. The information will enable the FAA to improve and enhance its automated staffing process.

ADDRESSES: Send comments to the FAA at the following address: Ms. Carla Mauney, Room 712, Federal Aviation Administration, IT Enterprises Business Services Division, AES–200, 800 Independence Ave., SW., Washington, DC 20591.

Comments are Invited On: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on March 20, 2008.

Carla Mauney,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. E8–6341 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Request Revision From the Office of Management and Budget of a Currently Approved Information Collection Activity, Request for Comments; Certificated Training Centers—Simulator Rule, Part 142

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: The FAA invites public comments about our intention to request the Office of Management and Budget (0MB) to approve a current information collection. To determine regulatory compliance, there is a need for airmen to maintain records of certain training and recentness of experience.

DATES: Please submit comments by May 30, 2008.

FOR FURTHER INFORMATION CONTACT: Carla Mauney on (202) 267–9895, or by e-mail at: *Carla.Mauney@faa.gov.*

SUPPLEMENTARY INFORMATION:

Federal Aviation Administration (FAA)

Title: Certificated Training Centers—Simulator Rule, Part 142.

Type of Request: Extension of an approved collection.

OMB Control Number: 2120–0570.

Forms(s): There are no FAA forms associated with this collection.

Affected Public: A total of 108 Respondents.

Frequency: The information is collected on occasion.

Estimated Average Burden per Response: Approximately 1177.5 hours per response.

Estimated Annual Burden Hours: An estimated 127,180 hours annually.

Abstract: To determine regulatory compliance, there is a need for airmen to maintain records of certain training and recentness of experience; training center have to maintain records of students' training, employee qualification and training, and training program approvals.

ADDRESSES: Send comments to the FAA at the following address: Ms. Carla Mauney, Room 712, Federal Aviation Administration, IT Enterprises Business Services Division, AES–200, 800 Independence Ave., SW., Washington, DC 20591.

Comments are Invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Issued in Washington, DC, on March 20, 2008.

Carla Mauney,

FAA Information Collection Clearance Officer, IT Enterprises Business Services Division, AES–200.

[FR Doc. E8–6342 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Airworthiness Criteria: Airship Design Criteria for Zeppelin Luftschifftechnik GmbH Model LZ N07 Airship

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of issuance of final design criteria.

SUMMARY: This document announces the issuance of final design criteria for the Zeppelin Luftschifftechnik GmbH model LZ N07 airship. The German aviation airworthiness authority, the Luftfahrt-Bundesamt (LBA), forwarded an application for type validation of the Zeppelin Luftschifftechnik GmbH Company KG (ZLT) model LZ N07 airship on October 1, 2001. The airship will meet the provisions of the Federal Aviation Administration (FAA) normal category for airships operations and will be certificated for day and night visual flight rules (VFR); additionally, an operator of this airship may petition for exemption to operate the airship in other desired operations.

EFFECTIVE DATE: March 21, 2008.

FOR FURTHER INFORMATION CONTACT: Federal Aviation Administration, Attention: Mr. Karl Schletzbaum, Project Support Office, ACE–112, 901 Locust, Kansas City, Missouri 64106; telephone: 816–329–4146; e-mail: *karl.schletzbaum@faa.gov*; facsimile (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Background

Under the provisions of the Bilateral Aviation Safety Agreement (BASA) between the United States and Germany, the German aviation airworthiness authority, the Luftfahrt-Bundesamt (LBA), forwarded an application for type validation of the Zeppelin Luftschifftechnik GmbH Company KG (ZLT) model LZ N07 airship on October 1, 2001. The LZ N07 has a rigid structure, 290,330 cubic foot displacement and has accommodations for twelve passengers and two crewmembers. The airship will meet the provisions of the FAA normal category for airships; additionally, an operator of this airship may petition for exemption to operate the airship in other desired operations. The airship will be certificated for day and night visual flight rules (VFR).

Discussion of Comments

On April 10, 2007, the Federal Aviation Administration issued a notice of availability of proposed airworthiness design criteria for the ZLT model LZ N07 airship. The criteria was the certification basis accepted for the U.S. validated of the airship according to 14 CFR part 21, § 21.17(b). This criteria consisted of the German national standard Lufttüchtigkeitsforderungen für Luftschiffe der Kategorien Normal und Zubringer (LFLS) [Airworthiness Requirements: Normal and Commuter Category Airships] and equivalent requirements identified by the national aviation authority of Germany, the LBA.

The notice was published for public comment on May 3, 2007 (72 FR 24656). The comment period closed on June 4, 2007.

A commenter from the airship design industry requested that we extend the comment period for the proposed design criteria. We agreed and issued the reopening of the comment period on July 7 and published a notice on July 16, 2007 (72FR 38858).

Three commenters provided their comments on the notice. While the notice was not a notice of a regulatory change or requirement, the FAA is responding to the comments.

Two commenters came from firms that proposed to operate airships. These comments were supportive of the standard and the process.

The third commenter came from an airship manufacturer, which provided extensive comments as discussed below in the sections of the LFLS.

General Comment

In its decision to accept the German LFLS certification requirements, the FAA has stated, ''the LFLS requirements are at least equivalent to and, in many cases, more conservative than the requirements for the normal category contained in the ADC.'' The LFLS requirements are for an airship designed to meet a ''commuter'' category for carrying passengers, hence a higher level of safety is appropriate. [*Note:* ADC means Airship Design Criteria.]

By this statement, it is implied that the ZLT airship will meet a higher standard of certification, where in fact, the airship does not currently meet several critical safety requirements in both the LFLS and FAA–P–8110–2 Design Criteria. It has, therefore, been designed and accepted to a lesser standard.

More importantly, several of the claims by ZLT to demonstrate an equivalent level of safety are not supported by reasonable argument but are really requests for exemption. They are also at odds with FAA determinations in previous U.S. airship certification programs in critical areas affecting safety of flight and in FAA efforts for standardization.

In reviewing the ZLT exemptions, it also became apparent that the Zeppelin airship design is a significant departure from a conventional non rigid design. The industry and the FAA understand that the designation of conventional non rigid design implies a certain level of capability, especially in emergency conditions, and, therefore a certain level of operating environment has been granted. If the applicant continues to seek exemptions or if these exemptions are granted, it is more appropriate to call this airship a hybrid and, thus, issue special operating limitations, which limit the regime it can fly in.

Generally, it is not understood why such latitude is being contemplated. In previous U.S. airship certification programs, the FAA has rigidly applied, and the airship industry has rigidly complied with certain fundamental airship certification requirements with no exemptions being granted. The ZLT airship certification program in Germany does not appear to have met some of these basic requirements. In addition, the FAA would appear to be

accepting the airship on the basis of the LFLS certification program without close scrutiny of the merits of the ZLT arguments for an equivalent level of safety.

By accepting the ZLT claims, a precedent would be set. To compound the matter, the claims for a dispensation against the requirements are numerous in these critical safety areas, thereby having a cumulative affect and potentially compromising safety.

FAA Response: The FAA reviewed the LFLS and the differences from this standard as applied by the LBA. We then, compared them to the currently accepted airship design criteria, the FAA–P–8110–2 Airship Design Criteria. The LFLS, with the additional or equivalent requirements applied by the LBA to the Zeppelin N07–100 (now referred to as the certification basis), was determined to provide the level of safety specified in 14 CFR part 21, § 21.17(b).

The certification basis criteria, as summarized in the notice, is accepted by the FAA as providing an equivalent level of safety, as specified by the 14 CFR part 21, § 21.17(b), and is the accepted airworthiness criteria for the ZLT LZ N07–100 as defined in that part. In accepting this certification basis, the FAA considered the entire proposed certification basis, and does not consider equivalent levels of safety (for specific regulations), special conditions, or exemptions in this process, as the need to issue such regulatory processes are not required when accepting an airworthiness criteria in total for a special class aircraft. In this case, a criterion that had not been previously accepted, along with equivalencies granted by the local authority, was accepted as the airworthiness criteria and is the certification basis for this special class aircraft.

The ZLT N07–100 airship is a rigid type airship that is capable of operations that have been previously type certificated by the FAA; the rigid structure is the only design feature that has not previously been type certificated. The FAA considers the noticed criteria suitable for the ZLT LZ N07 airship and does not consider it a hybrid type.

Technical Comments

The commenter continued with specific technical comments on the notice criteria:

These fundamental certification requirements where ABC [American Blimp Corporation] considers that ZLT are claiming an unreasonable equivalent level of safety are identified as follows:

1. LFLS Section 881(a) and ADC paragraph 3.4—Proof of Structure
2. LFLS Section 76 and ADC paragraph 2.11 Engine Failure and Ballast Requirements
3. LFLS Section 893(b) and ADC paragraph 4.49 Ballast Requirements during Normal Flight.
4. LFLS Section 143(b) and ADC paragraph 2.14(b)—No Engines—Safe Descent
5. LFLS Section 673(d) and ADC paragraph 4.14(d)—No Mech Linkage—Dual Redundancy.
6. LFLS Section 881 (f) and ADC paragraph 4.43 (f)(g) Emergency Deflation
7. LFLS Section 883(e) and ADC paragraph 4.44(e)—Air to helium Provision
8. LFLS Section 2498(b) and ADC paragraph 6.25 Position Lighting

(1) Comment:

With respect to item 1 above, the commenter stated:

LFLS Section 881(a) and ADC paragraph 3.4—Proof of Structure

The LFLS section 881(a) Envelope design requirement states that ''The envelope must be designed to be pressurized and maintain sufficient super pressure (amount of envelope pressure in excess of ambient pressure) to remain in tension while supporting the limit design loads for all flight conditions and ground conditions''. ZLT claims that they should be exempt from this requirement because the structural integrity of the LZ N07 airship is not dependent on the envelope tension but on the structural integrity of the rigid structure. The structure must, therefore, be subject to a full structural load analysis and full-scale structural tests to ensure it meets the requirement. We are assuming that the FAA will verify that full-scale structural tests were carried out. (The ADC paragraph 3.4 Proof of Structure requirement is very specific in this regard and states, ''Compliance with the strength and deformation requirements must be shown for each critical load condition. Structural analysis may be used only if the structure conforms to those for which experience has shown this method to be reliable.'')

FAA Response

Under the Bilateral Aviation Safety Agreement (BASA) between the FAA and the LBA, the FAA can accept the provisions of the proposed certification basis and the method of compliance accepted by the LBA. In this case, the alternate requirements imposed by the LBA for LFLS section 881(a) are considered acceptable; the method of compliance was also accepted. The corresponding LFLS section to ADC section 3.4 is LFLS section 307. Compliance for these sections was accepted as applied by the LBA. A review of the LFLS requirements shows that structural testing is required for certain parts of the structure.

(2) *Comment:*

With respect to items 2 and 3 above, the commenter stated:

LFLS Section 76 and ADC Paragraph 2.11—Engine Failure and Ballast Requirements and LFLS 893(b) and ADC Paragraph 4.49—Ballast Requirements During Normal Flight

The ADC paragraph 2.11 states ''The airship must be capable of rapidly restoring itself to a state of equilibrium following failure of one or more engines during any flight condition. Only designated ballast may be used.'' The FAA states ''ZLT met this requirement with an equivalent level of safety'' by demonstrating that a zero vertical speed condition can be established for any flight condition, by using the thrust vectoring capability of the remaining engines. Being able to only do this on one engine not on more engines is not equivalent. This equivalent level of safety claim ignores the essential airship capability to conduct a free balloon safe landing as required by LFLS 893(b) and ADC paragraph 4.49.

This requirement is applied to not only single engine failure but also the all-engine failure condition. The FAA in all previous Airship Certification programs in the U.S. has rigidly applied the requirement primarily because it is based on the airship's inability to glide to a safe landing or conduct an autorotation as in a helicopter.

FAA Response:

LFLS section 76 is slightly different than the ADC, in that the LFLS allows for the failure ''of any engine'' and the ADC specifies the failure of ''one or more engines.'' As the goal of the requirement is interpreted to be attaining a zero descent rate, the use of vectored thrust, as accepted by the LBA, was also accepted by the FAA as an acceptable approach.

The provisions of LFLS section 893 apply if a ballast system is installed. The LZ N07–100 airship has a water ballast system, but it is not approved for in-flight use. For this reason, this section was not applied to the LZ N07–100 by the LBA. The FAA has accepted this position.

(3) *Comment:*

With respect to item 4, the commenter stated:

LFLS Section 143(b)—Safe Descent

Section 143(b) and ADC paragraph 4.49 state that ''It must be shown that without engine power, a safe descent and landing under the conditions of section 561 can be made'' In the ZLT narrative, it is stated ''With the airship heavy there is no means to modulate the descent * * *.'' This (flying heavy) is a choice made by the applicant to make the airship more economically viable.

The equivalent level of safety argument that ''A qualitative safety analysis will be performed to show that the simultaneous occurrence of a loss of all engines (combined with worst case weight conditions) is extremely improbable'' is inaccurate. It is not unrealistic to expect a total engine failure at maximum heaviness, as could be the case with fuel contamination. Indeed, total engine failure was experienced in an airship in the U.S. leading to a free balloon landing. This accident occurred one hour into the cross-country flight with the airship in a heavy static weight condition.

Once again, the provisions of this and the previous LFLS section 76 and ADC paragraph 2.11 are a basic airship design requirement and based on the airships inability to glide or conduct an autorotation. It is required to also protect people and property on the ground and not just the occupants of the airship. If the applicant continues to choose to seek an exemption to the safety requirements of a blimp it is more appropriate to call this airship a hybrid and thus issue special operating limitations, which limit the regime it can fly in to unpopulated areas or at higher altitudes over populated areas.

FAA Response:

LFLS section 143 is the applicable requirement which was again subject to an equivalent level of safety issued by the LBA, which allowed an analysis to show that an all engine failure in conjunction with the maximum heaviness was extremely improbable. This approach was also accepted by the FAA. It should be noted that even with all engines inoperative, the airship is still in compliance with LFLS section 561, *Emergency Landing Conditions, General.* As previously stated, the FAA does not consider this airship a hybrid type.

(4) *Comment:*

With respect to item 5 above, the commenter stated:

LFLS Section 673(d) and ADC Para 4.14(d)—No Mechanical Linkage—Dual Redundancy

The LFLS section 673(d) requires that airship without a direct mechanical linkage between the cockpit and primary surfaces, be designed with a dual redundant control system. ABC does not understand why the following statement is made ''dual redundant is considered ambiguous in that it does not clearly define the degree of redundancy required.'' A dual redundant flight control system is a relatively straightforward concept that has been incorporated in many aircraft and the requirement seems quite unambiguous.

It is also stated that compliance will be shown as ''continued safe flight and landing is assured after complete failure of any one of the primary flight control system lanes.'' This ignores the requirements of LFLS section 683(c) for the ''hard over'' condition. Any demonstration must include one of the control fins in a hard-over condition and not just one failed lane. The argument that vectored thrust is part of the primary flight control system then means that it too must comply with Dual Redundancy. Any use of vectorable engines is going to compromise the ability to maintain forward speed and limit this recovery capability.

FAA Response:

LFLS section 673(d) is the applicable requirement, in this case the LBA referred to the requirements for analysis for the control systems as specified in LFLS 1309 as adequate substantiation to show that compliance with LFLS 673(d) had been met. The design of the fly-by-wire control system of the airship was found to be compliant with LFLS 673(d) when considering that the control system was compliant with LFLS 1309. The FAA concurred with the approach.

(5) *Comment:*

With respect to item 6 above, the commenter stated:

LFLS Section 881(f) and ADC paragraph 4.43(f)(g)—Emergency Deflation

LFLS Section 881(f) requires that provisions be maintained to allow for rapid envelope deflation on the airship should it break loose from the mast. ZLT's airship does not meet this requirement. ZLT's claim that the masthead design is fail proof is irrelevant if the airship tears apart behind the nose section and departs the mooring mast. It is not understood why this important design feature is not incorporated for the other reason that it can be used to ensure the airship stays on the ground in any emergency egress of passengers. This again, is a basic design requirement that, coupled with concessions against other design issues, adds to an overall compromised design standard. There is no reason this cannot be incorporated.

FAA Response:

The ADC and LFLS sections fundamentally have the same requirement. As the LZ N07–100 is a rigid type, envelope deflation is not considered a possible option in meeting the safety requirement of these sections. The LBA accepted that an analysis showing the safe life design of the mooring mast and its systems would be adequate to meet this requirement on an equivalent basis. The FAA accepted this as equivalent, with the additional requirement that the applicant also provide additional ground procedures for handling the airship on the ground, transponder activation and notification procedures in the case the airship was lost from the mast.

(6) *Comment:*

With respect to item 7 above, the commenter stated:

LFLS Section 883(e) and ADC Para 4.44(e)—Air to Helium Provision

LFLS section 883(e) and ADC paragraph 4.44(e) requires that provisions be maintained to blow air into the helium space in order to prevent wrinkling of the envelope. The other purpose is to prevent the ballonet from overfilling and possibly rupturing. The ZLT airship does not meet this requirement. In the case of the ZLT airship, one of the ballonets rupturing could bring about a large center of gravity shift. This again, is a basic and essential airship requirement that should have been met.

FAA Response:

Again, the ADC and LFLS sections fundamentally have the same requirement. As the LZ N07–100 is a rigid type, pressurization of the envelope to prevent envelope wrinkling is not applied, as the rigid structure eliminates the need for this requirement. With respect to ballonet rupturing and center of gravity issues, this issue is not identified as a compliance goal for this section.

(7) *Comment:*

With respect to item 8, the commenter stated:

LFLS Section 2498(b) and ADC Para 6.25—Position Lighting

LFLS Section 2498(b) and ADC paragraph 6.25 specify the position lighting requirements for airships. It is not understood why a dispensation should be given for something that can be easily fixed with properly TSO'd LED or similar lighting. ABC had to go through a stringent certification of the lighting on the one model. This was revisited in a new model and the FAA

asked ABC to modify our position lighting by providing two sets of bow lights in slightly different positions to further ensure adequate brilliance in all sectors. It is not understood why any latitude is being given to this basic legal requirement affecting safe navigation of aircraft.

FAA Response:

The FAA notes that there is no LFLS section 2498(b) and that the comparable LFLS section to ADC section 6.25 is LFLS section 1385. The only section where an equivalent level of safety to the LFLS lighting requirements was granted by the LBA is LFLS section 1387(b). The LBA granted this equivalency based on what was considered compensating features of the lighting system installed on the LZ N07–100, and the FAA agreed.

Conclusion

After review of the provided comments, the FAA sees no need to modify the proposed airworthiness criteria. Accordingly, the airworthiness criteria, as issued on April 10, 2007, is adopted as the certification basis for the ZLT LZ N07–100 airship under the provisions of 14 CFR part 21, § 21.17(b).

The design criterion is shown below:

Design Criteria

Applicable Airworthiness Criteria Under 14 CFR part 21

The only applicable requirement for airship certification in the United States is FAA document FAA–P–8110–2, Airship Design Criteria (ADC). This document has been the basis of bilateral validation of airships between Germany and the United States for many years. However, in 1995, the LBA issued the initial version of the *Lufttüchtigkeitsforderungen für Luftschiffe der Kategorien Normal und Zubringer*, (hereafter referred to as the LFLS), which added a commuter category to German airship categories and also added additional requirements for normal category airships. Due to this, where the previously mutually accepted ADC can be considered to be harmonized in practice, the issuance of the LFLS created regulatory differences for normal category airships between the United States and Germany.

In keeping with its bilateral obligations, the FAA has, with assistance from the LBA, determined that regulatory differences exist between the two requirements (ADC versus LFLS). This determination is the Significant Regulatory Differences analysis. In the case of the LZ N07 airship, the German certification was accomplished to the higher standard of the commuter category of the LFLS, with various LBA modifications and additions. The FAA desires to accept the Zeppelin airship model LZ N07 at the same airworthiness standard as it was certificated to in Germany, so we have decided to accept the requirements of the LFLS and the supplemental requirements issued by the LBA as the U.S. certification basis. With this decision, the bulk of the regulatory differences are not relevant, as the FAA is accepting the provisions of the German LFLS certification in the commuter category in its entirety. The FAA has, after comparing the normal category ADC to the commuter category LFLS requirements, determined that all of the LFLS requirements are at least equivalent to and, in many cases, more conservative than the requirements for normal category contained in the ADC.

Regulatory Differences

The LFLS was developed considering the ADC at Change 1, but Change 2 provisions were not considered. There will be one regulatory difference due to this; ZLT will show compliance to ADC § 4.14 at Change 2.

Additional and Alternative Requirements

The German aviation authority, the Luftfaht-Bundesamt (LBA) issued additional requirements, special conditions, and equivalent levels of safety to deal with certain design provisions and airworthiness concerns specific to the design of the LZ N07 that were not anticipated by the LFLS. These requirements will also become part of the U.S. certification basis for this airship.

The U.S. certification basis for the LZ N07 was proposed as an entire certification basis, including those changes required by the FAA and the LBA. Based on the provisions of 14 Code of Federal Regulations (CFR) part 21, §§ 21.17(b), 21.17(c) and 21.29, the following airworthiness requirements were evaluated and found applicable, suitable, and appropriate for this design, and they remained active until August 31, 2007, the FAA has now extended the project termination date to May 31, 2008 and the requirements will stay active until that date.

The German regulation *Lufttüchtigkeitsforderungen für Luftschiffe der Kategorien Normal und Zubringer*, (referred to as the LFLS), effective April 13, 2001; except:

(1) In lieu of compliance to LFLS § 673 the LZ N07 will comply with ADC § 4.14.

(2) B–1 LBA, Equivalent Safety Finding for § 76 LFLS, Engine Failure.

Discussion

The LFLS requires that the airship restore itself to a state of equilibrium after the failure of any one engine during any flight condition. In the case of the LZ N07, a state of equilibrium using designated ballast cannot be achieved as required by the LFLS. ZLT met this requirement with an equivalent level of safety.

In lieu of the provisions of LFLS § 76 the following is required:

In the case of failure of any one engine (of three) it must be shown that a zero vertical speed condition can be established for any flight condition by using the thrust vectoring capability of the remaining two engines and aerodynamic lift.

The time to achieve this zero vertical speed will be demonstrated to be not more than when using a designated ballast system with a minimum discharge rate established in LFLS § 893(d).

(3) B–2 LBA, Equivalent Safety Finding for LFLS § 143(b), Controllability and Maneuverability, General [all engines out].

Discussion

LFLS § 143(b) requires that the airship be capable of a safe descent and landing after failure of all engines under the conditions of LFLS § 561. ZLT met this requirement with an equivalent level of safety.

Even in the event of all engines failing, a limited means to control the descent of the airship is available, but only with the airship in equilibrium. With the airship heavy, there is no means to modulate the descent once speed has dissipated, since the descent rate is determined by heaviness only. However, descent will be stable and no unsafe attitude will result and the worst-case descent rate is still in compliance with the emergency landing conditions of LFLS § 561. This fulfills the safety objective of LFLS § 143(b).

To satisfy the provisions of LFLS § 143(b), the following is required:

A qualitative safety analysis will be performed to show that the simultaneous occurrence of a loss of all engines (combined with worst case weight conditions) is extremely improbable.

(4) B–3 LBA, Equivalent Safety Finding for LFLS § 33(d)(2), Propeller Speed and Pitch Limits.

Discussion

LFLS § 33(d)(2) requires a demonstration with the propeller speed control inoperative that there is a means to limit the maximum engine speed to

103 percent of the maximum allowable takeoff rotations per minute (rpm). The LZ N07 is designed so that in case of a zero thrust condition in flight, the affected engine is shut off. The shutoff rpm is above 103 percent of the maximum allowable takeoff rpm.

The LZ N07 airship is not equipped with a traditional propeller governor system. The propeller speed control function is provided by the AIU (engine control board). If the AIU fails, a means to shut down the engine is provided: called the Limiting System (Lasar). The limiting system provides two functional stages; the first stage limits rpm between 2725 and 2750, in case the AIU engine control board is unable to limit engine speed with the propeller in zero thrust pitch condition. The second stage shuts down the engine at 2900 rpm in case of limiting system first stage failure in order to avoid engine and propeller disintegration hazard to the airship. The shutdown of one engine is considered a major hazard. (*Note:* maximum rpm = 2700, 103 percent maximum rpm = 2781.)

In traditional governor systems during in-flight operation with zero thrust pitch selected, overspeed protection is not assured in case of a governor failure. The LZ N07 design is considered to provide equivalent or improved safety compared to previously certified (traditional) governor systems.

To satisfy the provisions of LFLS § 33(d)(2), the following is required:

The proper function of the systems will be demonstrated by performing a system ground test simulation.

The propeller overspeed capability of 126 percent of the maximum rpm will comply with the provisions of JAR P certification, (JAR P § 170(a)(2)).

(5) B–4 LBA, Equivalent Safety Finding for LFLS § 145, Longitudinal Control.

Discussion

LFLS § 145 requires a demonstration of nose-down pitch change out of a stabilized and trimmed climb and 30 degree pitch angle at maximum continuous power and a nose-up pitch change out of a stabilized and trimmed descent and -30 degree pitch angle at maximum continuous power on all engines. ZLT met this requirement with an equivalent level of safety. The LZ N07 ballonet system limitations prevent stabilized climbs or descents above certain vertical speeds. The procedure required in LFLS § 145 cannot be demonstrated by flight test without modification.

ZLT demonstrated through flight test that sufficient control authority was available to recover from a steep climb or descent when the airship is trimmed for the appropriate climb or descent and is operated under maximum continuous power.

Additionally, it was also shown that it is possible to produce a nose-down pitch change out of a stabilized and trimmed climbing flight and a nose-up pitch change out of a similar descent. The LZ N07 ballonet systems limitations prevent this from being demonstrated at maximum continuous power and 30-degree pitch angle because the climb or descent rates are too high at the resulting airspeed.

To satisfy the provisions of LFLS § 145 the following is required:

A flight test procedure will demonstrate that it is possible to produce:

(1) A nose-down pitch change out of a stabilized climb with a nose-up flight path angle as limited by the ballonet system for the relevant true airspeed or 30 degrees, whichever leads to a lower absolute value.

(2) A nose-up pitch change out of a stabilized descent with a nose-down flight path angle as limited by the ballonet system for the relevant true airspeed or -30 degrees, whichever leads to a lower absolute value.

(6) C–1 LBA, Additional Requirement for a Reliable Load Validation; 14 CFR part 25, § 25.301(b).

Discussion

The present LFLS does not include the requirement for the manufacturer to validate the load assumptions used for stress analyses. 14 CFR part § 25.301(b) requires that methods used to determine load intensities and distribution must be validated by flight load measurement unless the methods used for determining those loading conditions are shown to be reliable.

The following is added as an additional requirement:

The provisions of 14 CFR part 25, § 25.301(b) will be complied with.

(7) D–1 LBA, Additional Requirements for LFLS § 853(a), Compartment Interiors [Flammability of Seat Cushions].

Discussion

LFLS § 853 does not provide requirements for flammability standards for seat cushions as introduced by Amendment 59 of 14 CFR part 25. The LBA requested a proof test for seat cushions with the oil burner as specified in 14 CFR part 25, Appendix F, part II or equivalent for passenger seats, except for crew seats.

To satisfy the provisions of LFLS § 853(a), the following is required:

A proof test for seat cushions with the oil burner as specified in 14 CFR part 25, Appendix F, part II or equivalent for passenger seats will be performed successfully.

(8) D–5 LBA, Additional Requirements for LFLS § 673(d), Primary Flight Controls.

Discussion

LFLS § 673(d) requires that airships without a direct mechanical linkage between the cockpit and primary flight control surfaces be designed with a dual redundant control system. The terminology ''dual redundant'' is considered ambiguous in that it does not clearly define the degree of redundancy required.

To satisfy the provisions of LFLS § 853(a), the following is required:

Compliance with LFLS § 1309 will show that continued safe flight and landing is assured after complete failure of any one of the primary flight control system lanes.

(9) D–6 LBA, Equivalent Safety Finding for LFLS § 771(c), Pilot Compartment [Controls Location with Respect to Propeller Hub].

Discussion

LFLS § 771(c) requires that aerodynamic controls and pilots may not be situated within the trajectories of the designated propeller burst area. Since a thrust vectoring (including a non-swiveling lateral propeller) system has been incorporated into the airship, with two engines forward and one aft engine, formal non-compliance in some cases cannot be avoided.

To satisfy the provisions of LFLS § 771(c), the following is required:

A qualitative safety analysis will be accomplished that considers the mitigating effects of:

(1) The relationship of overall swivel angle of propeller rotational plane versus crucial swivel angle of propeller rotational plane,

(2) The distance between aft propeller and aerodynamic controls, and

(3) The potential energy absorbing and deflecting structure between aft propulsion unit and controls and pilot.

The analysis will consider the following:

The lateral propeller is continuously operating in idle with the exception of ground maneuvering and approach phases.

The rear propeller transitions through its crucial angle only, while swiveling from the horizontal to the vertical position from a takeoff/approach/landing/hover to a level flight configuration.

Aircraft Flight Manual (AFM) procedures, cockpit placarding, and swivel lever markings shall be

established to restrict normal operation in the crucial swivel range.

(10) D–7 LBA, Equivalent Safety Findings for LFLS § 777(c), Cockpit Controls; 1141(a), Powerplant Controls: General; 1143(c), Engine Controls; 1149(a)(2), Propeller Speed and Pitch Controls; 1167(c)(1), Vectored Thrust Controls.

Discussion

LFLS § 777(c), 1141(a), 1143(c), 1149(a)(2), and 1167(c)(1) all involve requirements governing the configuration and characteristics of throttle, propeller pitch, mixture, and thrust vectoring controls. Due to the constant speed throttle control concept allowing infinitely variable thrust vector control between maximum reverse and maximum forward thrust, a non-conventional control system was developed that is partially non-compliant with the requirements. The requirements and the configuration of the LZ N07 are summarized in Table 1 below.

To satisfy the provisions of LFLS § 777(c), 1141(a), 1143(c), 1149(a)(2) and 1167(c)(1) the following is required:

In the case of an identified non-compliance to the LFLS, as shown in Table 1, compliance will be by an evaluation of the airship and a finding that there are safe handling characteristics using the type design engine thrust control/thrust vectoring controls as described in Table 1.

TABLE 1

LFLS paragraph	Requirement	Compliant/non-compliant	Description of equivalent level of safety finding
777(c)	throttle, propeller pitch, mixture controls:. 1. order left to right ..... 2. arrange to prevent confusion	1. non-compliant ..... 2. compliant	Propeller speed, thrust, and mixture controls are arranged in this order from left to right. Propeller speed and mixture are grouped together forward of the THRUST levers because they are preset for individual operating conditions. The THRUST levers are located separately with the L/H and R/H THRUST levers and swivel controls grouped together in order to achieve convenient vector operation. Rear engine thrust control set is offset to the rear of the center pedestal, which makes its allocation to the rear engine obvious.
1141(a)	1. arrangement like 777 ..... 2. markings like 1555(a)	1. compliant as described above. 2. compliant	See 777(c) above; compliant.
1143(c)	1. separate control of engines .. 2. simultaneous control of engines.	1. compliant ..... 2. simultaneous control virtually compliant.	1. compliant 2. simultaneous control of forward engines allows for symmetric thrust applications, which are essential for effective handling of the airship. The aft engine THRUST lever is not located between the forward THRUST levers because it *requires* individual control especially during take-off, hover, landing and ground maneuvering. Unintentional operation of the aft engine is prevented by this arrangement.
1149(a)	simultaneous speed and pitch control of propellers.	Non-compliant for take-off, hover, landing, and ground maneuvering.	In contrast to conventional propeller controls, a constant propeller pitch is commanded directly by the THRUST lever and propeller speed is preselected by the RPM lever and is automatically governed by means of throttle variation. In this operating mode, full RPM is selected and pitch control is commanded directly from the THRUST levers, which are not grouped together, thus not allowing simultaneous pitch control. The reason for this arrangement is explained in issue 1143(c) above, In FLIGHT configuration maximum pitch is preselected by the THRUST levers, speed control is now accomplished by movement of the RPM levers, which are grouped together allowing simultaneous speed control.
1167(c)(1)	Thrust vectoring: ..... 1.—independent of other controls. 2.—separate and simultaneous control of all propulsion units.	1. compliant ..... 2. non compliant	1. compliant. 2. simultaneous vectoring control of forward engines allows for symmetric vectoring. Asymmetric control of forward swivel angle is made impossible in order to prevent pilot confusion during vector control. Aft swivel adjustment is limited to 0 for cruise and −90 for T/L. The aft swivel is separated due to the individual control requirement.

(11) D–8 LBA, Equivalent Safety Findings for LFLS § 807(d) and § 807(d)(1)(i), Emergency Exits.

Discussion

LFLS § 807(d) and (d)(1)(i) for commuter category airships carrying less than 15 passengers requires at least three emergency exits. Refer to Table 2.

TABLE 2

Category versus exits	First exit	Second exit	Third exit
Normal Category (Less than 10 passengers.).	External door/Main door: § 783(a) (19 x 26 inches).	One exit 19 x 26 inches opposite of main door: § 807(a)(1).	No requirement.

TABLE 2—Continued

Category versus exits	First exit	Second exit	Third exit
Commuter Category (Less than 15 passengers.).	Main door must be floor level: § 807(d)(1).	Same as above	In addition one exit 19 x 26 required.
Commuter Category Zeppelin LZ N07. Design comprising 12 passengers.	Floor level main door much larger as 19 x 26 inches provided.	Second floor level main door much larger as 19 x 26 inches provided.	Not provided. Equivalent safety requested for greater than 9 passengers.

The design of the LZ N07 fully complies with the requirement for the Normal Category; however, the third exit required for compliance in the Commuter Category is not provided. This results in a formal noncompliance.

To satisfy the provisions of LFLS § 807(d) and 807(d)(1)(i), the following is required:

Compliance for LFLS § 807(d) and 807(d)(1)(i) will be shown by:

(1) The first and second exits provided are both floor level exits and oversized compared to 19 by 26 inches.

(2) The evacuation demonstration required in § 803(e) shall be accomplished within 60 seconds, (with one exit blocked) instead of 90 seconds.

(12) D–9 LBA, Equivalent Safety Finding for § 881(a), Envelope Design [Envelope Tension].

Discussion

LFLS § 881(a) requires that the envelope maintain tension while supporting limit load conditions for all flight conditions. The rigid design of the LZ N07 allows for limited wrinkling of the envelope under limit load conditions with no effect on airship handling and performance.

Due to the unique kind of rigid structural design, the structural integrity of the LZ N07 airship is not dependent on the tension of the envelope, as rigid structure replaces the load-carrying envelope. The alignment of structure, engines, empennage, cabin and other components affecting handling qualities, performance, and other factors is independent of any wrinkling condition of the envelope.

To satisfy the provisions of LFLS § 881(a), the following is required:

Safe handling characteristics will be demonstrated by flight test, the limit load carrying capability by analysis.

(13) D–10 LBA, Equivalent Safety Finding for LFLS § 881(f), Envelope Design [Rapid Deflation Provisions].

Discussion

LFLS § 881(f) requires that provisions be maintained to allow for rapid envelope deflation of the airship should it break loose from the mast while moored. The present design does not include such a provision. For German certification, ZLT had to demonstrate an equivalent level of safety. As part of this, ZLT presented that, due to the unique kind of rigid structural design of the airship, any rapid deflation provision will not significantly reduce the effective cross section of the envelope; thus, the uncontrolled drift of the airship due to surface winds once free of its moorings could not be brought under control. ZLT presented that the overall level of safety is negatively affected by the potential unwanted operation of the required rapid deflation provision when unintentionally operated or operated due to individual failure conditions, and that this could lead to a potentially severe failure condition.

ZLT was required by the LBA to provide an equivalent level of safety by means of a qualitative safety analysis and by showing that the reliability of the mast coupling system design is significantly improved over typical non-rigid airship systems. It also provided proof of safe life design for the structural parts and to prove the fail-safe design of the hydraulically powered locking mechanism. These systems are part of the ground based mooring vehicle.

We understand that the rigid structure of the airship complicates or eliminates the deflation design feature expected of non-rigid types of airships, and we believe that this requirement cannot be met without an equivalent level of safety. The rapid deflation feature of a non-rigid airship is provided to allow emergency egress without the ship lifting and to deflate the envelope in case an airship is blown off of the mast and is subsequently uncontrolled. These concerns still apply to a rigid airship.

We accept the evacuation procedure, described in the section discussion LFLS § 809(e), as an acceptable equivalent feature for the evacuation requirement.

In the event that the airship is blown off of the mast, we believe that a rigid airship will present the same or enhanced hazard as the requirement for non-rigid type airships was developed to mitigate, that being of an unmanned and, or, uncontrolled airship in controlled airspace in the proximity of persons, property, or other aircraft.

To satisfy the provisions of LFLS § 881(f), the following is required:

Safe life design for the structural parts and fail-safe design of the hydraulically powered locking mechanism of the mooring vehicle will be shown.

The Airship Flight Manual will contain mast procedures for all approved mast mooring conditions. These procedures will also include a requirement to have transponder equipment active when the airship is moored on the mast, and define conditions when a pilot must be in the airship.

(14) D–11 LBA, Equivalent Safety Finding for LFLS § 883(e), Pressure System.

Discussion

LFLS § 883(e) requires that provisions be maintained to blow air into the helium space in order to prevent wrinkling of the envelope. The present design of the airship does not include this provision; therefore, ZLT had to demonstrate equivalent level of safety.

Due to the unique kind of rigid structural design, the structural integrity of the airship is not dependent on the tension of the envelope. Rigid structure replaces the load-carrying envelope. The alignment of structure, engines, empennage, and cabin, etc., affecting handling qualities and airship controllability is independent of any wrinkling condition of the envelope.

To satisfy the provisions of LFLS § 883(e), the following is required:

Safe operation at reduced helium pressures will be demonstrated.

(15) D–12 LBA, Interpretation of LFLS § 785(b), Seats, berths and safety belts [Approval of].

Discussion

The LFLS requires approval for seats; the LBA required approval of passenger and crew seats according to TSO C39b. The ZLT uses seats that are TSO C39b approved by a seat vendor; if this is not done, the seats used will demonstrate compliance to TSO C39b.

To satisfy the provisions of LFLS § 758(b), the following is required:

Seats will comply with the provisions of TSO C39b.

(16) D–13 LBA, Additional Requirement; LFLS § 1585(a)(10), Operating Procedures [Ditching, Emergency Evacuation].

Discussion

The LFLS does not provide requirements for ditching exits; the LBA requested a floatation analysis to be done, to analyze the case of an unplanned ditching. Helium loss during the emergency evacuation procedure was not considered. It was determined by calculation that the passenger cabin provides enough buoyancy for safe egress with the requirement that one emergency exit shall be usable above the static waterline for at least 90 seconds for emergency evacuation.

To satisfy the provisions of LFLS § 758(b), the following is required:

It shall be demonstrated by test or analysis that an emergency evacuation exit will remain above the waterline for at least 90 seconds after finally settling on the water. Relevant instructions will be included in the Airship Flight Manual.

(17) D–14 LBA, Interpretative Material; LFLS § 803(e), Emergency Evacuation Demonstration.

Discussion

LFLS § 803(e) requires an emergency evacuation demonstration. This evacuation must be completed within 90 seconds. Compliance with LFLS § 881(g) must be considered in conjunction with § 803(a) through (e).

This requirement demonstrates the ability of the entire cabin to be evacuated within 90 seconds using the maximum number of occupants, with flight crew preparation for the emergency evacuation. Normal valving of helium to provide emergency deflation on the ground during the emergency evacuation, according to § 881(g), is assumed.

To satisfy the provisions of LFLS § 803(e), the following is required:

(1) It will be demonstrated that the cabin can be emergency egressed within 90 seconds.

(2) In addition, the evacuation method established will include the preparation of the airship for the ground phase of the emergency evacuation on the ground. The applicant will demonstrate by analysis supported by tests that the preparation for cabin emergency evacuation could be conducted within 30 seconds (from time of landing until start of cabin emergency evacuation). This technique will be published in the AFM. Refer to Figure 1, ''ZLT Emergency Evacuation Technique.''

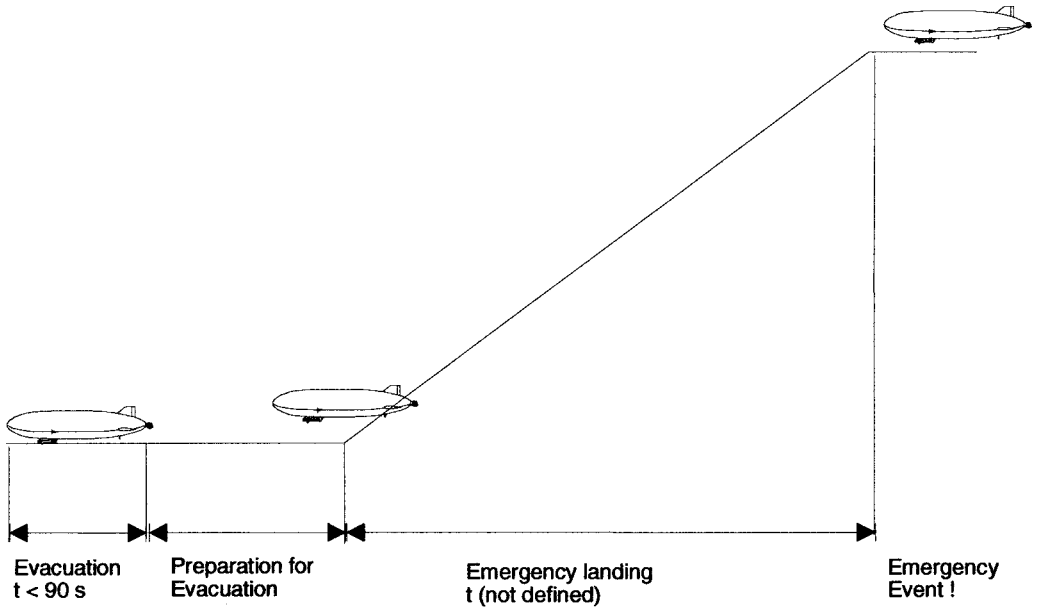

Figure 1: ZLT Emergency Evacuation Technique

(3) The evacuation method established will include four steps:

(a) After the occurrence of the emergency situation, the pilot has to prepare the airship for an emergency landing.

(b) The pilot has to land the airship.

(c) The pilot has to prepare the airship for the evacuation. This includes providing enough heaviness so that the airship cannot leave the ground during the passenger evacuation. Also, the pilot must keep the airship in a safe position before starting the evacuation. By controlling the deflation, the pilot must try to prevent trapping of the envelope over the occupants during the evacuation.

(d) The actual evacuation will only begin when a safe position of the airship can be maintained and when enough heaviness is provided.

These steps will be reflected in the AFM.

(18) D–15 LBA, Additional Requirements; 14 CFR part 23, §§ 23.859 and 23.1181(d), [cabin heating; fuel burner].

Discussion

ZLT wishes to install fuel burner heating equipment for a cabin heating and ventilation system in the lower shell of the passenger cabin. The LFLS does not provide adequate requirements for the installation of fuel burner equipment. The LBA required the application of 14 CFR part 23, §§ 23.859 and 23.1181(d), revised as of January 1, 1998, in addition to other applicable requirements of the LFLS. The LBA interpretation of § 23.859(a) is such that the entire heater compartment will be considered a fire region and has to be of fireproof construction. Part 23 § 23.859, paragraphs (a)(1) to (a)(3), will be complied with also. Other applicable FAA regulations introduced by reference to §§ 23.859 and 23.1181(d) by

the LBA will be complied with by compliance to applicable LFLS sections.

The airship will comply with the provisions of 14 CFR part 23, § 23.859, Combustion Heater Fire Protection, and § 23.1181(d), Firewalls.

(19) E–1 LBA, Additional Requirements Remote Propeller Drive System.

Discussion

The LZ N07 propellers of both forward and aft propulsion systems are not conventionally installed directly on the engine crankshaft. A remote propeller drive system consisting of torque shafts, swivel gears, friction clutches and a belt drive unit (on the aft engine only) is installed between engine and propeller to provide thrust and vector capability for the propellers. The LFLS does not contain requirements for such power transmission designs.

The LBA required compliance as described in LBA guidance paper I–231–87, applicable to components installed between engines and propellers. I–231–87(01) requires compliance with JAR 22H or 14 CFR part 33; however, instead of JAR 22H or 14 CFR part 33 compliance, compliance with applicable sections of JAR P (Change 7) as listed in Table 3 will be required.

TABLE 3.—APPLICABLE SECTIONS OF JAR P AND I–231–87

Section	Summary
I–231–87	Remote torque shafts/Fernwellen.
I–231–87(01)	Alle Bauteile zwischen Motor und Propeller FAR 33.
I–231–87(02)	Kräfte auf kürzestem Weg in tragende Bauteile.
I–231–87(03)	Konstruktive Maβnahmen gegen ungleiche Dehnung.
I–231–87(04)	Bei Drehgelenken ungleichförm. Drehbewegung meiden.
I–231–87(05)	Abstand Struktur zu rotierenden Teilen >13mm.
I–231–87(06)	FVB: Erweichungstemperatur TGA nicht überschreiten.
I–231–87(07)	Nicht feuersichere Wellen: Feuerschutz zum Motor.
I–231–87(08)	Keine Gefährdung durch angetr. Rest gebroch. Welle.
I–231–87(09)	Unterkritischer Lauf/Kritische Drehzahl 1,5*nmax.
I–231–87(10)	Schwingungsversuch mit Anlaβ- Abstellvorgängen.
JAR–P	Propellers: Change 7, dated 22.10.87.
JAR–P01	Section 1—Requirements.
JAR–P01 1A	SUB-SECTION A—GENERAL
JAR–P030(a)(1)	Specification detailing airworthiness requirements.
JAR–P040(b)	Fabrication methods.
JAR–P040(b)(1)	Consistently sound structure and reliable.
JAR–P040(b)(2)	Approved process specifications, if close control required.
JAR–P040(c)	Castings.
JAR–P040(c)(1)	Casting technique, heat treatment, quality control.
JAR–P040(c)(2)	AA Approval for casting production required.
JAR–P040(e)	Welded structures and welded components.
JAR–P040(e)(1)	Welding technique, heat treatment, quality control.
JAR–P040(e)(3)	Drawings annotated and with working instructions.
JAR–P040(e)(4)	If required, radiographic inspection, may be in steps.
JAR–P070	Failure analysis.
JAR–P070(a)	Failure analysis/assessment of propeller and control systems.
JAR–P070(b)(2)	Significant overspeed or excessive drag.
JAR–P070(c)	Proof of probability of failure.
JAR–P070(e)	Acceptability of failure analysis, if more on 1 of:
JAR–P070(e)(1)	A safe life being determined.
JAR–P070(e)(2)	A high level of integrity, parts to be listed.
JAR–P070(e)(3)	Maintenance actions, serviceable items.
JAR–P080	Propeller pitch limits and settings.
JAR–P090	Propeller pitch indications.
JAR–P130	Identification.
JAR–P140	Conditions applicable to all tests.
JAR–P140(a)	Oils and lubricants.
JAR–P140(b)	Adjustments.
JAR–P140(b)(1)	Adjustments prior to test not be altered after verification.
JAR–P140(b)(2)	Adjustment and settings checked/unintentional variations recorded.
JAR–P140(b)(2)(i)	At each strip examination.
JAR–P140(b)(2)(ii)	When adjustments and settings are reset.
JAR–P140(b)(3)	Instructions for (b)(1) proposed for Manuals.
JAR–P140(c)	Repairs and replacements.
JAR–P140(d)	Observations.
JAR–P150	Conditions applicable to endurance tests only.
JAR–P150(a)	Propeller accessories to be used during tests.
JAR–P150(b)	Controls (ground and flight tests).
JAR–P150(b)(1)	Automatic controls provided in operation.
JAR–P150(b)(2)	Controls operated in accordance with instructions.
JAR–P150(b)(3)	Instructions provided in Manuals.
JAR–P150(c)	Stops (ground tests).
JAR–P160	General.
JAR–P160(b)	Pass without evidence of failure or malfunction.
JAR–P160(c)	Detailed inspection before and after tests complete.
JAR–P170(c)	Spinner, deicing equipment, etc., subject to same test.

TABLE 3.—APPLICABLE SECTIONS OF JAR P AND I–231–87—Continued

Section	Summary
JAR–P190(c)	Propellers fitted with spinner and fans.
JAR–P200	Rig tests of propeller equipment.
JAR–P200(a)	Tests for feathering, beta control, thrust reverse.
JAR–P200(b)	Test to represent the amount of 1000 hour cycles.
JAR–P200(c)	Evidence of similar tests may be acceptable.
JAR–P210	Endurance tests.
JAR–P210(b)	Variable pitch propellers.
JAR–P210(b)(1)	Variable pitch propellers tested to one of following:
JAR–P210(b)(1)(i)	A 110-hour test.
JAR–P210(b)(1)(i)(A)	5 hours at takeoff power.
JAR–P210(b)(1)(i)(B)	50 hours maximum continuous power.
JAR–P210(b)(1)(i)(C)	50 hours consisting of ten 5-hour cycles.
JAR–P210(b)(2)	At conclusion of the endurance test total cycles.
JAR–P210(b)(2)(ii)	Governing propellers: 1500 cycles of control.
JAR–P210(b)(2)(iv)	Reversible-pitch propellers: 200 cycles + 30 seconds.
JAR–P220	Functional tests not less 50 in flight.
JAR–P220(b)	Variable pitch (governing) propellers.
JAR–P220(b)(1)	Propeller governing system compatible w. engine.
JAR–P220(b)(2)	Stability of governing under various oil temperatures conditions.
JAR–P220(b)(3)	Response to rapid throttle movements, balked landing.
JAR–P220(b)(4)	Governing and feathering at all speeds up to V_{NE}.
JAR–P220(b)(5)	Unfeathering, especially after cold soak.
JAR–P220(b)(6)	Beta control response and sensitivity.
JAR–P220(b)(7)	Correct operation of stops and warning lights.
JAR–P220(c)	Propeller design for operation in reverse pitch 50 landing.

To satisfy the additional required provisions, the following is required:

Compliance will be shown for the Remote Propeller Drive System to the requirements of LBA document I–237–87, dated September 1987, and the Joint Aviation Requirements (JARs) summarized in Table 3.

TABLE 3.—(REPEATED)

Section	Summary
I–231–87	Remote torque shafts/Fernwellen.
I–231–87(01)	Alle Bauteile zwischen Motor und Propeller FAR 33.
I–231–87(02)	Kräfte auf kürzestem Weg in tragende Bauteile.
I–231–87(03)	Konstruktive Mabnahmen gegen ungleiche Dehnung.
I–231–87(04)	Bei Drehgelenken ungleichfrm. Drehbewegung meiden.
I–231–87(05)	Abstand Struktur zu rotierenden Teilen >13mm.
I–231–87(06)	FVB: Erweichungstemperatur TGA nicht überschreiten.
I–231–87(07)	Nicht feuersichere Wellen: Feuerschutz zum Motor.
I–231–87(08)	Keine Gefährdung durch angetr. Rest gebroch. Welle.
I–231–87(09)	Unterkritischer Lauf/ Kritische Drehzahl 1,5*nmax.
I–231–87(10)	Schwingungsversuch mit Anlab-Abstellvorgängen.
JAR–P	Propellers Change 7, dated 22.10.87.
JAR–P01	Section 1—Requirements.
JAR–P01 1A	SUB-SECTION A—GENERAL.
JAR–P030(a)(1)	Specification detailing airworthiness requirements.
JAR–P040(b)	Fabrication Methods.
JAR–P040(b)(1)	Consistently sound structure and reliable.
JAR–P040(b)(2)	Approved process specification, if close control required.
JAR–P040(c)	Castings.
JAR–P040(c)(1)	Casting technique, heat treatment, quality control.
JAR–P040(c)(2)	AA Approval for casting production required.
JAR–P040(e)	Welded Structures and Welded Components.
JAR–P040(e)(1)	Welding technique, heat treatment, quality control.
JAR–P040(e)(3)	Drawings annotated and with working instructions.
JAR–P040(e)(4)	If required, radiographic inspection, may be in steps.
JAR–P070	Failure Analysis.
JAR–P070(a)	Failure analysis/assessment propeller/control system.
JAR–P070(b)(2)	Significant overspeed or excessive drag.
JAR–P070(c)	Proof of probability of failure.
JAR–P070(e)	Acceptability of failure analysis, if more on 1 of:
JAR–P070(e)(1)	A safe life being determined.
JAR–P070(e)(2)	A high level of integrity, parts to be listed.
JAR–P070(e)(3)	Maintenance actions, serviceable items.
JAR–P080	Propeller Pitch Limits and Settings.
JAR–P090	Propeller Pitch Indications.
JAR–P130	Identification.

TABLE 3.—(REPEATED)—Continued

Section	Summary
JAR–P140	Conditions Applicable to All Tests.
JAR–P140(a)	Oils and Lubricants.
JAR–P140(b)	Adjustments.
JAR–P140(b)(1)	Adjustment prior to test not be altered after verification.
JAR–P140(b)(2)	Adjustment and settings checked/unintentional variations recorded.
AR–P140(b)(2)(i)	At each strip examination.
JAR–P140(b)(2)(ii)	When adjustments and settings are reset.
JAR–P140(b)(3)	Instructions for (b)(1) proposed for Manuals.
JAR–P140(c)	Repairs and Replacements.
JAR–P140(d)	Observations.
JAR–P150	Conditions Applicable to Endurance Tests Only.
JAR–P150(a)	Propeller accessories to be used during tests.
JAR–P150(b)	Controls (Ground and Flight Tests).
JAR–P150(b)(1)	Automatic controls provided in operation.
JAR–P150(b)(2)	Controls operated in accordance with instructions.
JAR–P150(b)(3)	Instructions provided in Manuals.
JAR–P150(c)	Stops (Ground Tests).
JAR–P160	General.
JAR–P160(b)	Pass without evidence of failure or malfunction.
JAR–P160(c)	Detailed inspection before and after tests complete.
JAR–P170(c)	Spinner, deicing equipment, etc., subject to same test.
JAR–P190(c)	Propellers Fitted with Spinner and Fans.
JAR–P200	Rig Tests of Propeller Equipment.
JAR–P200(a)	Tests for feathering, Beta Control, thrust reverse.
JAR–P200(b)	Test to represent the amount of 1000 h cycles.
JAR–P200(c)	Evidence of similar tests may be acceptable.
JAR–P210	Endurance Tests.
JAR–P210(b)	Variable Pitch Propellers.
JAR–P210(b)(1)	Variable Pitch Propellers tested to one of following.
JAR–P210(b)(1)(i)	A 110-Hour Test.
JAR–P210(b)(1)(i)(A)	5 hours at Takeoff Power.
JAR–P210(b)(1)(i)(B)	50 hours Maximum Continuous Power.
JAR–P210(b)(1)(i)(C)	50 hours consisting of ten 5-hour cycles.
JAR–P210(b)(2)	At conclusion of the Endurance Test total cycles.
JAR–P210(b)(2)(ii)	Governing Propellers: 1500 cycles of control.
JAR–P210(b)(2)(iv)	Reversible-pitch Propellers: 200 cycles + 30 sec.
JAR–P220	Functional Tests not less 50 in flight.
JAR–P220(b)	Variable Pitch (Governing) Propellers.
JAR–P220(b)(1)	Propeller governing system compatible with engine.
JAR–P220(b)(2)	Stability of governing under various oil temperature conditions.
JAR–P220(b)(3)	Response to rapid throttle movements, balked landing.
JAR–P220(b)(4)	Governing and feathering at all speeds up to VNE.
JAR–P220(b)(5)	Unfeathering, especially after cold soak.
JAR–P220(b)(6)	Beta control response and sensitivity.
JAR–P220(b)(7)	Correct operation of stops and warning lights.
JAR–P220(c)	Propeller Design for Operation in Reverse Pitch 50 landing.

LBA DOCUMENT I–237–87

Preliminary Guideline for Compliance of Transmission-Shafts in Powerplant Installations of Airplanes (Part 23) and Powered Sailplanes (JAR 22)

LBA-Document: I231–87
Issue: 30. September 1987
Change record: translated into English, May 2002

Translation has been done by best knowledge and judgment. In any case, the officially published text in German language is authoritative.

At the present time the Airworthiness Requirements for motorized aircraft assume only propeller-engine-combinations, where the propeller is directly fixed at the engine flange.

Clutches, transmission shafts, intermediate bearings, angular drives (gearboxes), universal joints, shifting sleeves etc. are accommodated for neither by JAR–22, nor by part 23 (JAR–23), or part 33 (JAR–E).

The necessity to supplement/amend the Airworthiness Requirements became obvious for a powered sailplane, where a transmission shaft from the engine in the middle of the fuselage runs through the cockpit between the pilots (side-by-side seats) to the bow of the fuselage where the propeller is mounted.

The rupture of a so installed transmission shaft can, besides the loss of thrust, also by the whirling of the parts that remain attached to the run-away engine have catastrophic effects to pilots and aircrafts/aeroplanes.

Also differently arranged transmission shafts that do not pass through the cockpit can endanger the surrounding primary structure, the controls or other important systems critically.

For transmission shaft installations the following Special Requirements have to be applied for powered sailplanes and aircraft (aeroplanes) in addition to JAR–22 and part 23 (JAR–23), respectively part 33 (JAR–E):

(l) All parts between engine and propeller, that serve the transfer of engine-power to the propeller are regarded as parts of the engine and are, as far as practicable/applicable, to be shown to comply with JAR–22 Subpart H Engines or part 33 Aircraft Engines (JAR–E), respectively.

(2) Propeller thrust, lateral loads and gyroscopic moments have to be transferred to load carrying members on the shortest possible way.

(3) Dissimilar expansion/deformation between structural and powerplant parts, may it be under loads or/and temperatures has to be accounted for by appropriate means.

(4) Universal joints used in the transmission shaft installation have to be selected and arranged/installed so that an unsteadiness of the rotation speed is avoided.

(5) Wrappings, guidances, protective covers and all other structural members must have such a spacing from rotating parts, that under deformation due to flight or ground loads and if pressure is exerted by parts of the body (pilot or passenger) a radial or respectively longitudinal distance of at least 13 mm (0.5 inch) remains.

(6) It has to be guaranteed that parts made of fibre-reinforced materials during operation do not exceed (reach) the softening temperature. Softening temperature: TGA according to DIN 29971. Compliance has to be sought in a ''cooling test flight'' according to JAR 22.1041/22.1047 or part 23, §§ 23.1041/23.1045/23.1047 (or JAR 23...), respectively.

If the difference between the corrected maximum operational temperature and the softening temperature is less than 15, the operational temperature has to be monitored (continuously) by an instrument.

(7) If parts of the transmission shaft installation are made from material not being fireproof, these parts have to be protected against the effects of fire in the engine compartment.

(8) It has to be shown, that the whirling rest of a broken transmission shaft, still driven by the engine does neither directly endanger occupants (pilots included) nor parts of the primary structure in a way that the flight cannot be brought to a safe end. Compliance has to be sought in a test under the assumption that the shaft is broken at a place most critical for compliance and the engine running at take-off power.

(9) The repeated in-flight-stopping and re-starting of the engine is common practice for powered sailplane. To avoid passing through a critical RPM-range, transmission shaft installation must operate in a sub-critical RPM-range.

The critical RPM of any transmission shaft must be at least 1.5 times the maximum operational RPM. When determining the critical RPM the influences of the maximum imbalance to be expected from the manufacturing process, as well as the bending of the shaft under load factor and probable forced bending by fuselage deformation has to be considered.

(10) The vibration test required by JAR–22.1843 or FAR 33.43 (a)(b)/ (JAR–E) respectively must comprise the complete transmission shaft installation (engine-transmission-shaft-propeller). The effects of engine stopping and restarting must be investigated.

The stresses derived from the test above have to be superimposed with the stresses directly originating from load factors acting on the transmission shaft or are forced on the transmission shaft by deformation of the airframe.

The resulting peak stresses must not exceed the fatigue limit of the material used for the transmission shaft installation.

Figure 2: LBA Document

(20) E–2 LBA, Equivalent Safety Finding; LFLS § 1167(d), Vectored Thrust Components [Auxiliary Thrust Vectoring].

Discussion

LFLS § 1167(d) (subpart E) requires an auxiliary means be provided to return the vectoring thrust system into a normal operating position should the primary means fail. The current design does not include this design feature. The LZ N07 is equipped with a system of swiveling propellers. This system is used for conventional cruise flight with the propellers in a vertical position and also for steering the airship at low airspeeds with the propellers in swiveled positions. This results in no one ''normal position'' of the propeller than can be specified. Even if the propeller swiveling system fails, such a stuck position might be useful for the pilot. Also, since all three engines are operating individually, a single vectoring failure does not interfere with the two remaining propulsion units.

Instead of providing auxiliary means to return the system to the normal operating position, the design, operation, and function of the vectoring system on the Zeppelin LZ N07 airship provides an equivalent level of safety.

To satisfy the provisions of LFLS § 1167(d), the following is required:

It will be shown by flight test that continued safe flight and landing is possible with a propeller stuck in any one position with the affected engine (still) running or shut off.

(21) F–1 LBA, Additional Requirements; LFLS § 1301, Function and Installation; and LFLS § 1309, Equipment, Systems and Installations (HIRF).

Discussion

The LZ N07 utilizes new avionics/electronic systems that provide critical data to the flight crew. The applicable regulations do not contain adequate or appropriate safety standards for the protection of these systems from the effects of high intensity radiated fields (HIRF). The LBA's required additional safety standards considered necessary to establish a level of safety equivalent to that established by existing airworthiness standards.

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from the ground based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control the airship, especially under IFR conditions, have made it necessary to provide adequate protection. To ensure that the level of safety is achieved equivalent to that intended by the regulations incorporated by reference, additional requirements are needed for the LZ N07 to require that new technology electrical and electronic systems be designed and installed to preclude component damage and interruption of critical functions due to effect of HIRF.

High Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, coupled with electrical and electronic command and control of an airship, the immunity of critical systems to HIRF must be established. It is not possible to precisely define the HIRF to which the airship will be exposed in service. There is also uncertainty concerning the effectiveness of gondola shielding for HIRF. Furthermore, coupling of electromagnetic energy to gondola-installed equipment through the windows apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF special condition is shown.

To satisfy the provisions of LFLS § 1301 and LFLS § 1309 the following is required:

The airship systems and associated components, considered separately and in relation to other systems, must be designed and installed so that:

(a) Each system that performs a critical or essential function is not adversely affected when the airship is exposed to the normal HIRF environment.

(b) All critical functions must not be adversely affected when the airship is exposed to the certification HIRF environment.

(c) After the airship is exposed to the certification HIRF environment, each affected system that performs a critical function recovers normal operation without requiring any crew action, unless this conflicts with other operational or functional requirements of that system.

The following definitions apply:

(a) Critical function: A function whose failure would prevent continued safe flight and landing of the airship.

(b) Essential function: A function whose failure would reduce the capability of the airship or the ability of the crew to cope with adverse operating conditions.

(c) The definitions of normal and certification HIRF environments, frequency bands, and corresponding average and peak levels are defined in Table 4 and Table 5.

General Guidance Material

The User Guide for AC/AMJ 20–1317 THE CERTIFICATION OF AIRCRAFT ELECTRICAL AND ELECTRONICAL SYSTEMS FOR OPERATION IN THE HIGH RADIATED FIELDS (HIRF) ENVIRONMENT dated 9/21/98 must be used. In case of conflicting issues, this notice will supersede, unless otherwise notified.

Criticality Definitions

In order to perform hazard assessments, the table below defines equivalence:

TABLE 4

Definition CRI F–1/HIRF	Guidance according to AC/AMJ 20–1317	LFLS certification basis *
Critical	Catastrophic	Multiple failure analysis will not apply in general.
Essential	Hazardous Severe Major	Multiple failure analysis will not apply in general.

* Since the LFLS is based on 14 CFR part 23, multiple failure analysis will not apply in general. However, common mode failures, or failures if one failure would lead inevitably to another failure, have to be considered.

Equipment Test Requirements

If ZLT can demonstrate for Level A, B, or C equipment that equipment testing is adequate for showing compliance, the following equipment test requirement will be used:

RTCA DO–160 D, if equipment development was launched in 1996 or later a no TSO or JTSO certification will be obtained by the supplier.

RTCA DO–160 C, or earlier if equipment development was launched in 1995 or earlier, or if the equipment affected already holds a separate TSO or JZSO certification.

TABLE 5

Frequency	Peak	Average
10 kHz–100 kHz	40	40
100 kHz–500 kHz	40	40
500 kHz–2 MHz	40	40
2 MHz–30 MHz	100	100
30 MHz–70 MHz	20	20
70 MHz–100 MHz	20	20
100 MHz–200 MHz	50	30
200 MHz–400 MHz	70	70
400 MHz–700 MHz	730	30
700 MHz–1 GHz	1300	70
1 GHz–2 GHz	2500	160
2 GHz–4 GHz	3500	240
4 GHz–6 GHz	3200	280
6 GHz–8 GHz	800	330
8 GHz–12 GHz	3500	330
12 GHz–18 GHz	1700	180

Certification HIRF Environment

Field Strengths in Volts/Meter, (V/m).

Note: At 10 kHz–100kHz a Height Impedance Field of 320V/m peak exists.

TABLE 6

Frequency	Peak	Average
10 kHz–100 kHz	20	20
100 kHz–500 kHz	20	20
500 kHz–2 MHz	30	30
2 MHz–30 MHz	50	50
30 MHz–70 MHz	10	10
70 MHz–100 MHz	10	10
100 MHz–200 MHz	30	30
200 MHz–400 MHz	25	25

TABLE 6—Continued

Frequency	Peak	Average
400 MHz–700 MHz	730	30
700 MHz–1 GHz	40	10
1 GHz–2 GHz	1700	160
2 GHz–4 GHz	3000	170
4 GHz–6 GHz	2300	280
6 GHz–8 GHz	530	230

Normal HIRF Environment

Field Strengths in Volts/Meter, (V/m).

Abbreviations:

GHz Gigahertz
IFR Instrument Flight Rules
kHz Kilohertz
m Meter
MHz Megahertz
V Volt

(22) F–2 LBA, Additional Requirements; LFLS § 1301, Function and Installation, and LFLS § 1309, Equipment, Systems and Installations [Software development and transition to RTCA DO–178B/ED–12B].

Discussion

The LZ N07 will be certificated with microprocessor-based systems installed that contain software. The LBA considered that there was limited policy or guidance for transitioning to the use of RTCA DO 178B/ED–12B from earlier guidance regarding means of compliance for software-based systems. Specific transition criteria were specified for the LZ N07 compliance program.

RTCA DO 178B/ED–12B, ''Software Considerations in Airborne Systems and Equipment Certification,'' dated December 1, 1992, provides guidance for software development where industry and regulatory experience showed RTCA document DO 178A/ED–12A, ''Software Considerations in Airborne Systems and Equipment Certification,'' dated 1985, required revision. Through RTCA, Inc./EUROCAE, a joint committee comprised of representatives from both the public and private sectors, created DO 178B/ED–12B to reflect the experience gained in the certification of aircraft and engines containing software based systems and equipment and to provide guidance in the area not previously addressed by DO 178A/ED–12A. DO 178B/ED–12B contains more objectively determinable compliance criteria and considerably enhances the consistency of software evaluations. The use of DO 178B/ED–12B provides for a more thorough and sure compliance finding to objective standards, reducing the likelihood of software errors.

Due to being superseded for the reasons discussed above, DO 178A/ED–12A and prior versions were not recognized by the LBA as acceptable means of compliance for software being developed or being modified for an airship certification program (in Germany) whose application date was later than January 11, 1993 (except as noted in subparagraph 1(a) and 1(b) below). The LZ N07 program fell into this category. ZLT was allowed to propose exceptions to the use of DO 178B/ED–12B (or equivalently acceptable means of compliance) for specific systems or equipment. These requests were evaluated on a case-by-case basis and were considered when:

(a) The LBA determined that the software modification is so simple or straightforward that an upgrade of the applicant's processes to DO 178B/ED–12B from earlier revisions of DO 178/ED–12 is not necessary for assuring that the modification is specified, designed, and implemented correctly, and verified appropriately; or

(b) Where a straightforward and readily obvious determination could be made by the LBA that airworthiness will not be affected if some specific objectives of DO 178B/ED–12B were not met.

One example might be the modification of a code table or local or private data that can be readily verified by inspection. A second example might

be minor gain changes necessary for adoption of existing equipment to a new airframe. A third example might be the modification of a small percentage of code that has no effect on common or global data or other forms of coupling between modules nor interfaces with other equipment or where such effects are easily limited and where such limiting is easily verifiable. A fourth example might be where a non-essential system with Level 3 software per DO 178A/ED–12A would be appropriately re-categorized during the system safety assessment and DO 178B/ED–12B processes as Level E software. Exemptions such as the above were, for the most part, directed at previously approved software-based equipment that had an established and acceptable service history performing the same function in the same installation environment as the new application and for which only significant changes were being made such as outlined above.

Regardless of which version of DO 178/ED–12 was used, ZLT was required to submit to the LBA a Plan for Software Aspects of Certification (PSAC), a Software Configuration Index (SCI), and a Software Accomplishment Summary (SAS) containing the information specified in DO 178B/ED–12B, paragraphs 11.1, 11.16, and 11.20, respectively, in addition to any other information required by the version of DO 178/ED–12 used for the software approval.

For the software being modified, two acceptable methods of upgrading to DO 178B/ED–12B were specified:

(a) ZLT was allowed to upgrade the entire development baseline, including all processes and all data items per the provisions of DO 178B/ED–12B, section 12.1.4. Existing processes and data items that can be shown to already meet the objectives for DO 178B/ED–12B will not need upgrading.

(b) Alternatively, ZLT was allowed to choose an incremental approach, using DO 178B/ED–12B processes to make modifications and upgrading the products (data items) of the life cycle processes only where they are affected by the modification. A regression analysis should identify those areas of the code and other data items affected by the modification. Data items were upgraded in those areas where they were directly affected by the modification (for instance, new requirements) and where required in order to satisfy the objectives of DO 178B/ED–12B, Annex A (for instance, where otherwise unmodified requirements must be upgraded to provide sufficient data for the requirements-based testing of the modified code sections).

In planning the transition activities using either alternative, ZLT should perform an analysis to see where the processes and products of the software life cycle do not satisfy the DO 178B/ED–12B objectives. This will provide a limit to the activity required and criteria for assessing the upgrade.

To satisfy the provisions of LFLS § 1301 and LFLS § 1309, the following is required:

Software development for the LZ N07 will be accomplished according to DO 178B/ED–12B (or equivalently acceptable means of compliance) for specific systems or equipment. Deviations from this requirement will be considered when:

(a) The software modification is so simple or straightforward that an upgrade of the applicant's processes to DO 178B/ED–12B from earlier revisions of DO 178/ED–12 is not necessary for assuring that the modification is specified, designed, and implemented correctly, and verified appropriately; or

(b) Where a straightforward and readily obvious determination can be made by the certifying authority that airworthiness will not be affected if some specific objectives of DO 178B/ED–12B were not met.

The applicant will submit a Plan for Software Aspects of Certification (PSAC), a Software Configuration Index (SCI), and a Software Accomplishment Summary (SAS) containing the information specified in DO 178B/ED–12B, paragraphs 11.1, 11.16, and 11.20, respectively, in addition to any other information required by the version of DO 178/ED–12 used for the software approval.

For software modifications, two methods of upgrading to DO 178B/ED–12B are acceptable:

(a) Upgrade the entire development baseline, including all processes and all data items, per the provisions of DO 178B/ED–12B, section 12.1.4. Existing processes and data items that can be shown to already meet the objectives for DO 178B/ED–12B will not need upgrading.

(b) Choose an incremental approach, using DO 178B/ED–12B processes to make modifications and upgrading the products (data items) of the life cycle processes only where they are affected by the modification. A regression analysis should identify those areas of the code and other data items affected by the modification. Data items were upgraded in those areas where they were directly affected by the modification (for instance, new requirements), and where required in order to satisfy the objectives of DO 178B/ED–12B, Annex A (for instance, where otherwise unmodified requirements must be upgraded to provide sufficient data for the requirements-based testing of the modified code sections).

In planning the transition activities using either alternative, an analysis will be performed to determine where the processes and products of the software life cycle do not satisfy the DO 178B/ED–12B objectives.

Equipment comprising software that is already certified under TSO, JTSO, FAA–STC, or LBA requirements, will be excluded from this requirement. However, the software qualification standard of such equipment will be at least according to DO 178A.

Equipment comprising software that is specifically developed for use in LZ N07 and modifications to equipment comprising software specific for LZ N07 that is not, or is not yet, certified under TSO, JTSO, FAA–STC, or LBA requirement, will be certified according to this requirement.

(23) F–3 LBA, Additional Requirements, LFLS § 1301, Function and Installation, and LFLS § 1309, Equipment, Systems and Installations [Electronic Hardware Design Assurance (ASIC)].

Discussion

The LZ N07 will utilize electronic systems that may perform critical and essential functions. During its certification of the airship, the LBA made the determination that LBA airworthiness requirements did not contain adequate standards or guidance for the assurance that the internal hardware of these electronic systems are designed to meet the appropriate safety standards.

There was no existing LBA policy or guidance for showing compliance to the existing rules for those aspects of certification associated with Application Specific Integrated Circuits (ASICs) and Electronic Programmed Logic Devices (EPLDs). Recently, EUROCAE Working Group 46 *''Complex Electronic Hardware''* was established to work in cooperation with RTCA SC–180 to consider this subject.

LFLS § 1309 was intended by the LBA as a general requirement that should be applied to all systems and powerplant installations (as required by LFLS § 901(a)) to determine the effect on the airship of a functional failure or malfunction. It is based on the principle that there should be an inverse relationship between the severity of the effect of a failure and the probability of its occurrence.

Definitions

a. *Continued Safe Flight and Landing:* The capability for continued controlled flight and landing, possibly using emergency procedures, but without requiring exceptional pilot skill or strength. Some airship damage may be associated with a Failure Condition, during flight or upon landing.

b. *Error:* An occurrence arising as a result of incorrect action by the flight crew or maintenance personnel.

c. *Event:* An occurrence that has its origin distinct from the airship, such as atmospheric conditions (e.g., gusts, temperature variations, icing, and lightning strikes) runway conditions, cabin and baggage fires. The term is not intended to cover sabotage.

d. *Failure:* A loss of function, or a malfunction, of a system or part thereof.

e. *Failure Condition:* The effect on the Airship and its occupants, both direct and consequential, caused or contributed to by one or more failures, considering relevant adverse operational or environmental conditions. Failure Conditions may be classified according to their severities as follows:

(1) *Minor:* Failure Conditions that would not significantly reduce Airship safety and which involve crew actions that are well within their capabilities. Minor failure conditions may include, for example, a slight reduction in safety margins or functional capabilities, a slight increase in crew workload, such as routine flight plan changes, or some inconvenience to occupants.

(2) *Major:* Failure Conditions that would reduce the capability of the Airship or the ability of the crew to cope with adverse operating conditions to the extent that there would be, for example, a significant reduction in safety margins or functional capabilities, a significant increase in crew workload or in conditions impairing crew efficiency, or discomfort to occupants, possibly including injuries.

(3) *Hazardous:* Failure conditions that would reduce the capability of the airship or the ability of the crew to cope with adverse operating conditions to the extent that there would be:

(a) A large reduction in safety margins or functional capabilities;

(b) Physical distress or higher workload such that the flight crew cannot be relied upon to perform their tasks accurately or completely; or

(c) Serious or fatal injury to a relatively small number of the occupants.

(4) *Catastrophic:* Failure conditions that would prevent Continued Safe Flight and Landing.

f. Redundancy: The presence of more than one independent means for accomplishing a given function or flight operation. Each means need not necessarily be identical.

Technical Discussion

LFLS § 1309(b) and (d) require substantiation by analysis and, where necessary, by appropriate ground, flight, or simulator tests, that a logical and acceptable inverse relationship exists between the probability and the severity of each Failure Condition. However, tests are not required to verify Failure Conditions that are postulated to be Catastrophic. The goal is to ensure an acceptable overall Airship safety level, considering all Failure Conditions of all systems.

a. The requirements of LFLS § 1309(b) and (d) are intended to ensure an orderly and thorough evaluation of the effects on safety of foreseeable failures or other events, such as errors or external circumstances, separately or in combination, involving one or more system functions. The interactions of these factors within a system and among relevant systems should be considered.

b. The severities of Failure Conditions may be evaluated according to the following considerations:

(1) Effects on the Airship, such as reductions in safety margins, degradations in performance, loss of capability to conduct certain flight operations, or potential or consequential effects on structural integrity.

(2) Effects on crewmembers, such as increases above their normal workload that would affect their ability to cope with adverse operational or environmental conditions.

(3) Effects on the occupants; i.e., passengers and crewmembers.

(4) For convenience in conducting design assessments, Failure Conditions may be classified according to their severities as Minor, Major, Hazardous, or Catastrophic. Chapter 1, ''Definitions'' provides accepted definitions of these terms.

(a) The classification of Failure Conditions does not depend on whether or not a system or function is the subject of a specific requirement. Some ''required'' systems, such as transponders, position lights, and public address systems, may have the potential for only Minor Failure Conditions. Conversely, other systems that are not ''required,'' such as flight management systems, may have the potential for Major, Hazardous, or Catastrophic Failure Conditions.

(b) Regardless of the types of assessment used, the classification of Failure Conditions should always be accomplished with consideration of all relevant factors; e.g., system, crew, performance, operational, external, etc. Examples of factors would include the nature of the failure modes, any effects or limitations on performance, and any required or likely crew action. It is particularly important to consider factors that would alleviate or intensify the severity of a Failure Condition. An example of an alleviating factor would be the continued performance of identical or operationally similar functions by other systems not affected by the Failure Condition. Examples of intensifying factors would include unrelated conditions that would reduce the ability of the crew to cope with a Failure Condition, such as weather or other adverse operational or environmental conditions.

The probability that a Failure Condition would occur may be assessed as Probable, Improbable (Remote or Extremely Remote), or Extremely Improbable. Each Failure Condition should have a probability that is inversely related to its severity.

1. Minor Failure Conditions may be Probable.

2. Major Failure Conditions must be no more frequent than Improbable (Remote).

3. Hazardous Failure Conditions must be no more frequent than Improbable (Extremely Remote).

4. Catastrophic Failure Conditions must be Extremely Improbable.

c. An assessment to identify and classify Failure Conditions is necessarily qualitative. On the other hand, an assessment of the probability of a Failure Condition may be either qualitative or quantitative. An analysis may range from a simple report that interprets test results or compares two similar systems to a detailed analysis that may (or may not) include estimated numerical probabilities. The depth and scope of an analysis depends on the types of functions performed by the system, the severities of Failure Conditions, and whether or not the system is complex. Regardless of its type, an analysis should show that the system and its installation can tolerate failures to the extent that Major and Hazardous Failure Conditions are Improbable and *Catastrophic Failure Conditions are Extremely Improbable:*

(1) Experienced engineering and operational judgment should be applied when determining whether or not a system is complex. Comparison with similar, previously approved systems is sometimes helpful. All relevant systems Attributes should be considered; however, the complexity of the software used to program a digital-computer-

based system should not be considered because the software is assessed and controlled by other means, as described in paragraph 2.i.

(2) An analysis should consider the application of the fail-safe design concept described in paragraph 5 and give special attention to ensuring the effective use of design techniques that would prevent single failures or other events from damaging or otherwise adversely affecting more than one redundant system channel or more than one system performing operationally-similar functions. When considering such common-cause failures or other events, consequential or cascading effects should be taken into account if they would be inevitable or reasonably likely.

(3) Some examples of such potential common-cause failures or other events would include rapid release of energy from concentrated sources such as uncontained failures of rotating parts or pressure vessels, pressure differentials, non-catastrophic structural failures, loss of environmental conditioning, disconnection of more than one subsystem or component by over temperature protection devices, contamination by fluids, damage from localized fires, loss of power, excessive voltage, physical or environmental interactions among parts, human or machine errors, or events external to the system or to the Airship.

d. Compliance for a system or part thereof that is not complex may sometimes be shown by design and installation appraisals and evidence of satisfactory service experience on other Airships using the same or other systems that are similar in their relevant Attributes.

e. In general, a Failure Condition resulting from a single failure mode of a device cannot be accepted as being Extremely Improbable. In very unusual cases, however, experienced engineering judgment may enable an assessment that such a failure mode is not a practical possibility. When making such an assessment, all possible and relevant considerations should be taken into account, including all relevant Attributes of the device. Service experience showing that the failure mode has not yet occurred may be extensive, but it can never be enough. Furthermore, flight crew or ground crew checks have no value if a Catastrophic failure mode would occur suddenly and without any prior indication or warning. The assessment's logic and rationale should be so straightforward and readily obvious that, from a realistic and practical viewpoint, any knowledgeable, experienced person would unequivocally conclude that the failure mode simply would not occur.

f. LFLS § 1309(c) provides requirements for system monitoring, failure warning, and capability for appropriate corrective crew action. Guidance on acceptance means of compliance is provided in paragraph 8.g.

g. In general, the means of compliance described in this Appendix to CRI F–ASIC's are not directly applicable to software assessments because it is not feasible to assess the number or kinds of software errors, if any, that may remain after the completion of system design, development, and test. RTCA DO–178A and EUROCAE ED–12A, or later revisions thereto, provide acceptable means for assessing and controlling the software used to program digital-computer-based systems. The documents define and use certain terms to classify the criticalities of functions. These terms have the following relationships to the terms used in this Appendix to CRI F–ASIC's to classify Failure Conditions: Failure Conditions adversely affecting non-essential functions would be Minor, Failure Conditions adversely affecting essential functions would be Major or Hazardous, and Failure Conditions adversely affecting critical functions would be Catastrophic.

h. Functional Hazard Assessment.

Before an applicant proceeds with a detailed safety assessment, it is useful to prepare a preliminary hazard assessment of the system functions in order to determine the need for and scope of subsequent analysis. This assessment may be conducted using service experience, engineering and operational judgment, or a top-down deductive qualitative examination of each function performed by the system. A functional hazard assessment is a systematic, comprehensive examination of a system's functions to identify potential Major, Hazardous and Catastrophic Failure Conditions that the system can cause or contribute to not only if it malfunctions or fails to function but also in its normal response to unusual or abnormal external factors. It is concerned with the operational vulnerabilities of the system rather than with the detailed hardware analysis.

Each system function should also be examined with respect to functions performed by other Airship systems because the loss of different but related functions provided by separate systems may affect the severity of Failure Conditions postulated for a particular system. In assessing the effects of a Failure Condition, factors that might alleviate or intensify the direct effects of the initial Failure Condition should be considered, including consequent or related conditions existing within the Airship that may affect the ability of the crew to deal with direct effects, such as the presence of smoke, acceleration vectors, interruption of communication, interference with cabin pressurization, etc.

When assessing the consequences of a given Failure Condition, account should be taken of the warnings given, the complexity of the crew action, and the relevant crew training. The number of overall Failure Conditions involving other than instinctive crew actions may influence the flight crew performance that can be expected. Training requirements may need to be specified in some cases.

A functional hazard assessment may contain a high level of detail in some cases, such as for a flight guidance and control system with many functional modes, but many installations may need only a simple review of the system design by the applicant. The functional hazard assessment is a preliminary engineering tool. It should be used to identify design precautions necessary to ensure independence, to determine the required software level, and to avoid common mode and cascade failures.

If further safety analysis is not provided, then the functional hazard assessment could itself be used as certification documentation.

(1) Analysis of Hazardous and Catastrophic Failure Conditions

(a) A detailed safety analysis will be necessary for each Hazardous and Catastrophic Failure Condition identified by the functional hazard assessment. Hazardous Failure Conditions should be Improbable (Extremely Remote), and Catastrophic Failure Conditions should be Extremely Improbable. The analysis will usually be a combination of qualitative and quantitative assessment of the design. Probability levels that are related to Catastrophic Failure Conditions should not be assessed only on a numerical basis, unless this basis can be substantiated beyond reasonable doubt.

(b) For simple and conventional installations, i.e., low complexity and similarity in relevant Attributes, it may be possible to assess a Catastrophic Failure Condition as being Extremely Improbable on the basis of experienced engineering judgment, without using all the formal procedures listed above. The basis for the assessment will be the degree of redundancy, the established independence and isolation of the channels and the reliability record of the technology involved. A Failure Condition resulting from a single failure

mode of a device cannot generally be accepted as being Extremely Improbable, except in very unusual cases.

To satisfy the provisions of LFLS § 1301 and LFLS § 1309 Equipment, Systems and Installations with respect to Electronic Hardware Design Assurance (ASIC), the design considerations and analyses described in the above *Discussion and Technical Discussion* will be utilized to accomplish the following:

Correct operation will be demonstrated by test or analysis under all combinations and permutations of conditions of the gates within the device for electronic hardware whose anomalous behavior would cause or contribute to a failure of a system resulting in a catastrophic or hazardous failure condition for the airplane as defined in Advisory Circular 23.1309–1C.

Correct operation will also be demonstrated by test or analysis under all combinations and permutations of conditions at the pins of the device for electronic hardware whose anomalous behavior would cause or contribute to a failure of a system resulting in a major or minor failure condition for the airplane as defined in Advisory Circular 23.1309–1C.

If the testing and analysis methods outlined above are impractical due to the complexity of the device, the electronic hardware should be developed using a structured development process. The applicant may use the guidelines in RTCA DO–254, ''Design Assurance Guidance for Airborne Electronic Hardware'' or another process that is acceptable to the FAA. If the applicant chooses to use the guidelines in RTCA DO–254, the hardware development assurance levels should be the same as the software development assurance levels agreed to by the applicant and the FAA.

(24) F–4 LBA, Additional Requirements concerning LFLS § 1301, § 1303, § 1305, § 1309, § 1321, § 1322, § 1330, § 1431 with respect to Liquid Crystal Displays.

Discussion

ZLT proposed to use Liquid Crystal Displays (LCDs) for presentation of Airspeed/Altitude/Attitude/Engine/Warning and Caution information to the pilots. The LBA had no published approval criteria for LCD technology.

The LCDs to be installed in the LZ–N07 flight deck will display flight information, including functions critical to safe flight and landing. There is presently no existing guidance material for Liquid Crystal Display airworthiness certification in the LFLS. For the LZ–N07 certification, the following Guidance Material for LCD airworthiness approval was developed. The following Guidance Material provides acceptable guidance for airworthiness approval of display systems using LCD technology in the LZ–N07.

Guidance Material

Guidance Material for Electronic Liquid Crystal Display Systems Airworthiness Approval

Purpose

This Guidance Material provides guidance for certification of Liquid Crystal Display (LCD) based electronic display systems used for guidance, control, or decision-making by the pilots of an Airship. Like all guidance material, this document is not, in itself, mandatory and does not constitute a regulation. It is issued to provide guidance and to outline a method of compliance with the rules.

Scope

The material provided in this section consists of guidance related to pilot displays and specifications for LCDs in the cockpit of an Airship. The content of the Appendix is limited to statements of general certification considerations, including color, symbology, coding, clutter, dimensionality, and attention-getting requirements, and display visual characteristics.

a. Information Separation

(1) Color Standardization

(a) Although color standardization is desirable, during the initial certification of electronic displays, color standards for symbology were not imposed (except for cautions and warnings in LFLS § 1322). At that time, the expertise did not exist within industry or the LBA, nor did sufficient service experience exist to rationally establish a suitable color standard.

(b) In spite of the permissive LCD color atmosphere that existed at the time of initial LCD display certification programs, an analysis of the major certifications to date reveals many areas of common color design philosophy; however, if left unrestricted, in several years there will be few remaining common areas of color selection. If that is the case, information transfer problems may begin to occur that have significant safety implications. To preclude this, the following colors are being recommended based on current-day common usage. Deviations may be approved with acceptable justification.

(c) The following depicts acceptable display colors related to their functional meaning recommended for electronic display systems.

1. Display features should be color-coded as follows:

Warnings	Red
Flight envelope and system limits.	Red
Cautions, abnormal sources	Amber/Yellow
Earth	Tan/Brown
Engaged modes	Green
Sky	Cyan/Blue
ILS deviation pointer	Magenta
Flight director bar	Magenta/ Green

2. Specified display features should be allocated colors from one of the following color sets:

	Color set 1	Color set 2
Fixed reference symbols	White	Yellow*
Current data, values	White	Green
Armed modes	White	Cyan
Selected data, values	Green	Cyan
Selected heading	Magenta**	Cyan
Active route/flight plan	Magenta	White

*The extensive use of the color yellow for other than caution/abnormal information is discouraged.

**In color Set 1, magenta is intended to be associated with those analogue parameters that constitute ''fly to'' or ''keep centered'' type information.

(d) When deviating from any of the above symbol color assignments, the manufacturer should ensure that the chosen color set is not susceptible to confusion or color meaning transference problems due to dissimilarities with this standard. The Authority test pilot should be familiar with other systems in use and evaluate the system specifically for confusion in color meanings.

(e) The LBA does not intend to limit electronic displays to the above colors, although they have been shown to work well. The colors available from a symbol generator/display unit combination should be carefully selected on the basis of their chrominance separation. Research studies indicate that regions of relatively high color confusion exist between red and magenta, magenta and purple, cyan and green, and yellow and orange (amber). Colors should track with brightness so that chrominance and relative chrominance separation are maintained as much as possible over day/night operation. Requiring the flight crew to discriminate between shades of the same color for symbol meaning in one display is not recommended.

(f) Chrominance uniformity should be in accordance with the guidance provided in SAE Document ARP 1874. As designs are finalized, the manufacturer should review his color selections to ensure the presence of color works to the advantage of separating logical electronic display functions or separation of types of displayed data. Color meanings should be consistent throughout all color LCD displays in the cockpit. In the past, no criteria existed requiring similar color schemes for left and right side installations using electro-mechanical instruments.

(2) Color Perception versus Workload

(a) When color displays are used, colors should be selected to minimize display interpretation workload. Symbol coloring should be related to the task or crew operation function. Improper color-coding increases response times for display item recognition and selection, and it increases the likelihood of errors in situations where response rate demands exceed response accuracy demands. Color assignments that differ from other displays in use, either electromechanical or electronic, or that differ from common usage (such as red, yellow, and green for stoplights), can potentially lead to confusion and information transferal problems.

(b) When symbology is configured such that symbol characterization is not based on color contrast alone but on shape as well, then the color information is seen to add a desirable degree of redundancy to the displayed information. There are conditions in which pilots whose vision is color deficient can obtain waivers for medical qualifications under National crew license regulations. In addition, normal aging of the eye can reduce the ability to sharply focus on red objects or discriminate blue/green. For pilots with such deficiency, display interpretation workload may be unacceptably increased unless symbology is coded in more dimensions than color alone. Each symbol that needs separation because of the criticality of its information content should be identified by at least two distinctive coding parameters (size, shape, color, location, etc.).

(c) Color diversity should be limited to as few colors as practical to ensure adequate color contrast between symbols. Color grouping of symbols, annunciations, and flags should follow a logical scheme. The contribution of color to information density should not make the display interpretation times so long that the pilot perceives a cluttered display.

(3) Standard Symbology. Many elements of electronic display formats lend themselves to standardization of symbology, which would shorten training and transition times when pilots change airplane types.

(4) Symbol Position

(a) The position of a message or symbol within a display conveys meaning to the pilot. Without the consistent or repeatable location of a symbol in a specific area of the electronic display, interpretation errors and response times may increase. The following symbols and parameters should be position consistent:

(1) All warning/caution/advisory annunciation locations.

(2) All sensor data: altitude, airspeed, glideslope, etc.

(3) All sensor failure flags. (Where appropriate, flags should appear in the area where the data is normally placed.)

(4) Either the pointer or scale for analogue quantities should be fixed. (Moving scale indicators that have a fixed present value may have variable limit markings.)

(b) An evaluation of the positions of the different types of alerting messages and annunciations available within the electronic display should be conducted, with particular attention given to differentiation of normal and abnormal indications. There should be no tendency to misinterpret or fail to discern a symbol, alert, or annunciation due to an abnormal indication being displayed in the position of a normal indication and having similar shape, size or color.

(c) Pilot and copilot displays may have minor differences in format, but all such differences should be evaluated specifically to ensure that no potential for interpretation error exists when pilots make cross-side display comparisons.

(5) Clutter. A cluttered display is one that uses an excessive number and/or variety of symbols, colors, or small spatial relationships. This causes increased processing time for display interpretation. One of the goals of display format design is to convey information in a simple fashion in order to reduce display interpretation time. A related issue is the amount of information presented to the pilot. As this increases, tasks become more difficult as secondary information may detract from the interpretation of information necessary for the primary task. A second goal of display format design is to determine what information the pilot actually requires in order to perform the task at hand. This will serve to limit the amount of information that needs to be presented at any point in time. Addition of information by pilot selection may be desirable, particularly in the case of navigational displays, as long as the basic display modes remain uncluttered after pilot de-selection of secondary data. Automatic de-selection of data has been allowed in the past to enhance the pilot's performance in certain emergency conditions.

(6) Interpretation of Two-Dimensional Displays. Modern electromechanical attitude indicators are three-dimensional devices. Pointers overlay scales; the fixed airplane symbol overlays the flight director single cue bars that, in turn, overlay a moving background. The three-dimensional aspect of a display plays an important role in interpretation of instruments. Electronic flight instrument system displays represent an attempt to copy many aspects of conventional electromechanical displays but in only two dimensions. This can present a serious problem in quick-glance interpretation, especially for attitude. For displays using conventional, discrete symbology, the horizon line, single cue flight director symbol, and fixed airplane reference should have sufficient conspicuity such that the quick-glance interpretation should never be misleading for basic attitude. This conspicuity can be gained by ensuring that the outline of the fixed airplane symbol(s) always retains its distinctive shape, regardless of the background or position of the horizon line or pitch ladder. Color contrast is helpful in defining distinctive display elements but is insufficient by itself

because of the reduction of chrominance difference in high ambient light levels. The characteristics of the flight director symbol should not detract from the spatial relationship of the fixed airplane symbol(s) with the horizon. Careful attention should be given to the symbol priority (priority of displaying one symbol overlaying another symbol by editing out the secondary symbol) to assure the conspicuity and ease of interpretation similar to that available in three-dimensional electromechanical displays.

Note: Horizon lines and pitch scales that overwrite the fixed airplane symbol or roll pointer have been found unacceptable in the past.

(7) Attention-Getting Requirements

(a) Some electronic display functions are intended to alert the pilot to changes: navigation sensor status changes (VOR flag), computed data status changes (flight director flag or command cue removal), and flight control system normal mode changes (annunciator changes from armed to engaged) are a few examples. For the displayed information to be effective as an attention-getter, some easily noticeable change must be evident. A legend change by itself is inadequate to annunciate automatic or uncommanded mode changes. Color changes may seem adequate in low light levels or during laboratory demonstrations but become much less effective at high ambient light levels. Motion is an excellent attention-getting device. Symbol shape changes are also effective, such as placing a box around freshly changed information. Short-term flashing symbols (approximately 10 seconds or flash until acknowledge) are effective attention-getters. A permanent or long-term flashing symbol that is non-cancelable should not be used.

(b) In some operations, continued operation with inoperative equipment is allowed (under provisions of an MEL). The display designer should consider the applicant's MEL desires because in some cases a continuous strong alert may be too distracting for continued dispatch.

(8) Color Drive Failure. Following a single color drive failure, the remaining symbology should not present misleading information, although the display does not have to be usable. If the failure is obvious, it may be assumed that the pilot will not be susceptible to misleading information due to partial loss of symbology. To make this assumption valid, special cautions may have to be included in the AFM procedures that point out to the pilot that important information formed from a single primary color may be lost, such as red flags.

(9) For Both Active Matrix and Segmented Liquid Crystal Displays

Viewing Envelope: The installed display must meet all the following requirements when viewed from a rectangle centered on the design eye position and sized 1-foot vertical dimension and 2-feet horizontal dimension.

General: The display symbology must be clearly readable throughout the viewing envelope under all ambient illumination levels ranging from 1.1 lux (0.10 fc) to sun shaft illumination of 86,400 lux (8000 fc) at 45 degrees incidence to the face of the display.

Symbol Alignment: Symbols that are interpreted relative to each other must be aligned to preclude erroneous interpretation.

Flicker: Flicker must not be readily discernible or distracting under day, twilight, or night conditions, considering both foveal and full peripheral vision, and using a format most susceptible to producing flicker.

Multiple Images: Multiple display images produced by light not normal to the display surface must neither be distracting nor cause erroneous interpretation.

Luminance: The display luminance must be sufficient to provide a comfortable level of viewing under all conditions and provide rapid eye adaptation when transitioning from looking outside the flight deck.

Minimum Luminance: Under night lighting, with the display brightness set at the lowest usable level for flight with normal symbology, all flags and annunciators must be adequately visible.

Lighting: In order to aid daylight viewing, the displays' backlighting must be designed such that adequate daylight backlighting is provided when the cockpit discrete lighting control is set to the 'bright' position. In ''non-bright'' positions, the displays must be modulated in a balanced fashion in conjunction with other cockpit lighting.

(10) For Active Matrix Displays

Matrix Anomalies: For both static and dynamic formats, the display must have no matrix anomalies that cause distraction or erroneous interpretation.

Line Width Uniformity: Lines of specified color and luminance must remain uniform in width at all orientations. Unintended line width variation must not be readily apparent or distracting in any case.

Symbol Quality: Symbols must not have distracting gaps or geometric distortions that cause erroneous interpretations.

Symbol Motion: Display symbology that is in motion must not have distracting or objectionable jitters, jerkiness, or ratcheting effects.

Image Retention: Image retention must not be readily discernible day or night and must not be distracting or cause an erroneous interpretation or smearing effect for motion dynamic symbology.

Defects: Visible defects on the display surface (such as ''on'' elements, ''off'' elements, spots, discolored areas, etc.) must not be distracting or cause an erroneous interpretation. Service limits for defects must be established.

Luminance Uniformity: Display areas of a specified color and luminance must have a luminance uniformity of less than 50 percent across the utilized display surface. The rate of change of luminance within any small area shall be minimized to eliminate distracting visual effects. These requirements apply for any eye position within the display viewing envelope.

Contrast Ratios: The average contrast ratio over the usable display surface must be a minimum of 201 at the design eye position and 101 for any eye position within the display viewing envelope when measured under a dark ambient illumination. This requirement is based on a 0.5 mm (0.0201) line width. Smaller line widths must have a comparable readability, which may require a higher contrast ratio.

(11) For Segmented Displays

Activated Segments: Activated segments must have a contrast ratio with the immediately adjacent inactivated background of 21 for viewing angles of on-axis to 50 degrees off-axis.

Inactivated Segments: When segments are not electrically activated, there must be no obtrusive difference between the normal background luminance, color, or texture and the inactivated segments of the area surrounding them. The contrast ratio between inactivated segments and the background must not be greater than 1.151 in a light ambient when viewed from an angle normal to the display up to an angle 50 degrees off-axis.

For the purpose of this Issue Paper, the following definition applies:

Luminance Uniformity = $(L_{max} - L_{min} / L_{ave}$ (expressed in percent)

Where

L_{max} = Maximum luminance measured anywhere on the utilized display surface

L_{min} = Minimum luminance measured anywhere on the utilized display surface

L_{ave} = Average luminance of the utilized display surface

To satisfy the provisions of LFLS § 1301, § 1303, § 1305, § 1309, § 1321,

§ 1322, § 1330, § 1431 with respect to Liquid Crystal Displays, the design considerations and analyses described in the above Guidance Material will be utilized:

(a) Equipment comprising LCDs that is not specifically developed for use in the LZ–N07, and which is already certified under TSO, JTSO, FAA–STC, or LBA Kennblatt, will be excluded and not certified according to these guidelines.

(b) Equipment comprising LCDs that is specifically developed for the use in LZ–N07, and modifications to equipment comprising LCDs specific for the LZ–N07, and that is not, or not yet, certified under TSO, JTSO, FAA–STC, or LBA Kennblatt, will be certified according to these guidelines.

(25) F–5 LBA, Additional Requirements; LFLS § 1301, Function and Installation, and LFLS § 1309, Equipment, Systems and Installations, Use of Commercial Off-The-Shelf (COTS) Software in Airship Avionics Systems.

General Discussion

The LZ N07 will be certificated with digital microprocessor based systems installed that may contain commercial off-the-shelf (COTS) software. This Guidance Material identifies acceptable means of certifying airborne systems and equipment containing COTS software on the airship.

Background

Many COTS software applications and components have been developed for use outside the field of commercial air transportation. Much of the COTS software has been developed for systems for which safety is not a concern or for systems with safety criteria different from that of commercial airships. Consequently, for COTS software, adequate artifacts may not be available to assess the adequacy of the software integrity. Available evidence may be insufficient to show that adequate software life cycle processes were used. RTCA DO 178B/ED–12B recognizes the above and addresses means by which COTS may be shown to comply with airship certification requirements.

Technical Discussion

Document RTCA DO 178B/ED–12B provides a means for obtaining the approval of airborne COTS software. For those systems that make use of COTS software, the objectives of RTCA DO 178B/ED–12B should be satisfied. If deficiencies exist in the life cycle data of COTS software, DO 178B/ED–12B addresses means to augment that data to satisfy the objectives. If Zeppelin chooses to utilize a means other than DO 178B/ED–12B, the LBA requests Zeppelin to propose, via the Plan for Software Aspects of Certification (PSAC), how it intends to show that all COTS software complies with Airship Requirements LFLS §§ 1301, 1309. Zeppelin should obtain agreement on the means of compliance from the LBA prior to implementation.

Abbreviations Used in this Guidance

TABLE 7

Abbreviation	Explanation
COTS	Commercial Off-the-Shelf Software
CRI	Certification Review Item
EUROCAE	European Organization for Civil Aviation Electronics
LBA	Luftfahrt Bundesamt
LFLS	Airworthiness Requirements for Airships
PSAC	Plan for Software Aspects of Certification
RTCA	Radio Technical Commission for Aeronautics

To satisfy the provisions of LFLS § 1301, Function and Installation, and LFLS § 1309, Equipment, Systems and Installations, Use of Commercial Off-the-Shelf (COTS) Software in Airship Avionics Systems the design considerations and analyses described in the above Guidance Material will be utilized:

Equipment comprising COTS that is not specifically developed for use in the LZ–N07, and which is already certified under TSO, JTSO, FAA–STC, or LBA Kennblatt, will be excluded and not certified according to this Guidance Material.

Equipment comprising COTS that is specifically developed for use in the LZ–N07, and modifications to equipment comprising COTS specific for LZ–N07, and that is not, or not yet, certified under TSO, JTSO, FAA–STC, or LBA Kennblatt, will be certified according to this Guidance Material.

(26) F–6 LBA, §§ 1301, 1322, 1528, 1585; LFLS (Equivalent Safety Finding) Envelope Pressure Indicator—Color Coding.

Discussion

To indicate the envelope pressure of the LZ–N07, ZLT will propose an instrument (Envelope Pressure Indicator, EPI) that will provide annunciation of the Helium and Ballonet Pressure as well as indications of the aft and forward Fan and Sensor Fail status using LED columns. The measurement range covers a red, amber, and green band by a colored scale adjacent to the LED columns. The LED columns are continuously of an amber color, due to the technical solution possible only. In addition, any out-of-limit pressure determination will trigger a discrete warning output to the Integrated Instrument Display System (IIDS) for crew alerting and generation of an appropriate warning message.

Using the pressure indications, the flight crew is able to monitor and control the airship throughout the flight. Furthermore, the ground crew will utilize the EPI to maintain constant pressures in the hull.

Messages on displays should be unambiguous and easily readable and should be designed to avoid confusion to the crew. The use of an amber colored LED column, indicating possible red, amber, and green status of the associated systems, is not in line with the general color philosophy of the LZ N07 cockpit and the applicable LFLS requirements, and it was considered by the LBA as an unusual design feature.

While the LBA allowed the use of amber based on an equivalent safety finding, we believe that the provisions of LFLS § 1322, where an amber indication is reserved to indicate where immediate crew awareness is required and subsequent crew action will be required, should be adhered to.

The control and indicating systems will, therefore, comply with the provisions of LFLS § 1322.

(27) F–7 LBA, Equivalent Safety Finding § 1387(b) LFLS, Bow Light Dihedral Angle.

Discussion

LFLS § 1387(b) requires a dihedral angle formed by two intersecting vertical planes making angles of 110 degrees to the right and to the left. LFLS appendix table 10 requires, in addition, a minimum light intensity of 20 cd throughout the dihedral angle. The LZ–N07 system only attains the required intensity over 100 degrees but is still visible from 100 degrees to 110 degrees (left and right) at a reduced intensity. The LBNA granted an equivalency to LFLS § 1387(b) based on the greater dihedral angle coverage of the aft light, +/-80 degrees rather than +/-70 degrees at the specified intensity. This is acceptable to the FAA.

To satisfy the provisions of LFLS § 1387(b), the following is required:

The LFLS § 1387(b) required dihedral angle will be no less than 100 degrees at the intensities specified in Table 10 of the appendix of the LFLS. In addition, the rear light will have an included angle of +/-80 degrees at the specified intensity from Table 10 of the appendix of the LFLS. Refer to Figure 3.

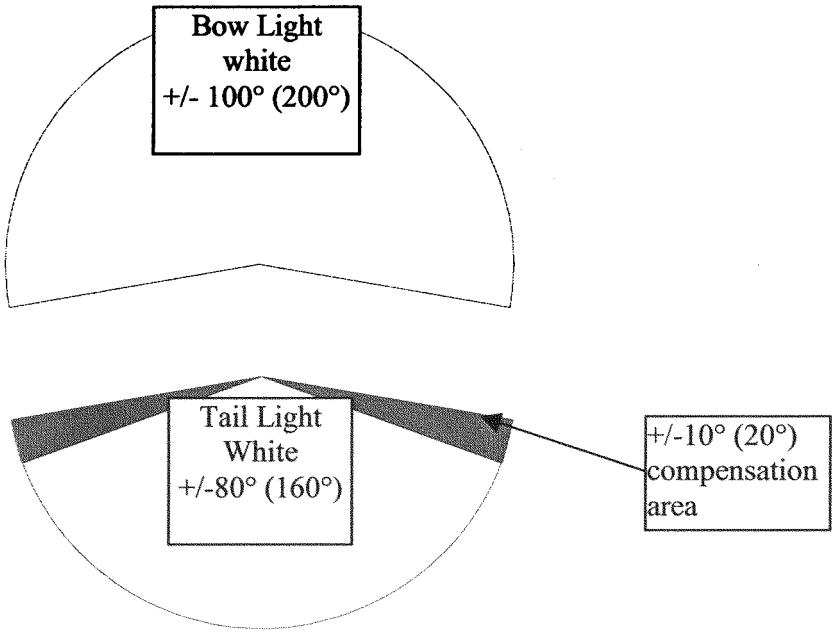

Figure 3: Dihedral Angles for Position Lights

(28) Ballast Water.

Discussion

To minimize the possibility of environmental contamination from ballast water, there will be provisions in the airship or servicing provisions that ensure that biological or chemical contamination does not occur due to the servicing of ballast water of one location and dumping of water in a different location. This provision will be added to the certification basis as a special environmental requirement:

Under no circumstances may water ballast be loaded or released that does not comply with the provisions of 40 CFR part 141, National Primary Drinking Water Regulations. Obtaining water from a water supply use for human consumption is acceptable; water aerially released or otherwise dumped cannot degrade beyond the limits set by 40 CFR part 141. If ballast water is contaminated, it can only be released into appropriate sewage facilities in accordance with national and local laws and regulations. These provisions will be explained in the Airship Flight Manual and ground operations materials and manuals. Procedures will also be developed that will eliminate the possibility of biological contamination growing in the ballast system and then being jettisoned or dumped, unless detected and treated.

The ballast system will have a method of securing filler locations to eliminate the possibility of tampering with the system.

Issued in Kansas City, Missouri, on March 21, 2008.

David R. Showers

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. E8–6600 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Commercial Space Transportation Advisory Committee—Open Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Commercial Space Transportation Advisory Committee Open Meeting.

SUMMARY: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App. 2), notice is hereby given of a meeting of the Commercial Space Transportation Advisory Committee (COMSTAC). The meeting will take place on Friday, May 16, 2008, starting at 8 a.m. at the Federal Aviation Administration Headquarters Building, 800 Independence Avenue SW., Washington, DC, in the Bessie Coleman Conference Center, located on the 2nd Floor. This will be the forty-seventh meeting of the COMSTAC.

The proposed agenda for the meeting will feature the release of the 2008 Commercial Space Transportation Forecasts, a briefing on the FAA Commercial Space Transportation Safety Approval process; and a report on AST activities. An agenda will be posted on the FAA Web site at *http://ast.faa.gov.* Meetings of the COMSTAC Working Groups (Technology and Innovation, Reusable Launch Vehicle, Risk Management, and Launch Operations and Support) will be held on Thursday, May 15, 2008. For specific information concerning the times and locations of the working group meetings, contact the Contact Person listed below.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below in advance of the meeting.

FOR FURTHER INFORMATION CONTACT: Brenda Parker (AST–100), Office of Commercial Space Transportation, 800 Independence Avenue SW., Room 331, Washington, DC 20591, telephone (202) 267–3674; E-mail *brenda.parker@faa.gov.*

Issued in Washington, DC, March 21, 2008.

George C. Nield,

Acting Associate Administrator for Commercial Space Transportation.

[FR Doc. E8–6589 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Minnesota

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of limitation on claims for judicial review of actions by FHWA and other Federal agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed highway project, the extension of Scott County State Aid Highway (CSAH) 21 between CSAH 42 in Prior Lake and CSAH 18 at Southbridge Parkway in Shakopee and construction of a 500-space surface transit station (park-and-ride) in the southwest quadrant of the CSAH 21/CSAH 16 intersection in Scott County, Minnesota. Those actions grant approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(1)(1). A claim seeking judicial review of the Federal agency actions of the highway project will be barred unless the claim is filed on or before 180 days from the date of this notice. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Mr. Thomas Sorel, Division Administrator, Federal Highway Administration, Galtier Plaza, Suite 500, 380 Jackson Street, St. Paul, Minnesota 55101, Telephone (651) 291–6100, e-mail: *Thomas.sorel@fhwa.dot.gov*. The Minnesota Division Office's normal business hours are 7:30 a.m. to 4 p.m. (central time). For Scott County: Mr. Mitchell Rasmussen, P.E., County Engineer, Scott County Public Works Department, 600 Country Trail East, Jordan, Minnesota 55352, Telephone (952) 496–8346, (800) 627–3529 TTY, e-mail: *mrasmussen@co.scott.mn.us*.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing approvals for the following highway project in Minnesota: Extension of Scott CSAH 21 between Prior Lake and Shakopee, Scott County, Minnesota. The project includes construction of an approximately three-mile, four-lane expressway. The project also includes construction of a 500-space surface transit station (park-and-ride) in the southwest quadrant of the CSAH 2l/CSAH 16 intersection. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS) for the project, approved on December 19, 2007; in the FHWA Record of Decision (ROD) issued on March 3, 2008; and in other documents in the FHWA project files. The FEIS, ROD and other project records are available by contacting the FHWA or Scott County at the addresses provided above. The FHWA FEIS and project information can be viewed and downloaded from the project Web site at *http://www.co.scott.mn.us/wps/portal/ShowPage?CSF=825&CSI=csc0l5464*.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

3. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

4. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq*.]; Archaeological and Historic Preservation Act [16 U.S.C. 469–469(c)].

5. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

6. Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

7. Executive Orders: E.O. 11990, Protection of Wetlands; E.O. 11988, Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593, Protection and Enhancement of Cultural Resources; E.O. 13007, Indian Sacred Sites; E.O. 13287, Preserve America; E.O. 13175, Consultation and Coordination with Indian Tribal Governments; E.O. 11514, Protection and Enhancement of Environmental Quality; E.O. 13112, Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(1)(1).

Issued on: March 24, 2008.

Robin L. Schroeder,

Assistant Division Administrator, Federal Highway Administration, St. Paul, Minnesota.

[FR Doc. E8–6352 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Minnesota

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of Limitation on Claims for Judicial Review of Actions by FHWA and Other Federal Agencies.

SUMMARY: This notice announces actions taken by the FHWA and other Federal agencies that are final within the meaning of 23 U.S.C. 139(l)(1). The actions relate to a proposed highway project in and around Paynesville, Minnesota, which includes improvements to Trunk Highway (TH) 23 from the intersection with County State Aid Highway (CSAH) 6 in Kandiyohi County to 0.4 mile southwest of CSAH 123 in Stearns County. Those actions grant approvals for the project.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(1)(1). A claim seeking judicial review of the Federal agency actions of the highway project will be barred unless the claim is filed on or before 180 days from the date of this notice. If the Federal law that authorizes judicial review of a claim provides a time period of less than 180 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA: Mr. Thomas Sorel, Division Administrator, Federal Highway Administration, Galtier Plaza, Suite 500, 380 Jackson Street, St. Paul, Minnesota 55101, Telephone (651) 291–6100, e-mail: *Thomas.sorel@fhwa.dot.gov*. The Minnesota Division Office's normal business hours are 7:30 a.m. to 4 p.m. (central time). For the Minnesota Department of Transportation (Mn/DOT): Mr. Lowell Flaten, Project Manager, District 8, 2505 Transportation Road, P.O. Box 768, Willmar, Minnesota 56201–0768, Telephone (320) 231–5195, (800) 627–3529 TTY, e-mail: *Lowell.flaten@dot.state.mn.us*.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the FHWA and other Federal agencies have taken final agency actions by issuing approvals for the following highway project in Minnesota: TH 23 in and around Paynesville from CSAH 6 in Kandiyohi County to near CSAH 123 in Stearns County. The project will be a 7.7-mile long, four-lane divided highway using a new alignment that meets the design standards for a rural expressway with a 70-mph design speed and controlled access. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Final Environmental Impact Statement (FEIS)/Final Section 4(f) Evaluation for the project, approved on January 30, 2007; in the FHWA Record of Decision (ROD) issued on February 28, 2008; and in other documents in the FHWA project files. The EElS, ROD and other project records are available by contacting the FHWA or Mn/DOT at the addresses provided above. This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) [42 U.S.C. 4321–4351]; Federal-Aid Highway Act [23 U.S.C. 109].

2. Land: Section 4(f) of the Department of Transportation Act of 1966 [49 U.S.C. 303]; Landscaping and Scenic Enhancement (Wildflowers) [23 U.S.C. 319].

3. Wildlife: Endangered Species Act [16 U.S.C. 1531–1544 and Section 1536]; Fish and Wildlife Coordination Act [16 U.S.C. 661–667(d)]; Migratory Bird Treaty Act [16 U.S.C. 703–712].

4. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended [16 U.S.C. 470(f) *et seq.*]; Archaeological and Historic Preservation Act [16 U.S.C. 469–469(c)].

5. Social and Economic: Civil Rights Act of 1964 [42 U.S.C. 2000(d)–2000(d)(1)]; Farmland Protection Policy Act (FPPA) [7 U.S.C. 4201–4209].

6. Safe Drinking Water Act (SDWA) [42 U.S.C. 300(f)–300(j)(6)]; Flood Disaster Protection Act [42 U.S.C. 4001–4128].

7. Executive Orders: E.O. 11990, Protection of Wetlands; E.O. 11988, Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations; E.O. 11593, Protection and Enhancement of Cultural Resources; E.O. 13007, Indian Sacred Sites; E.O. 13287, Preserve America; E.O. 13175, Consultation and Coordination with Indian Tribal Governments; E.O. 11514, Protection and Enhancement of Environmental Quality; E.O. 13112, Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(1)(1).

Issued on: March 24, 2008.

Robin L. Schroeder,

Assistant Division Administrator, Federal Highway Administration, St. Paul, Minnesota.

[FR Doc. E8–6354 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–22–M

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket ID. FMCSA–2008–0071]

Qualification of Drivers; Exemption Applications; Diabetes

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions from the diabetes standard; request for comments.

SUMMARY: FMCSA announces receipt of applications from 29 individuals for exemptions from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate commercial motor vehicles in interstate commerce.

DATES: Comments must be received on or before April 30, 2008.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2008–0071 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.
- *Fax:* 1–202–493–2251.

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Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78; Apr. 11, 2000). This information is also available at *http://Docketinfo.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' The statutes also allow the Agency to renew exemptions at the end of the 2-year period. The 29 individuals listed in this notice have recently requested an exemption from the diabetes prohibition in 49 CFR 391.41(b)(3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the

exemption will achieve the required level of safety mandated by the statutes.

Qualifications of Applicants

Gary D. Coonfield

Mr. Coonfield, age 45, has had ITDM since 2003. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Coonfield meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A Commercial Driver's License (CDL) from Wisconsin.

Edward F. Connole

Mr. Connole, 53, has had ITDM since 2007. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Connole meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2008 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

Jason C. Daily

Mr. Daily, 37, has had ITDM since 1990. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Daily meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class C operator's license from New Hampshire.

Mark B. Demmer

Mr. Demmer, 44, has had ITDM since 2006. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Demmer meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Francis W. Devine

Mr. Devine, 66, has had ITDM since 2007. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Devine meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Paul W. Dietz

Mr. Dietz, 45, has had ITDM since 2007. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dietz meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Harold W. Goodwill

Mr. Goodwill, 50, has had ITDM since 2003. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Goodwill meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

Shannon D. Hanson

Mr. Hanson, 37, has had ITDM since 1975. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hanson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from South Dakota.

Craig A. Hendrickson

Mr. Hendrickson, 39, has had ITDM since 2007. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hendrickson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Illinois.

Michael T. Johnson

Mr. Johnson, 34, has had ITDM since 1992. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using

insulin, and is able to drive a CMV safely. Mr. Johnson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Minnesota.

Michael K. Limberg

Mr. Limberg, 54, has had ITDM since 1973. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Limberg meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he has stable proliferative and nonproliferative diabetic retinopathy. He holds a Class O operator's license from Nebraska, which allows him to drive any non-commercial vehicle except motorcycles.

Maurice R. McGill, Jr.

Mr. McGill, 53, has had ITDM since 2001. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McGill meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

Aundra Menefield

Mr. Menefield, 50, has had ITDM since 2001. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Menefield meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Mississippi.

Charles E. Murphy

Mr. Murphy, 46, has had ITDM since 2001. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Murphy meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Ohio.

Eric B. Pies

Mr. Pies, 44, has had ITDM since 1985. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Pies meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class C operator's license from Oregon.

Douglas G. Puckett

Mr. Puckett, 65, has had ITDM since 2006. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Puckett meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Virginia.

Eric A. Quisling

Mr. Quisling, 37, has had ITDM since 1986. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Quisling meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

James T. Rothwell

Mr. Rothwell, 38, has had ITDM since 1984. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rothwell meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class D operator's license from Tennessee.

Bob L. Rumble

Mr. Rumble, 61, has had ITDM since 2004. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Rumble meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Idaho.

Larry D. Schweisberger

Mr. Schweisberger, 55, has had ITDM since 2001. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another

person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Schweisberger meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2008 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Missouri.

Randy A. Shannon

Mr. Shannon, 44, has had ITDM since 2004. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Shannon meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2008 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Montana.

Dalton T. Smith, Jr.

Mr. Smith, 44, has had ITDM since 2004. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Smith meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Kim M. Stickelmeyer

Ms. Stickelmeyer, 53, has had ITDM since 2007. Her endocrinologist examined her in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Stickelmeyer meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2007 and certified that she does not have diabetic retinopathy. She holds a Class A CDL from Washington.

Marvin D. Webster

Mr. Webster, 44, has had ITDM since 2003. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Webster meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kentucky.

Harold A. Wendt

Mr. Wendt, 72, has had ITDM since 2004. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wendt meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A operator's license from Minnesota.

Donald D. Willard

Mr. Willard, 62, has had ITDM since 1982. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Willard meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Anthony O. Wilson

Mr. Wilson, 45, has had ITDM since 1985. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wilson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Georgia.

Travis S. Wolfe

Mr. Wolfe, 26, has had ITDM since 2006. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wolfe meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2008 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from West Virginia.

Jason J. Wolff

Mr. Wolff, 34, has had ITDM since 1983. His endocrinologist examined him in 2007 and certified that he has had no hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 5 years; understands diabetes management and monitoring; and has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wolff meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2007 and certified that he does not have diabetic retinopathy. He holds a Class D operator's license from Minnesota.

Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of

business on the closing date indicated in the dates section of the Notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU) requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) The elimination of the requirement for three years of experience operating CMVs while being treated with insulin; and (2) the establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 Notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 USC. 31136 (e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary. FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 Notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 Notice, except as modified by the Notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

The Agency announces a correction regarding Jonathan B. Estridge, a Federal diabetes exemption applicant who was first published in a notice for comments on February 1, 2008 (73 FR 6251). There were no comments to the docket regarding granting him an exemption but he was omitted from the notice of final disposition that was published on March 12, 2008. Therefore, he will be granted an exemption with an effective date of March 12, 2008.

[1] Section 4129(a) refers to the 2003 Notice as a ''final rule.'' However, the 2003 Notice did not issue a ''final rule'' but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

Dated: March 21, 2008.

Larry W. Minor,

Associate Administrator for Policy and Program Development.

[FR Doc. E8–6478 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2007–0071]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 31 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting the prescribed vision standard. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to, or greater than, the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions are effective March 31, 2008. The exemptions expire on March 31, 2010.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202)–366–4001, *fmcsamedical@dot.gov*, FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at: *http://www.regulations.gov*.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The FDMS is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review the DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19476, Apr. 11, 2000). This information is also available at *http://Docketinfo.dot.gov*.

Background

On February 1, 2008, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (73 FR 6242). That notice listed 31 applicants' case histories. The 31 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 31 applications on their merits and made a determination to grant exemptions to all of them. The comment period closed on March 3, 2008.

Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing standard red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision standard, but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely.

The 31 exemption applicants listed in this notice are in this category. They are unable to meet the vision standard in one eye for various reasons, including amblyopia, prosthesis, posterior uveitis, optic nerve atrophy, retinal detachment, macular scar, macular degeneration, cataract, retinal scar, retinal vein occlusion, and loss of vision due to trauma. In most cases, their eye conditions were not recently developed. All but nine of the applicants were either born with their vision impairments or have had them since childhood. The nine individuals who sustained their vision conditions as adults have had them for periods ranging from 5 to 47 years.

Although each applicant has one eye which does not meet the vision standard in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to evaluate their qualifications to operate a CMV. All these applicants satisfied the testing standards for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a commercial vehicle, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 31 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision for careers ranging from 3 to 45 years. In the past 3 years, five of the drivers had convictions for traffic violations and none of them were involved in crashes.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the February 1, 2008 notice (73 FR 6242).

Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision standard in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered not only the medical reports about the applicants' vision, but also their driving records and experience with the vision deficiency. To qualify for an exemption from the vision standard, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at docket number FMCSA–98–3637.

We believe we can properly apply the principle to monocular drivers, because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively. (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly. (See Bates and Neyman, University of California Publications in Statistics, April 1952.) Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes. (See Weber, Donald C., ''Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process,'' Journal of American Statistical Association, June 1971) A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 31 applicants, three of the applicants had a traffic violation for speeding, one of the applicants had a traffic violation for passing in a wrong lane, and one of the applicants had a traffic violation for failure to obey a traffic sign but none of the applicants were involved in crashes. The applicants achieved this record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe the applicants' intrastate driving experience and history provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision standard in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 31 applicants

listed in the notice of February 1, 2008 (73 FR 6242).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 31 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the standard in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the certification when driving, for presentation to a duly authorized Federal, State, or local enforcement official.

In a previous final disposition (72 FR 52419), the Agency stated that a public comment challenging the validity of Mr. Raymond Ochse's reported CMV driving experience and other information submitted in his application was received. Therefore, the Agency was unable to make a decision regarding his exemption application at that time. As part of the investigation, we requested that Mr. Ochse provide additional employment information within 30 days; this information was never received. In the absence of this information, the Agency has made the decision to deny Mr. Ochse's request to receive a Federal vision exemption.

Discussion of Comments

FMCSA received one comment in this proceeding. The comment was considered and discussed below.

Advocates for Highway and Auto Safety (Advocates) expressed opposition to FMCSA's policy to grant exemptions from the FMCSRs, including the driver qualification standards. Specifically, Advocates: (1) Objects to the manner in which FMCSA presents driver information to the public and makes safety determinations; (2) objects to the Agency's reliance on conclusions drawn from the vision waiver program; (3) claims the Agency has misinterpreted statutory language on the granting of exemptions (49 U.S.C. 31136(e) and 31315); and finally (4) suggests that a 1999 Supreme Court decision affects the legal validity of vision exemptions.

The issues raised by Advocates were addressed at length in 64 FR 51568 (September 23, 1999), 64 FR 66962 (November 30, 1999), 64 FR 69586 (December 13, 1999), 65 FR 159 (January 3, 2000), 65 FR 57230 (September 21, 2000), and 66 FR 13825 (March 7, 2001). We will not address these points again here, but refer interested parties to those earlier discussions.

Conclusion

Based upon its evaluation of the 31 exemption applications, FMCSA exempts Dennis R. Baillargeon, Alberto Blanco, Michael B. Canedy, John Cencora, Larry A. Cossin, Charles W. Cox, Gary W. Ellis, Dennis J. Evers, Hector O. Flores, Roger W. Goold, K. Lee Guse, Steven W. Halsey, John D. Hamm, Clifford J. Harris, John C. Henricks, Michael A. Hilderbrand, Richard L. Larson, Thomas M. Leadbitter, John L. Lewis, Jonathan P. Lovel, Douglas A. Mendoza, Antonio Ribeiro, Enrique G. Salinas, Jr., Anthony T. Smith, David N. Stubbs, J.D. Taylor, Charles W. Towner, Jr., James D. Tucker, John J. Wagner, Kevin D. White, and Richard W. Wylie, from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)).

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: March 21, 2008.

Larry W. Minor,

Associate Administrator for Policy and Program Development.

[FR Doc. E8–6485 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket Nos. FMCSA–01–10578, FMCSA–05–21711, FMCSA–05–22194, 05–22727]

Qualification of Drivers; Exemption Renewals; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA previously announced its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 7 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has reviewed the comments submitted in response to the previous announcement and concluded that granting these exemptions will provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202) 366–4001, *maggi.gunnels@dot.gov,* FMCSA, Department of Transportation, 400 Seventh Street, SW., Room 8301, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Document Management System (DMS) at *http://dmses.dot.gov.*

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The comment period ended on March 3, 2008.

Discussion of Comments

FMCSA received no comment in this proceeding.

Conclusion

The Agency has not received any adverse evidence on any of these drivers

that indicates that safety is being compromised. Based upon its evaluation of the 7 renewal applications, FMCSA renews the Federal vision exemptions for James S. Ayers, Curtis F. Caddy, III, Vernon J. Dohrn, Steven R. Felks, Douglas J. Mauton, Dennis L. Maxcy, and Dean B. Ponte.

In accordance with 49 U.S.C. 31136(e) and 31315, each renewal exemption will be valid for 2 years unless revoked earlier by FMCSA.

The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: March 21, 2008.

Larry W. Minor,

Associate Administrator for Policy and Program Development.

[FR Doc. E8–6488 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket Nos. FMCSA–01–10578, FMCSA–05–21711, FMCSA–05–22194, 05–22727]

Qualification of Drivers; Exemption Renewals; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA previously announced its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 12 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has reviewed the comments submitted in response to the previous announcement and concluded that granting these exemptions will provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

FOR FURTHER INFORMATION CONTACT: Dr. Mary D. Gunnels, Director, Medical Programs, (202) 366–4001, *maggi.gunnels@dot.gov,* FMCSA, Department of Transportation, 400 Seventh Street, SW., Room 8301, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

You may see all the comments online through the Document Management System (DMS) at *http://dmses.dot.gov.*

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The comment period ended on February 28, 2008.

Discussion of Comments

FMCSA received one comment in this proceeding. The comment was considered and discussed below.

Advocates for Highway and Auto Safety (Advocates) expressed opposition to FMCSA's policy to grant exemptions from the FMCSR, including the driver qualification standards. Specifically, Advocates: (1) Objects to the manner in which FMCSA presents driver information to the public and makes safety determinations; (2) objects to the Agency's reliance on conclusions drawn from the vision waiver program; (3) claims the Agency has misinterpreted statutory language on the granting of exemptions (49 U.S.C. 31136(e) and 31315); and finally (4) suggests that a 1999 Supreme Court decision affects the legal validity of vision exemptions.

The issues raised by Advocates were addressed at length in 64 FR 51568 (September 23, 1999), 64 FR 66962 (November 30, 1999), 64 FR 69586 (December 13, 1999), 65 FR 159 (January 3, 2000), 65 FR 57230 (September 21, 2000), and 66 FR 13825 (March 7, 2001). We will not address these points again here, but refer interested parties to those earlier discussions.

Conclusion

The Agency has not received any adverse evidence on any of these drivers that indicates that safety is being compromised. Based upon its evaluation of the 12 renewal applications, FMCSA renews the Federal vision exemptions for Francis M. Anzulewicz, Donald J. Bierwirth, Jr., Arthur L. Bousema, Matthew Daggs, Donald R. Date, Jr., John E. Kimmet, Jr., Jason L. Light, Robert Mollicone, Kenneth R. Murphy, Jr., Paul D. Schnautz, Robert A. Sherry, and John R. Synder.

In accordance with 49 U.S.C. 31136(e) and 31315, each renewal exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

Issued on: March 21, 2008.

Larry W. Minor,

Associate Administrator for Policy and Program Development.

[FR Doc. E8–6489 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA–2008–0019]

Notice of Request for the Extension of Currently Approved Information Collections

AGENCY: Federal Transit Administration, DOT.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to extend the following currently approved information collection: 49 U.S.C. 5309 and 5307 Capital Assistance Programs.

DATES: Comments must be submitted before May 30, 2008.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. *Web site: http://www.regulations.gov*. Follow the instructions for submitting comments on the U.S. Government electronic docket site. (Note: The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at *http://www.regulations.gov*. Commenters should follow the directions below for mailed and hand-delivered comments.

2. *Fax:* 202–366–7951.

3. *Mail:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30,

West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001.

4. *Hand Delivery:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to Internet users, without change, to *http://www.regulations.gov*. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit *http://www.regulations.gov*. Docket: For access to the docket to read background documents and comments received, go to *http://www.regulations.gov* at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE., Docket Operations, M–30, West Building, Ground Floor, Room W12–140, Washington, DC 20590–0001 between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Scott Faulk, Office of Program Management, (202) 366–1660, or e-mail: *ScottFaulk@dot.gov*.

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of these information collections, including: (1) The necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: 49 U.S.C. Sections 5309 and 5307 Capital Assistance Programs (*OMB Number: 2132–0502*).

Background: 49 U.S.C. 5309 Capital Program and Section 5307 Urbanized Area Formula Program authorize the Secretary of Transportation to make grants to State and local governments and public transportation authorities for financing mass transportation projects. Grant recipients are required to make information available to the public and to publish a program of projects for affected citizens to comment on the proposed program and performance of the grant recipients at public hearings. Notices of hearings must include a brief description of the proposed project and be published in a newspaper circulated in the affected area. FTA also uses the information to determine eligibility for funding and to monitor the grantees' progress in implementing and completing project activities. The information submitted ensures FTA's compliance with applicable federal laws, OMB Circular A–102, and 49 CFR Part 18, ''Uniform Administrative Requirements for Grants and Cooperative Agreements with State and Local Governments.''

Respondents: State and local government, business or other for-profit institutions, and non-profit institutions.

Estimated Annual Burden on Respondents: 54 hours for each of the 3,675 respondents.

Estimated Total Annual Burden: 198,466 hours.

Frequency: Annual.

Issued: March 25, 2008.

Ann M. Linnertz,

Associate Administrator for Administration.

[FR Doc. E8–6484 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2008–0027]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel TRUANT.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2008–0027 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Pub. L. 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before April 30, 2008.

ADDRESSES: Comments should refer to docket number MARAD–2008–0027. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel TRUANT is:

Intended Use: ''Coastwise, small passenger carrying, recreational, day sailing.''

Geographic Region: ''ME, NH, MA, RI, CT, NY, NJ, PA, DE, MD, VA, NC, SC, GA, FL''.

Privacy Act

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).

Dated: March 19, 2008.

By order of the Maritime Administrator.

Christine Gurland,

Acting Secretary, Maritime Administration.

[FR Doc. E8–6576 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2008–0028]

Requested Administrative Waiver of the Coastwise Trade Laws

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Invitation for public comments on a requested administrative waiver of the Coastwise Trade Laws for the vessel WITCH OF ENDOR.

SUMMARY: As authorized by Public Law 105–383 and Public Law 107–295, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below. The complete application is given in DOT docket MARAD–2008–0028 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with Public Law 105–383 and MARAD's regulations at 46 CFR Part 388 (68 FR 23084; April 30, 2003), that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR Part 388.

DATES: Submit comments on or before April 30, 2008.

ADDRESSES: Comments should refer to docket number MARAD–2008–0028. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joann Spittle, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue, SE., Room W21–203, Washington, DC 20590. Telephone 202–366–5979.

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel WITCH OF ENDOR is:

Intended Use: ''Passenger (6 or fewer)''.

Geographic Region: ''Maine, Massachusetts, Rhode Island, Connecticut, New York, Delaware, Maryland, Florida, California, Oregon, Washington''.

Privacy Act

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).

Dated: March 19, 2008.

By order of the Maritime Administrator.

Christine Gurland,

Acting Secretary, Maritime Administration.

[FR Doc. E8–6578 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket Number: MARAD 2008 0029]

Use of Foreign-Flag Anchor Handling Vessels in the Beaufort Sea or Chukchi Sea Adjacent to Alaska

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: As authorized by Public Law 109–347, the Secretary of Transportation, as represented by the Maritime Administration, is authorized to make determinations permitting the use of foreign-flag anchor handling vessels in certain cases (and for a limited period of time) if no U.S.-flag vessels are found to be suitable and reasonably available.

A request for such a determination regarding anchor handling vessels with a minimum ice class A3 has been received by the Maritime Administration. If the Maritime Administration determines that U.S.-flag vessels are not suitable and reasonably available for the proposed service, a determination will be granted allowing for the conditional use of these vessels, within a set time frame. Those interested in providing the names of suitable and available vessels for the proposed service should refer to the docket number, and identify the U.S.-flag vessels available.

DATES: Submit U.S.-flag anchor handling ice class A3 or above vessel nominations on or before April 30, 2008.

ADDRESSES: U.S.-flag vessel nominations should refer to docket number MARAD 2008 0029. Written nominations may be submitted by hand or by mail to the Docket Clerk, U.S. DOT Dockets, Room PL–401, Department of Transportation, 1200 New Jersey Avenue, SE., Washington, DC 20590–0001. You may also send documents electronically via the Internet at *http://www.regulations.gov.* All submissions will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document, and all documents entered into this docket, is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Thomas W. Harrelson, U.S. Department of Transportation, Maritime Administration, MAR–730, Room W21–314, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone 202–366–5515.

SUPPLEMENTARY INFORMATION: The Maritime Administration has received a request from an attorney on behalf of a client seeking permission to charter foreign-flag ice-classed A3 anchor handling vessels adjacent to the coast of Alaska. The two foreign-flag anchor handling vessels (VLADIMIR

IGNATYUK #8127804 and JIM KILABUK #7420754) would operate in the Beaufort Sea or Chukchi Sea adjacent to Alaska, under certain conditions, and for a limited period of time. Section 705 of Pub.L. 109–347 allows the use of foreign-flag vessels in this regard if the Maritime Administration determines that U.S.-flag vessels are not suitable or reasonably available.

The Maritime Administration is posting this notice in the **Federal Register** providing the public 30 days notice of our intention to provide a determination allowing for the use of foreign-flag vessels in this regard, if suitable and available U.S.-flag vessels are not otherwise identified. The Maritime Administration's determination will be for the period through December 31, 2009.

By order of the Maritime Administrator.

Dated: March 25, 2008.

Christine Gurland,

Acting Secretary, Maritime Administration.

[FR Doc. E8–6567 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[NHTSA Docket No. 2008–0030]

Highway Safety Programs; Model Specifications for Screening; Devices to Measure Alcohol in Bodily Fluids

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Notice.

SUMMARY: This notice revises Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids (Model Specifications) published in the **Federal Register** on August 2, 1994 (59 FR 39382). These devices test for the presence of alcohol using breath or bodily fluids such as saliva. The Model Specifications support State laws that target youthful offenders (i.e., ''zero tolerance'' laws) and the Department of Transportation's regulations on Alcohol Misuse Prevention, and encourage industry efforts to develop new technologies (e.g., non-breath devices) that measure alcohol content from bodily fluids.

This notice removed testing of Interpretive Screening Devices (ISDs) and use of the Breath Alcohol Sample Simulator (BASS) device from the Model Specifications. The ISDs did not provide an unambiguous test result, as test results for ISDs are subjective and require interpretation by a test administrator or technician. Because the agency has determined the BASS device is not necessary for inclusion in the Model Specifications, this notice removes all references to the BASS device.

Additionally, in order to ensure product integrity, this notice provides guidelines for retesting devices when manufacturers contemplate changes, revisions, or upgrades to alcohol screening devices on the Conforming Products List (CPL).

These revisions to the Model Specifications will not affect devices currently listed on the CPL.

DATES: Effective Date: Revisions to these Model Specifications become effective on March 31, 2008.

FOR FURTHER INFORMATION CONTACT: *For technical issues:* Ms. De Carlo Ciccel, Behavioral Research Division, NTI–131, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; Telephone: (202) 366–1694. *For legal issues:* Mr. David Bonelli, Office of Chief Counsel, NCC–113, National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590; Telephone: (202) 366–5834.

SUPPLEMENTARY INFORMATION:

I. Background

As indicated in the Model Specifications published in 1994, the agency will modify and improve the Model Specifications as new data and test procedures become available and will alter the test procedures, as necessary, to meet unique design features of specific devices. Since publication of the Model Specifications, the agency encountered difficulties ensuring the accuracy of testing ISDs and also determined the use of the BASS is not necessary for inclusion in the Model Specifications. These events made it necessary to revise the Model Specifications.

On December 14, 2007, (72 FR 71188), NHTSA proposed and sought comments on amendments and revisions to the Model Specifications published in 1994. In the notice, NHTSA explained that the 1994 Model Specifications allowed for evaluation of screening devices that require subjective interpretation of test results by a test administrator or technician. These ISDs differ from devices that provide objective test results, including the use of digital technology or the appearance of lights or marks based on the presence or absence of alcohol. For instance, use of pass/fail lights or enzymes that react with alcohol to produce an unambiguous mark provide objective test results. Also, the 1994 Model Specifications required that interpretive devices be evaluated subjectively under five lighting conditions (fluorescent, incandescent, mercury, sodium and daylight) by a panel of ten novice evaluators who are not color blind. Since publication of the 1994 Model Specifications, NHTSA evaluated eight separate ISDs. Of those eight ISD evaluations, none resulted in a successful outcome in the panel test described above. In one evaluation, the device passed the test under all lighting conditions except sodium. This device is no longer manufactured. Although many novice evaluators were able to judge the correct test outcome in the eight ISD evaluations, some could not, even though the manufacturers' instructions were conveyed to the evaluators and all evaluators passed tests to determine their color perception ability. This subjective interpretation of test results does not ensure accuracy and precision required to protect public safety. Due to repeated problems in evaluating ISDs, NHTSA proposed to remove altogether testing of ISDs and all references to interpretive or color indicator tests from the Model Specifications.

The 1994 Model Specifications provided for the use of the Breath Alcohol Sample Simulator (BASS) device for delivering alcohol-in-air test samples. The use of the BASS device is not necessary for inclusion in the Model Specifications because the BASS device is intended for use in testing the sampling efficiency of evidential breath testers. There is no sampling efficiency test in the Model Specifications for alcohol screening devices. The alcohol-in-air test sample for breath alcohol screening devices is supplied by a calibrating unit. Therefore, the agency proposed to remove all references to the BASS device from the Model Specifications.

The 1994 Model Specifications also provide procedures to conduct special investigations and re-test a device if information gathered indicates that a device listed on the CPL is not performing in accordance with the Model Specifications. The agency proposed the addition of Appendix B to provide guidance regarding notification and re-testing when manufacturers contemplate revisions to devices listed on the CPL. The proposed Appendix follows the language used in the Model Specifications for evidential breath testing devices (58 FR 48705). Upon notification by a manufacturer of a contemplated change to a device listed

on the CPL, NHTSA proposed that it would determine whether re-testing is required. Such determination would look at several factors, including the nature and reason for the change, the scope of the change, the effects of the change on the performance of the device, and how the change will be documented for the benefit of the user. NHTSA would list device revisions and whether re-testing was required in the next update to the CPL. Appendix B also would state that NHTSA may re-test any device listed on the CPL at any time to determine continued compliance and performance with the Model Specifications. A device found not to perform in accordance with the Model Specifications would be subject to the special investigation procedures discussed below.

Having received no comments on any aspect of the agency's proposal, this notice adopts the proposed revisions, including the ''Procedures'' and ''Model Specifications for Alcohol Screening Devices,'' without change.

II. Procedures

This section describes the current procedures. The DOT Volpe National Transportation Systems Center (VNTSC), RTV–4F, Kendall Square, Cambridge, MA 02142 tests products manufacturers submit to determine whether the products meet the model specifications. Tests are conducted semiannually, or as necessary. Manufacturers are required to apply to NHTSA for a test date by writing to the Office of Behavioral Safety Research, NTI–130, NHTSA, 1200 New Jersey Avenue, SE., Washington, DC 20590. At least 30 days are typically required from the date of notification until the test can be scheduled.

One week prior to the scheduled initiation of the test program, manufacturers must deliver their devices to VNTSC. If the devices are disposable, the manufacturer must deliver at least 300 such devices; if the devices are reusable, the manufacturer need submit only a single device. If a manufacturer of a reusable device wishes to submit a duplicate, backup instrument, it may so do. The manufacturer is responsible for ensuring that the devices operate properly and are packaged correctly. The manufacturer must also deliver the operator's manual (or instructions) and the maintenance manual (if any) that is to be supplied with the purchase of the device, as well as specifications and drawings fully describing the device and its use. Information determined to be proprietary will be respected. (See 49 CFR Part 512, regarding the procedure by which NHTSA will consider claims of confidentiality.)

In addition, the manufacturer must submit a self-certification, certifying that the manufacturer meets the requirements according to the U.S. Food and Drug Administration (FDA) Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820), and that the device's label meets the requirements in FDA's Labeling regulations for devices used for medical purposes (21 CFR Part 809.10), even if the devices are not to be used for medical purposes. See Appendix A to this notice.

The manufacturer has the right to check its device(s) between the time of arrival at VNTSC and the start of the tests, but will have no access to the device(s) during the tests. Any malfunction of a device resulting in failure to complete any of the tests satisfactorily will result in a determination that the device does not conform to the Model Specifications. If a device is found not to conform to the Model Specifications, it may be resubmitted for the next testing cycle after appropriate corrections have been made. However, the agency reserves the discretion to determine whether to conduct any retest.

The agency intends to update and republish the CPL in the **Federal Register** annually. Republications of the CPL add conforming alcohol screening devices tested since the last CPL republication.

NHTSA will continue to provide notification in the **Federal Register** when the agency amends the Model Specifications as new data and test procedures become available and will retest devices when necessary.

The NHTSA Office of Behavioral Safety Research is the point of contact for information about acceptance testing and field performance of devices that are in the marketplace. NHTSA requests that users of alcohol screening devices provide both acceptance and field performance data to the Office of Behavioral Safety Research when such data indicate potential performance problems. Information from users will help NHTSA monitor whether alcohol screening devices are performing according to the NHTSA Model Specifications.

If information gathered indicates that a device on the CPL is not performing in accordance with the Model Specifications, NHTSA may direct VNTSC to conduct a special investigation. An investigation may include visits to users and additional tests of devices obtained on the open market. If the investigation indicates that a device actually sold on the market does not meet the Model Specifications, the manufacturer will be notified that the device may be removed from the CPL. In this event, the manufacturer will have 30 days from the date of notification to reply. Based on the VNTSC investigation and any data provided by the manufacturer, NHTSA will decide whether the device should remain on the CPL. If the device is removed from the CPL, the manufacturer will be permitted to resubmit an improved device to VNTSC for testing when it believes the problems causing its failure have been resolved. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems that led to failure of the device. The agency reserves the discretion to determine whether to conduct any retest.

If information gathered indicates that the manufacturer of a device on the CPL does not comply with the requirements in FDA's Good Manufacturing Practices regulations for devices used for medical purposes or that the device's label does not comply with the requirements in FDA's labeling regulations for devices used for medical purposes, NHTSA may investigate the matter in consultation with FDA and will notify the manufacturer that the device may be removed from the CPL. The manufacturer will have 30 days from the date of notification to reply. Based on any data provided by the manufacturer and investigative findings, NHTSA will decide whether the device should remain on the CPL. If the device is removed from the CPL, the manufacturer will be permitted to resubmit a self-certification, certifying that the manufacturer or its device complies with these FDA requirements when it believes the problems causing its non-compliance have been resolved. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems that led to non-compliance.

In accordance with the foregoing, the amendments of the Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids, are set forth below.

Model Specifications for Alcohol Screening Devices

1. Purpose and Scope

These specifications establish performance criteria and methods for testing of alcohol screening devices. Alcohol screening devices use bodily fluids to detect the presence of 0.020 or more BAC (see below) with sufficient

accuracy for screening purposes. These specifications are intended primarily for use in the conformance testing of alcohol screening devices.

2. Classification

2.1 Disposable Alcohol Screening Devices.

Alcohol screening devices designed for a single use.

2.2 Reusable Alcohol Screening Devices.

Alcohol screening devices designed to be reused.

3. Definitions

3.1 Alcohol.

The intoxicating agent in beverage alcohol, ethyl alcohol or other low molecular weight alcohols including methyl or isopropyl alcohol.

3.2 Alcohol Screening Device.

A device that is used to detect the presence of 0.020 or more BAC. The device may measure any bodily fluid for this purpose, but shall provide output in BAC units. Test results must be indicated unambiguously by numerical read-out or by other means, such as by the use of lights or by the appearance of a distinctive mark but not by color change.

3.3 Blood alcohol concentration (BAC).

Grams alcohol per 100 milliliters of blood or grams alcohol per 210 liters of breath in accordance with the Uniform Vehicle Code, Section 11–903(a)(5) [1] (BrAC is often used to indicate that the measurement is a breath measurement); or grams alcohol per 100 milliliters of saliva.

3.4 Calibrating Unit.

A device that produces an alcohol-in-air test sample of known concentration and that meets the NHTSA Model Specifications for Calibrating Units (72 FR 34742).

3.5 Bodily Fluid.

Any bodily fluid capable of being used to estimate alcohol concentration, provided the relationship between such bodily fluid and BAC has been established according to scientifically acceptable standards. Such fluids include but are not limited to blood, exhaled deep lung breath and saliva.

3.6 Scientifically Acceptable Substitutes.

Fluids that have been scientifically accepted as equivalent to bodily fluids for testing purposes, such as aqueous alcohol test solutions on a one-to-one basis for blood or saliva.

[1] Available from the National Committee on Uniform Traffic Laws and Ordinances, 107 S. West Street, # 10, Alexandria, VA 22314. Web site address: *http://www.ncutle.org*

4. Test Methods and Requirements

Testing will be performed according to the instructions that normally accompany the submitted device and under the conditions specified in the tests below.

4.1 Test 1. Precision and Accuracy.

Perform 40 trials under normal laboratory conditions including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices. Perform tests using a VNTSC investigator.

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.2 Test 2. Blank Reading.

Perform 20 trials under normal laboratory conditions at 0.000 BAC. Use non-alcoholic human breath for breath devices and non-alcoholic bodily fluids or scientifically acceptable substitutes for non-breath devices. Perform tests using a VNTSC investigator.

To conform: no positive results. If the device is capable of providing a reading of greater than 0.000 BAC and less than 0.020 BAC, not more than one such result.

4.3 Test 3. Cigarette smoke interference (only breath and saliva test devices).

Perform five trials at 0.000 BAC. Select an alcohol-free person who smokes cigarettes for this test. Ask the person selected to smoke approximately one half of a cigarette. Within one minute after smoking, or after a waiting period specified in the manufacturer's instructions, administer the alcohol screening device test according to the manufacturer's instructions. Then ask the person to take another smoke and repeat the test to produce a total of five trials.

To conform: no positive results.

4.4 Temperature.

Test at low and high ambient temperature.

4.4.1 Test 4.1. Low Ambient Temperature.

Perform 40 trials at 10 degrees Centigrade (C), including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.4.2 Test 4.2 High Ambient Temperature.

Perform trials of 40 devices at 40 degrees C, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC, not more than one non-positive result.

4.5. Test 5. Vibration.

Perform 40 trials, including 20 trials at 0.008 BAC and 20 trials at 0.032 BAC. Use a calibrating unit for this test for breath devices and preparations of bodily fluids or scientifically acceptable substitutes for non-breath devices.

Mount the screening device on a shake table and vibrate the table in simple harmonic motion through each of its three major axes, as specified below. Sweep through each frequency range in 2.5 minutes, then reverse the sweep to the starting frequency in 2.5 minutes. Disposable testers may be placed in a suitable box mounted on the shake table. Test after vibration.

Frequency (hertz)	Amplitude (inches, peak to peak)
10 to 30	0.30
30 to 60	0.15

To conform at 0.008 BAC, not more than one positive result. To conform at 0.032 BAC not more than one non-positive result.

Appendix A—Labeling Instructions for Alcohol Screening Devices' Intended Use Provide the intended use including the specimen matrix (e.g. saliva, breath), the assay type (quantitative, semi-quantitative), the purpose of performing the assay, and the individual designated to perform the assay.

e.g.: This product is intended for the (quantitative, semi-quantitative) determination of alcohol in —define matrix (for e.g., saliva, breath, sweat) to perform screening alcohol assays.

This product is recommended for use by individuals who have been trained in the administration of screening devices.

Description of Testing System

Provide the principles of the procedure for performing the alcohol screening assay.

e.g.: This product uses (alcohol dehydrogenase, infrared technology, etc.) to perform the test.

Chemical Reaction Sequence

Describe the chemical reaction sequence, if applicable.

Reagents: List the concentration, strength, and composition of the reactive ingredients.

List the non-reactive ingredients.

Reagent Preparation and Storage

Provide instructions for preparing the reagents, if applicable.

Provide instructions for storing the reagents, if applicable.

Provide any signs of deterioration of the reagents, if applicable.

Provide the reagents' shelf life and opened expiration dating, if applicable.

e.g.: Tests in unopened packaging are stable until the date printed on the product container when stored at 22–28 degrees C. If packaging is opened, tests must be conducted at once.

Provide a caution not to use the reagents beyond the expiration date.

Precautions

1. List any reagents that may be hazardous such as caustic compounds, sodium azide or other hazardous reagents and instructions for disposal, if applicable.

2. Provide warning to user to treat all samples as potentially infective. Include instructions for handling and disposal of the sample.

Specimen Collection

Provide instructions for collecting and handling the sample.

Provide criteria for specimen rejection, if applicable.

Calibration

Disposable tests are pre-calibrated. No additional calibration is required.

Reusable (Instrumented) tests require calibration.

Provide information regarding how calibrations are to be conducted, if applicable, including the number and concentration of calibrators, and the frequency of calibration.

Provide instructions for calibration and recalibration.

Provide the criteria for acceptability of calibration.

Test Procedure (Disposable)

Provide adequate step-by-step instructions for performing the test and determining the results.

Test Procedure (Re-usable/Instrumented)

Provide adequate step-by-step instruction for performing the test.

Provide the installation procedures and, if applicable, any special requirements.

Provide the space and ventilation requirements.

Provide the description of the required frequency of equipment maintenance and function checks.

Provide the instructions for any remedial action to be taken when the equipment performs outside of its operating range.

Provide any operational precautions and limitations.

Provide instructions for the protection of equipment and instrumentation from fluctuations or interruptions in electrical current that could adversely affect test results and reports, if applicable.

Quality Control (QC)

Disposable Tests

If applicable, the function and stability of the test can be determined by the examination of the procedural ''built in'' controls contained in the product. If these controls are not working, the test is invalid and must be repeated.

Disposable/Instrumented Devices

If external quality control materials are used, provide the number, type, matrix and concentration of the QC materials.

Provide directions for performing quality control procedures.

Provide an adequate description of the remedial action to be taken when the QC results fail to meet the criteria for acceptability.

Provide directions for interpretation of the results of quality control samples.

Results

Describe how the user obtains the test results, e.g., from an instrument read-out, printout, etc.

Describe the results in terms of blood alcohol concentration.

Describe what concentration indicates a positive result and what concentration indicates a negative result.

Limitations

List the substances or factors that may interfere with the test and cause false results including technical or procedural errors.

Dynamic Range

Provide the operating range of the product.

Precision and Accuracy

Only devices that meet the precision and accuracy of these Model Specifications will be included on NHTSA's Conforming Products List for alcohol screening devices.

Specificity

List the substances that have been evaluated with your product that do or do not interfere at the concentration indicated.

References

Provide pertinent bibliography.

Technical Assistance

List an 800 number the user may contact for further information or technical assistance.

Appendix B—Guidelines for Re-testing of Modified Screening Devices

Manufacturers contemplating revisions to an alcohol screening device listed on the Conforming Products List (CPL) are advised that the revision may affect the status of the device on the CPL. The manufacturer should inform NHTSA of the contemplated change so that a judgment can be made whether or not re-testing the revised alcohol screening device is necessary. The following lists the type of information NHTSA uses in determining the necessity to re-test an alcohol screening device, and is provided as guidance to manufacturers:

- Manufacturer and Model Name.
- Nature and reason for change(s).
- Scope of change(s) (e.g., Will existing devices be retrofitted? Will the change apply to some users but not others?)
- Will the change(s) affect performance of the device with regard to the Model Specifications? (Precision and accuracy, blank reading, temperature operations, or vibrations.)
- How will the change(s) be documented for the benefit of the user? (e.g., Will the change(s) be documented in service bulletins and/or service manuals? If not, why not?)

If necessary for clarity, drawings of the listed and changed device may also be helpful in NHTSA's deliberations.

If, upon review of information provided by a manufacturer, it is determined that re-testing is not warranted, a statement to that effect will be included in the next scheduled CPL update.

NHTSA reserves the right to test any CPL-listed device on the open market to determine continued compliance and performance in accordance with these Model Specifications. Devices found not to comply with or perform in accordance with the Model Specifications are subject to the investigation provisions stated above in section II, Procedures.

Authority: 23 U.S.C. 403; 49 CFR 1.50; 49 CFR Part 501.

Issued on: March 25, 2008.

Marilena Amoni,

Associate Administrator for the Office of Research and Program Development.

[FR Doc. E8–6520 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2008–0051]

Notice of Receipt of Petition for Decision That Nonconforming 2000 Chevrolet Tahoe Multipurpose Passenger Vehicles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 2000 Chevrolet Tahoe multipurpose passenger vehicles are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 2000 Chevrolet Tahoe multipurpose passenger vehicles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards (FMVSS) are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is April 30, 2008.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted by any of the following methods:

• *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

• *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.

• *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

• *Fax:* 202–493–2251.

Instructions: Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: 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 (65 FR 19477–78).

How to Read Comments Submitted to the Docket: You may read the comments received by Docket Management at the address and times given above. You may also view the documents from the Internet at *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. The docket ID number and title of this notice are shown at the heading of this document notice. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically search the Docket for new material.

FOR FURTHER INFORMATION CONTACT: Coleman Sachs, Office of Vehicle Safety Compliance, NHTSA (202–366–3151).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR Part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Barry Taylor Enterprises of Richmond, California (BTE)(Registered Importer 01–280) has petitioned NHTSA to decide whether nonconforming 2000 Chevrolet Tahoe multipurpose passenger vehicles are eligible for importation into the United States. The vehicles which BTE believes are substantially similar are 2000 Chevrolet Tahoe multipurpose passenger vehicles that were manufactured for sale in the United States and certified by their manufacturer as conforming to all applicable FMVSS.

The petitioner claims that it carefully compared non-U.S. certified 2000 Chevrolet Tahoe multipurpose passenger vehicles to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most FMVSS.

BTE submitted information with its petition intended to demonstrate that non-U.S. certified 2000 Chevrolet Tahoe multipurpose passenger vehicles, as originally manufactured, conform to many FMVSS in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 2000 Chevrolet Tahoe multipurpose passenger vehicles are identical to their U.S.-certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect,* 103 *Windshield Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 106 *Brake Hoses,* 111 *Rearview Mirrors,* 113 *Hood Latch System,* 114 *Theft Protection,* 116 *Motor Vehicle Brake Fluids,* 118 *Power-Operated Window, Partition, and Roof Panel Systems,* 119 *New Pneumatic Tires for Vehicles Other than Passenger Cars,* 120 *Tire Selection and Rims for Motor Vehicles Other than Passenger Cars,* 124 *Accelerator Control Systems,* 135 *Passenger Car Brake Systems,* 201 *Occupant Protection in Interior Impact,* 202 *Head Restraints,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 208 *Occupant Crash*

Protection, 210 *Seat Belt Assembly Anchorages,* 212 *Windshield Mounting,* 214 *Side Impact Protection,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* 225 *Child Restraint Anchorage Systems,* 301 *Fuel System Integrity, and* 302 *Flammability of Interior Materials.*

The petitioner additionally states that the vehicle identification plates affixed to the vehicles meet the requirements of 49 CFR part 565.

The petitioner also contends that the vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* Inscription of the word ''brake'' on the dash in place of the international ECE warning symbol.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* Installation of a U.S.-conforming model front side-mounted reflex reflectors and installation of U.S.-conforming model front turn signal lamps or modification of the existing lamps to meet the requirements of this standard.

Standard No. 209 *Seat Belt Assemblies:* Inspection of all vehicles and installation, on vehicles that are not already so equipped, of U.S.-conforming model components to meet the requirements of this standard.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above addresses both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: March 24, 2008.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. E8–6492 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2008–0058]

Notice of Receipt of Petition for Decision That Nonconforming 1994 and 1995 Land Rover Defender 90 Multipurpose Passenger Vehicles Are Eligible for Importation

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Notice of receipt of petition for decision that nonconforming 1994 and 1995 Land Rover Defender 90 multipurpose passenger vehicles are eligible for importation.

SUMMARY: This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that 1994 and 1995 Land Rover Defender 90 multipurpose passenger vehicles that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards (FMVSS) are eligible for importation into the United States because (1) they are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards, and (2) they are capable of being readily altered to conform to the standards.

DATES: The closing date for comments on the petition is April 30, 2008.

ADDRESSES: Comments should refer to the docket and notice numbers above and be submitted by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Docket Management Facility: U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Instructions: Comments must be written in the English language, and be no greater than 15 pages in length, although there is no limit to the length of necessary attachments to the comments. If comments are submitted in hard copy form, please ensure that two copies are provided. If you wish to receive confirmation that your comments were received, please enclose a stamped, self-addressed postcard with the comments. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: 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 (65 FR 19477–78).

How to Read Comments submitted to the Docket: You may read the comments received by Docket Management at the address and times given above. You may also view the documents from the Internet at *http://www.regulations.gov.* Follow the online instructions for accessing the dockets. The docket ID number and title of this notice are shown at the heading of this document notice. Please note that even after the comment closing date, we will continue to file relevant information in the Docket as it becomes available. Further, some people may submit late comments. Accordingly, we recommend that you periodically search the Docket for new material.

FOR FURTHER INFORMATION CONTACT: Coleman Sachs, Office of Vehicle Safety Compliance, NHTSA (202–366–3151).

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the

petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Export Auto sales, Inc., of Chicopee, Massachusetts (Export Auto)(Registered Importer 01–284) has petitioned NHTSA to decide whether nonconforming 1994 and 1995 Land Rover Defender 90 multipurpose passenger vehicles are eligible for importation into the United States. The vehicles which Export Auto believes are substantially similar are 1994 and 1995 Land Rover Defender 90 multipurpose passenger vehicles that were manufactured for sale in the United States and certified by their manufacturer as conforming to all applicable FMVSS.

The petitioner claims that it carefully compared non-U.S. certified 1994 and 1995 Land Rover Defender 90 multipurpose passenger vehicles to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most FMVSS.

Export Auto submitted information with its petition intended to demonstrate that non-U.S. certified 1994 and 1995 Land Rover Defender 90 multipurpose passenger vehicles, as originally manufactured, conform to many FMVSS in the same manner as their U.S. certified counterparts, or are capable of being readily altered to conform to those standards.

Specifically, the petitioner claims that non-U.S. certified 1994 and 1995 Land Rover Defender 90 multipurpose passenger vehicles are identical to their U.S.-certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence,* 103 *Defrosting and Defogging Systems,* 104 *Windshield Wiping and Washing Systems,* 105 *Hydraulic and Electric Brake Systems,* 106 *Brake Hoses,* 107 *Reflecting Surfaces,* 113 *Hood Latch Systems,* 114 *Theft Protection,* 115 *Vehicle Identification Number—Basic Requirements,* 116 *Brake Fluid,* 124 *Accelerator Control Systems,* 202 *Head Restraints,* 203 *Impact Protection for the Driver from the Steering Control System,* 204 *Steering Control Rearward Displacement,* 205 *Glazing Materials,* 206 *Door Locks and Door Retention Components,* 207 *Seating Systems,* 210 *Seat Belt Assembly Anchorages,* 211 *Wheel Nuts, Wheel Discs and Hub Caps,* 212 *Windshield Retention,* 216 *Roof Crush Resistance,* 219 *Windshield Zone Intrusion,* and 302 *Flammability of Interior Materials.*

Petitioner states that the vehicle is equipped with a vehicle identification number plate that complies with the requirements of 49 CFR Part 565.

Petitioner also observes that the vehicle is not subject to the Theft Prevention Standard found in 49 CFR part 541.

Petitioner also contends that the vehicle is capable of being readily altered to meet the following standards, in the manner indicated:

Standard No. 101 *Controls and Displays:* (a) replacement or conversion of the speedometer to read in miles per hour; (b) inspection of all vehicles to ensure that components subject to the standard are identical to those found on the vehicle's U.S.-certified counterpart and replacement of noncompliant components with U.S-model parts on vehicles that are not already so equipped.

Standard No. 108 *Lamps, Reflective Devices and Associated Equipment:* (a) Installation of U.S.-model headlights; (b) modification of the amber sidemarker lights to meet the requirements of the standard; (c) inspection of all vehicles and replacement of noncompliant lighting system components with U.S-model parts on vehicles that are not already so equipped.

Standard No. 111 *Rearview Mirror:* inscription of the required warning statement on the face of the passenger side rearview mirror, or replacement of the mirror with one that is already so marked.

Standard No. 118 *Power Window Systems:* inspection of all vehicles and modification of the wiring system, where necessary, to ensure compliance with the standard.

Standard No. 119 *New Pneumatic Tires for Vehicles other than Passenger Cars:* inspection of all vehicles to ensure compliance with the standard.

Standard No. 120 *Tire Selection and Rims for Vehicles other than Passenger Cars:* inspection of all vehicles to ensure compliance with the standard. The petitioner asserts that the tires and rims on the non-U.S. certified vehicle it has examined are properly marked.

Standard No. 201 *Occupant Protection in Interior Impact:* inspection of all vehicles and replacement of any components subject to the standard that are not identical to those found on the vehicle's U.S.-certified counterpart. The petitioner asserts that those components on the non-U.S. certified vehicle it has examined are identical to those found on the vehicle's U.S.-certified counterpart.

Standard No. 208 *Occupant Crash Protection:* inspection of all vehicles and modification, as necessary, to ensure compliance with the standard. The petitioner asserts that the occupant crash protection system on the non-U.S. certified vehicle it has examined is identical to that found on the vehicle's U.S.-certified counterpart.

Standard No. 209 *Seat Belt Assemblies:* inspection of all vehicles and modification, as necessary, to ensure compliance with the standard. The petitioner asserts that the seat belt assemblies on the non-U.S. certified vehicle it has examined are in compliance with the standard.

Standard No. 214 *Side Impact Protection:* inspection of all vehicles and modification, as necessary, to ensure compliance with the standard. The petitioner asserts that the door beams on the non-U.S. certified vehicle it has examined are identical to those found on the vehicle's U.S.-certified counterpart.

Standard No. 301 *Fuel System Integrity:* installation of an U.S.-model rollover valve to meet the requirements of the standard.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above addresses both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

Authority: 49 U.S.C. 30141(a)(1)(A) and (b)(1); 49 CFR 593.8; delegations of authority at 49 CFR 1.50 and 501.8.

Issued on: March 25, 2008.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. E8–6503 Filed 3–28–08; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[REG–209485–86]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the

Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, REG–209485–86 (TD 8812), Continuation Coverage Requirements Application to Group Health Plans (§§ 54.4980B–6, 54.4980B–7, and 54.4980B–8).

DATES: Written comments should be received on or before May 30, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of regulation should be directed to Carolyn N. Brown, (202) 622–6688, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Carolyn.N.Brown@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Continuation Coverage Requirements Application to Group Health Plans.

OMB Number: 1545–1581.

Regulation Project Number: REG–209485–86 (TD8812).

Abstract: The regulations require group health plans to provide notices to individuals who are entitled to elect COBRA (The Consolidated Omnibus Budget Reconciliation Act of 1985) continuation coverage of their election rights. Individuals who wish to obtain the benefits provided under the statute are required to provide plans notices in the cases of divorce from the covered employee, a dependent child's ceasing to be dependent under the terms of the plan, and disability. Most plans will require that elections of COBRA continuation coverage be made in writing. In cases where qualified beneficiaries are short by an insignificant amount in a payment made to the plan, the regulations require the plan to notify the qualified beneficiary if the plan does not wish to treat the tendered payment as full payment. If a health care provider contacts a plan to confirm coverage of a qualified beneficiary, the regulations require that the plan disclose the qualified beneficiary's complete rights to coverage.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, individuals or households, and not-for-profit institutions.

Estimated Number of Respondents: 1,800,000.

The estimated time per respondent varies from 30 seconds to 330 hours, depending on individual circumstances, with an estimated average of 14 minutes.

Estimated Total Annual Burden Hours: 404,640.

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: March 18, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–6515 Filed 3–28–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

[EE–45–93]

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning an existing final regulation, EE–45–93, Electronic Filing of Form W–4 (§ 31.3402(f)(5)–1).

DATES: Written comments should be received on or before May 30, 2008 to be assured of consideration.

ADDRESSES: Direct all written comments to Glenn P. Kirkland, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to Carolyn N. Brown, at (202) 622–6688, or at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet, at *Carolyn.N.Brown@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Electronic Filing of Form W–4.

OMB Number: 1545–1435.

Regulation Project Number: EE–45–93.

Abstract: Information is required by the Internal Revenue Service to verify compliance with regulation section 31.3402(f)(2)–1(g)(1), which requires submission to the Service of certain withholding exemption certificates. The affected respondents are employers that choose to make electronic filing of Forms W–4 available to their employees.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations, not for-profit institutions, and Federal, state, local or tribal governments.

Estimated Number of Respondents: 2,000.

Estimated Time per Respondent: 20 hours.

Estimated Total Annual Burden Hours: 40,000.

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: March 18, 2008.

Glenn P. Kirkland,

IRS Reports Clearance Officer.

[FR Doc. E8–6516 Filed 3–28–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

United States Mint

Notification of United States Mint Coin Product Price Adjustment

SUMMARY: The United States Mint is announcing the prices of the 2008 American Eagle Gold Uncirculated Coin Program.

Pursuant to the authority that 31 U.S.C. 5111(a) and 5112(a)(7–10) grant the Secretary of the Treasury to mint and issue gold coins, and to prepare and distribute numismatic items, the United States Mint mints and issues 2008 American Eagle Gold Proof and Uncirculated Coins with the following weights: One-ounce, one-half ounce, one-quarter ounce, one-tenth ounce. The United States Mint also produces an American Eagle four-coin set that contains one coin of each denomination.

Because of increases in the cost of gold, the United States Mint will begin accepting orders for 2008 American Eagle Gold Uncirculated Coins at the prices indicated below, effective April 1, 2008:

Description	Price
American Eagle Gold Uncirculated Coins:	
One-ounce gold uncirculated coin	$1,119.95
One-half ounce gold uncirculated coin	565.95
One-quarter ounce gold uncirculated coin	295.95
One-tenth ounce gold uncirculated coin	124.95
Four-coin gold uncirculated set	2,039.95

FOR FURTHER INFORMATION CONTACT: Gloria C. Eskridge, Associate Director for Sales and Marketing; United States Mint; 801 Ninth Street, NW., Washington, DC 20220; or call 202–354–7500.

Authority: 31 U.S.C. 5111, 5112 & 9701.

Dated: March 25, 2008.

Edmund C. Moy,

Director, United States Mint.

[FR Doc. E8–6480 Filed 3–28–08; 8:45 am]

BILLING CODE 4810–02–P

Federal Register

Monday,
March 31, 2008

Part II

Nuclear Regulatory Commission

10 CFR Part 26
Fitness for Duty Programs; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

RIN 3150–AF12

Fitness for Duty Programs

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations for Fitness for Duty (FFD) programs to update these requirements and enhance consistency with advances in other relevant Federal rules and guidelines, including the U.S. Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other Federal drug and alcohol testing programs that impose similar requirements on the private sector. The amendments require nuclear power plant licensees and other entities, including facilities possessing Category 1A material, to strengthen the effectiveness of their FFD programs. In addition, the amendments require nuclear power plant licensees and other entities to enhance consistency between with the FFD programs with NRC's access authorization requirements for nuclear power plants. The amendments also require nuclear power plant licensees to ensure against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue. The final rule ensures that individuals who are subject to these regulations are trustworthy and reliable, as demonstrated by avoiding substance abuse; are not under the influence of drugs or alcohol while performing their duties; and are not mentally or physically impaired from any other cause that would in any way adversely affect their ability to perform their duties safely and competently.

This final rule also grants, in part, a petition for rulemaking (PRM–26–1) submitted by Virginia Electric and Power Company (now Dominion Virginia Power) on December 30, 1993, by relaxing several required FFD program audit frequencies, and partially grants a petition for rulemaking (PRM–26–2) submitted by Barry Quigley on December 28, 1999.

DATES: This final rule is effective April 30, 2008. However, licensees and other applicable entities may defer implementation of this rule, except for Subparts I and K, until March 31, 2009. Subpart I must be implemented by licensees and other applicable entities no later than October 1, 2009. Licensees and other applicable entities shall comply with the requirements of Subpart K as of April 30, 2008.

FOR FURTHER INFORMATION CONTACT: David Diec, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–2834, Timothy McCune, Office of Nuclear Security and Incident Response, telephone (301) 415–6474, Dr. David R. Desaulniers, Office of New Reactors, telephone (301) 415–1043, or Dr. Valerie Barnes, Office of Nuclear Regulatory Research, telephone (301) 415–5944. All of the above contacts may also be reached by e-mail to *FITNESSFORDUTY@NRC.GOV.*

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I. Background

A. Drug and Alcohol Testing Provisions, and General Fitness-for-Duty Program Provisions

On June 7, 1989, the Commission announced the adoption of a new rule, 10 CFR Part 26, Fitness for Duty Programs (54 FR 24468), that required each licensee authorized to operate or construct a nuclear power reactor to implement an FFD program for all personnel having unescorted access to the protected area of its plant. A subsequent final rule published in the **Federal Register** on June 3, 1993 (58 FR 31467), expanded the scope of Part 26 to include licensees authorized to possess, use, or transport formula quantities of Strategic Special Nuclear Materials (SSNM).

At the time the FFD rule was published in 1989, the Commission directed the NRC staff to continue to analyze licensee programs, assess the effectiveness of the rule, and recommend appropriate improvements or changes. The NRC staff reviewed information from several sources including inspections, periodic reports by licensees on FFD program performance, reports of significant FFD events, industry-sponsored meetings, and current research literature, as well as initiatives by industry, the Substance Abuse and Mental Health Services Administration of the Department of HHS (SAMHSA, formerly the National Institute on Drug Abuse), and SAMHSA's Drug Testing Advisory Board, and recommended improvements and changes.

As a result, the NRC published proposed amendments to the FFD rule in the **Federal Register** on May 9, 1996 (61 FR 21105). The 90-day public comment period for the proposed rule closed on August 7, 1996. The NRC staff reviewed and considered public comments on the proposed rule, and submitted a final rule to the Commission in a Commission paper (SECY–00–0159), dated July 26, 2000. The Commission affirmed the rule in a Staff Requirements Memorandum (SRM–M001204A) dated December 4, 2000. The affirmed rule was sent to the Office of Management and Budget (OMB) to obtain a clearance under the Paperwork Reduction Act. The request for comments on the clearance was published in the **Federal Register** on February 2, 2001 (66 FR 8812). OMB and NRC received public comments that objected to some aspects of the rule. In SECY–01–0134, dated July 23, 2001, the NRC staff recommended withdrawing the request for clearance and preparing a new proposed rule. In a Staff

Requirements Memorandum (SRM–SECY–01–0134) dated October 3, 2001, the Commission approved the staff's recommendation to withdraw the request for clearance and prepare a new proposed rule.

B. Worker Fatigue Provisions

The NRC's ''Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors'' (referred to in this document as NRC's Policy on Worker Fatigue) was first published in the **Federal Register** on February 18, 1982 (47 FR 7352), and later issued through Generic Letter (GL) 82–12, ''Nuclear Power Plant Staff Working Hours,'' on June 15, 1982 (referred to in this document as GL 82–12). In GL 82–12, the NRC requested licensees to revise the administrative section of their technical specifications to ensure that plant administrative procedures were consistent with the work-hour guidelines. Those guidelines were:

(1) An individual should not be permitted to work more than 16 consecutive hours (excluding shift turnover time);

(2) An individual should not be permitted to work more than 16 hours in any 24-hour period, nor more than 24 hours in any 48-hour period, nor more than 72 hours in any 7-day period (all excluding shift turnover time);

(3) A break of at least 8 hours should be allowed between work periods (including shift turnover time); and

(4) Except during extended shutdown periods, the use of overtime should be considered on an individual basis and not for the entire staff on a shift.

Further, the guidelines permitted deviations from these limits in very unusual circumstances if authorized by the plant manager, his deputy, or higher levels of management in some cases. The NRC's Policy on Worker Fatigue was incorporated, directly or by reference, and with variations in wording and detail, into the technical specifications of all but three nuclear power plant sites who implemented the concept using other administrative controls.

When 10 CFR Part 26 was issued on June 7, 1989 (54 FR 24468), it focused on establishing requirements for preventing and detecting personnel impairment from drugs and alcohol. However, consistent with SRM–SECY–88–129, dated July 18, 1988, several requirements addressed other causes of impairment, including fatigue. Those requirements included general performance objectives [§ 26.10(a) and (b)] that provided for ''reasonable assurance that nuclear power plant personnel * * * are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause'' and ''early detection of persons who are not fit to perform activities within the scope of this part.'' A requirement was also included in § 26.20(a) for licensee policies to ''address other factors that could affect fitness for duty such as mental stress, fatigue and illness.''

In a letter dated February 25, 1999, Congressmen Dingell, Klink, and Markey expressed concerns to former NRC Chairman Shirley Ann Jackson that low staffing levels and excessive overtime may present a serious safety hazard at some commercial nuclear power plants. The Union of Concerned Scientists (UCS) expressed similar concerns on March 18, 1999, in a letter from David Lochbaum to Chairman Jackson, and in the UCS report ''Overtime and Staffing Problems in the Commercial Nuclear Power Industry,'' dated March 1999. In a letter dated May 18, 1999, to the Congressmen, the Chairman stated that the NRC staff would assess the need to revise the policy.

On September 28, 1999, the Commission received a petition for rulemaking (PRM–26–2) from Barry Quigley. (The petition is discussed in greater detail in Section II.B of this document.) The petition requested that the NRC amend 10 CFR Parts 26 and 55 to establish clear and enforceable work-hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work.

The UCS petitioned the NRC on April 24, 2001, under 10 CFR 2.206, to issue a Demand for Information (DFI) to specified licensees. The petition asserted that Wackenhut Corporation has the contractual right to fire security guards who refuse to report for mandatory overtime, and that this contractual right conflicts with 10 CFR Part 26. The NRC denied the DFI request (ADAMS Accession No. ML013230169), but addressed the concerns of the petition through the NRC's generic communication process. On May 10, 2002, the NRC issued NRC Regulatory Issue Summary (RIS) 2002–07, ''Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-for-Duty.'' The RIS addressed the applicability of 10 CFR Part 26 to worker fatigue, the potential for sanctions related to worker FFD concerns to have adverse implications for maintaining a work environment conducive to reporting FFD concerns, and the protections afforded workers by 10 CFR 50.7, ''Employee Protection.''

On January 10, 2002, in SRM–SECY–01–0113, the Commission approved a rulemaking plan, ''Fatigue of Workers at Nuclear Power Plants,'' dated June 22, 2001 (referred to in this document as SECY–01–0113). Under the approved plan, the NRC initiated a rulemaking to incorporate fatigue management into 10 CFR Part 26 in order to strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue.

During the development of the fatigue management requirements, the NRC observed an increase in concerns (e.g., allegations, media and public stakeholder reports) related to the workload and fatigue of security personnel following the terrorist attacks of September 11, 2001. Subsequent to an NRC review of the control of work hours for security force personnel, and public interactions with stakeholders, the Commission issued Order EA–03–038 on April 29, 2003, requiring compensatory measures related to fitness-for-duty enhancements for security personnel at nuclear power plants, including work hour limits.

The compensatory measures imposed by Order EA–03–038 were similar to the guidelines of the NRC's Policy on Worker Fatigue. The compensatory measures differed from the Policy guidelines in a few areas in which the NRC believed it was necessary to address previously identified deficiencies in the guidelines, including the need to address cumulative fatigue from prolonged periods of extended work hours, matters unique to security personnel and stakeholder input obtained through public meetings concerning the worker fatigue rulemaking and the order. The NRC imposed the requirements in the order to provide the Commission with reasonable assurance that the public health and safety and common defense and security continue to be adequately protected. The provisions specified in 10 CFR Part 26, Subpart I, Managing Fatigue, for security force personnel replace the requirements imposed by the order. Differences between the requirements in Subpart I and the requirements imposed by the order, and the rationale for those differences, are discussed in Section IV.D of this document.

C. Combined Part 26 Rulemaking

On March 29, 2004, in COMSECY–04–0014, the NRC staff informed the Commission of the status of both

rulemaking activities. The NRC staff also noted that because both rulemaking activities were being completed in parallel, the draft proposed fatigue rule language was based on the draft language in the proposed overall revision to Part 26, rather than on the former language in Part 26. Therefore, meaningful public comment could be confounded by the simultaneous promulgation of two draft rules which are somewhat interdependent, and staff action to address a comment on one proposed rule could easily impact the other proposed rule, creating a high potential for the need to issue one or both proposed rules. In SRM–COMSECY–04–0014, dated May 25, 2004, the Commission directed the staff to combine the rulemaking related to nuclear power plant worker fatigue with the ongoing Part 26 rulemaking activity. This combined final rule withdraws the proposed rule published on May 9, 1996.

D. Public Input Accepted Since 2000 ''Affirmed Rule''

In preparing this rule, the NRC considered comments received by OMB on the prior Part 26 final rule affirmed by the Commission in an SRM dated December 4, 2000. The NRC also considered feedback received from industry, as well as other interested parties and members of the public. The NRC held 11 stakeholder meetings on the drug and alcohol testing portions of the rule during 2001–2004, and 13 stakeholder meetings on the fatigue portions of the rule during 2002–2003. Following the Commission's decision to combine the two rulemaking efforts, the NRC held one stakeholder meeting on the combined rule in July, 2004, and two subsequent meetings on the fatigue provisions of the combined rule in August and September 2004.

Throughout the time the meetings were being held, drafts of proposed rule language, regulatory and backfit analysis data, and other pertinent information were made available to the public on the Internet, as announced in the **Federal Register** on February 15, 2002 (67 FR 7093). The NRC received feedback from stakeholders both through the public meetings and the NRC's Web site. Address questions about our rulemaking Web site to Carol Gallagher (301) 415–5905; e-mail *cag@nrc.gov*.

These interactions with stakeholders were a significant benefit to the NRC in developing the language for the final rule in a manner to ensure it is clearly understandable, will be consistently interpreted, and does not result in unintended consequences. Many of the stakeholders' comments directly resulted in changes. When a comment was included in a provision, the comment is discussed in Section VI of this document.

Many comments were received during the years the meetings were held. The draft proposed rule language was changed and re-posted to the Web numerous times.

Following the publication of the August 25, 2005 (70 FR 50442) proposed rule, the NRC proposed a 4-month period to accept public comment submissions. However, the NRC accepted comments for several months after the proposed deadline for the submission of public comments. These comments are discussed in Section V of this document.

The NRC also held several public meetings after the proposed rule was published to increase stakeholder involvement in the rulemaking. These meetings were held on September 21, 2005 (ADAMS Accession No. ML052420363), November 7 and 9, 2005 (ADAMS Accession No. ML052990048), December 15, 2005 (ADAMS Accession No. ML053400002), and March 29–30, 2006 (ADAMS Accession No. ML060650535).

II. Petitions and Request for Exemption

A. Petition for Rulemaking PRM–26–1

On December 30, 1993, Virginia Electric and Power Company (now Dominion Virginia Power) submitted a Petition for Rulemaking (PRM–26–1) requesting relaxation of the required 1-year audit frequency of licensee FFD programs and the program elements of contractors and vendors (C/Vs) that are relied upon by licensees. The petition requested that the first sentence of former 10 CFR 26.80(a) be amended to read:

> Each licensee subject to this Part shall audit the fitness-for-duty program nominally every 24 months * * *. In addition, audits must be conducted, nominally every 24 months, of those portions of fitness-for-duty programs implemented by contractors and vendors.

In a letter dated March 14, 1994, the NRC informed the petitioner that the petition would be addressed in a proposed rulemaking that was under development. The NRC has periodically communicated with the petitioner regarding the status of this rulemaking since that time.

Section 26.41(b) of the final rule partially grants two aspects of the petition. The required audit frequency for licensees and other entities who are subject to 10 CFR Part 26 has been reduced from the nominal 1-year frequency in the former rule to a nominal 2-year frequency. Further, audits of C/V services that are performed on site and under the direct daily supervision or observation of licensee personnel will be conducted as part of the 2-year audits of the licensee or other entity's FFD program, under § 26.41(b).

Section 26.41(c)(1) of the final rule partially denies two aspects of the petition. The nominal annual audit requirement for HHS-certified laboratories has been retained. In addition, the annual audit requirement has been retained for FFD program elements provided by C/Vs whose personnel ''are off site or are not under the direct daily supervision or observation of licensee personnel.''

The bases for these changes to the audit requirements in the rule are addressed in the subsequent sections of this supplementary information.

B. Petition for Rulemaking PRM–26–2

On September 28, 1999, Barry Quigley submitted a Petition for Rulemaking (PRM–26–2) requesting that the NRC amend 10 CFR Parts 26 and 55 to establish clear and enforceable work hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work. The PRM was published for public comment on December 1, 1999, (64 FR 67202). As described in detail in Attachment 3 to SECY–01–0113, the petition requested the NRC to:

(1) Add enforceable working hour limits to 10 CFR Part 26;

(2) Add a criterion to 10 CFR 55.33(a)(1) to require evaluation of known sleeping disorders;

(3) Revise the NRC Enforcement Policy to include examples of working hour violations that warrant various NRC sanctions; and

(4) Revise NRC Form 396 to include self-disclosure of sleeping disorders by licensed operators.

The NRC received 176 comment letters in response to the petition. The majority of the comments (157) were in favor of a rule. These comments were principally from individuals and public interest groups. Comments received from licensees, the Nuclear Energy Institute (NEI) and Winston and Strawn, a law firm representing several utilities, were opposed to PRM–26–2. A summary of the comments and responses is available in SECY–01–0113 as Attachment 2. This document may be obtained from the NRC's Web site, *http://www.nrc.gov,* by selecting the electronic reading room and then collections of documents by type. It is also available in the NRC's Agencywide Documentation and Management

System (ADAMS) under Package Accession Number ML010180224.

Although the NRC received many comments concerning the specific requirements proposed in PRM–26–2, in general, letters in support of the rulemaking—

(1) Cited the importance of ensuring that personnel who perform safety-related functions are not impaired by fatigue;

(2) Expressed concern that the NRC does not have a regulation limiting working hours and the perception that the NRC lacks the authority to enforce the guidelines in the NRC's Policy on Worker Fatigue;

(3) Asserted that the guidelines are ambiguous and that licensees interpret the guidelines as not applicable when the plant is in an outage;

(4) Asserted that ''the NRC appears to look the other way'' when licensee work scheduling practices appear inconsistent with the guidelines; and

(5) Expressed the concern that utility restructuring and cost competition will cause reductions in staffing levels and increased working hours and fatigue.

Further, several commenters noted that the Federal Government has established work-hour limits for personnel in other industries and suggested that similar limits should apply to nuclear power plant workers.

In general, comments that opposed the petition expressed the opinion that existing regulatory requirements (*i.e.*, technical specifications and 10 CFR Part 26) are adequate to ensure that personnel are not impaired by fatigue, that the requirements would impose an unnecessary and excessive burden that could not be justified through a backfit analysis, and that industry performance data refute the petitioner's argument that a rule is necessary to prevent fatigued personnel from performing safety-related work.

The NRC evaluated the merits of PRM–26–2, the comments received in response to the PRM, and assessed the Policy on Worker Fatigue. The NRC concluded that the petitioner proposed a comprehensive set of requirements that could reasonably be expected to effectively address fatigue from individual and programmatic causes. However, the NRC concluded that it is possible to achieve these objectives through alternative requirements that are more flexible, more directly focused on risk, and more aligned and integrated with current regulatory requirements. Therefore, the final rule grants, PRM–26–2, in part. A detailed discussion of the principal findings that led to the decision to grant, in part, PRM–26–2 through rulemaking are included in Section IV.D of this document. In addition, for item 3 of PRM–26–2, the NRC revised Inspection Procedure (IP) 71130.08, ''Fitness For Duty Programs'' on February 19, 2004, to reflect the requirements of Order EA–03–038, dated April 29, 2003, which required compensatory measures related to fitness-for-duty enhancements for security personnel at nuclear power plants, including work hour limits. The NRC will similarly revise this inspection procedure following issuance of the final rule. The self-disclosure of sleeping disorders by licensed operators (item 4) is being addressed by the NRC as a separate effort from this rule through changes to Regulatory Guide 1.134, ''Medical Evaluation of Licensed Personnel at Nuclear Power Plants.''

C. Request for Exemption Under 10 CFR 26.6

The former rule required random drug and alcohol testing for personnel with unescorted access to the protected area of a nuclear power plant. By letter dated March 13, 1990, the International Brotherhood of Electrical Workers (IBEW) Local 1245 requested an exemption from random testing for clerical, warehouse, and maintenance workers at the Diablo Canyon Nuclear Power Plant (Diablo Canyon) under the provisions of 10 CFR 26.6. The NRC denied the request and IBEW Local 1245 sought judicial review. In 1992, the Ninth Circuit Court of Appeals affirmed the NRC's denial of the request (IBEW, Local 1245 v. NRC, No. 90–70647, 9th Cir., June 11, 1992). In its opinion, the court said that random testing may well be impermissible for clerical workers at Diablo Canyon who perform no safety-sensitive work and have no access to vital areas. However, in the record before the court at that time, IBEW Local 1245 had not established that such a group existed. On January 26 and December 6, 1993, IBEW Local 1245 renewed its request for exemption, specifically asking that the NRC exempt from 10 CFR Part 26 requirements for random drug testing, clerical employees at Diablo Canyon who are members of Local 1245 of the IBEW and who have unescorted access to the protected area (PA) only, but not to the radiologically controlled areas (RCAs) or vital areas (VAs) and who are not required to staff the plant's emergency response center (ERC). The PA is the area inside the security fence of a nuclear power plant, which surrounds the entire plant, and the immediately surrounding area, whereas the VAs enclose key safety systems and are located within the PA. The RCAs contain elevated levels of radiation or contamination and are generally located within the PA. The ERC is located off site and is where the licensee evaluates and coordinates licensee activities related to an emergency, and communicates to Federal, State and local authorities responding to radiological emergencies. The NRC requested public comment on the issue in the **Federal Register** of May 11, 1994 (59 FR 24373). Comments were received from the nuclear industry, which largely opposed a reduction in the scope of random testing, and from elements of the IBEW, including Local 1245, which favored it. In SRM–SECY–04–0229, dated January 10, 2005 (available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/commission/srm/*), the Commission denied the IBEW exemption request because it—

(1) Would endanger the common defense and security (as a result of increasing the likelihood of an insider threat); and

(2) Was not in the public interest (because reducing the scope of random drug testing could increase the risk to public health and safety due to a greater risk of both sabotage (insider threat due to vulnerability to coercion) and of an accident (impaired worker)).

Consequently, this final rule maintains the former requirement for random drug and alcohol testing for all personnel with unescorted access to the PA at a nuclear power plant.

III. Abbreviations

The following abbreviations and acronyms are used in this Statement of Considerations.

AEA Atomic Energy Act
ASDs Alcohol screening devices
BAC Blood alcohol concentration
CPL Conforming products list
C/V Contractor/vendor
DOT Department of Transportation
EAP Employee assistance program
EBT Evidential breath testing device
EPRI Electric Power Research Institute
FFD Fitness for duty
GC/MS Gas chromatography/mass spectrometry
HHS Department of Health and Human Services
IBEW International Brotherhood of Electrical Workers
ITAAC Inspections, Tests, Analyses, and Acceptance Criteria
KAs Knowledge and abilities
LOD Limit of detection
LOQ Limit of quantitation
mg/dL Milligrams per deciliter
MRO Medical Review Officer
NEI Nuclear Energy Institute
ng/dL Nanograms per deciliter
NHTSA National Highway Transportation Safety Administration

NRC Nuclear Regulatory Commission
NSF National Sleep Foundation
OMB Office of Management and Budget
PDFFDI Potentially disqualifying fitness-for-duty information
pH potential of hydrogen
POGO Project on Government Oversight
PROS Professional Reactor Operator Society
QA/QC Quality assurance/quality control
SAE Substance Abuse Expert
SAMHSA Substance Abuse and Mental Health Services Administration
SSNM Strategic special nuclear material
THC Tetrahydrocannabinol, delta-9-tetrahydrocannabinol-9-carboxylic acid
UCS Union of Concerned Scientists
6–AM 6-acetylmorphine

IV. Discussion of Final Action

A. Overview

A review of FFD program experience confirms that the former regulatory approach of 10 CFR Part 26 was fundamentally sound and provided a means of deterrence and detection of substance abuse at licensee facilities. FFD Program Performance Reports through 2005 are published on the NRC's Web site, *http://www.nrc.gov/reactors/operating/ops-experience/fitness-for-duty-programs/performance-reports.html.*

Nonetheless, the NRC believes that revisions were needed to improve the effectiveness and efficiency of FFD programs; enhance consistency with advances in similar rules and guidelines, including HHS' Mandatory Guidelines for Federal Workplace Drug Testing Programs (herein called the HHS Guidelines) and other Federal drug and alcohol testing programs that place similar requirements on the private sector; strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue; enhance consistency with the NRC's access authorization requirements; improve clarity in the organization and language of the rule; and improve Part 26 by eliminating or modifying unnecessary requirements.

B. Goals of the Rulemaking Activity

The NRC is amending 10 CFR Part 26, Fitness For Duty Programs. The goals are to:

(1) Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the HHS Guidelines and other Federal drug and alcohol testing programs (*e.g.*, those required by the U.S. Department of Transportation [DOT]) that impose similar requirements on the private sector;

(2) Strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue;

(3) Improve the effectiveness and efficiency of FFD programs;

(4) Improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003;

(5) Improve Part 26 by eliminating or modifying unnecessary requirements;

(6) Improve clarity in the organization and language of the rule; and

(7) Protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Each of these goals is expected to result in substantial improvements in FFD programs. Many changes in the final rule relate to each goal. The major changes for each subpart and the reasons for those changes are described in Section IV.C of this document. For each of the many specific changes, detailed discussions are included in Section VI. However, the following discussion provides a description of each goal, a basis for the need to accomplish that goal, and several examples of changes to the former rule that will contribute to meeting the goal.

Goal 1—Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including HHS Guidelines and other Federal drug and alcohol testing programs (*e.g.*, those required by the DOT that impose similar requirements on the private sector.) Goal 1 is central to this rulemaking activity. Many changes are included in the final rule to maintain consistency with advances in the conduct of FFD programs, including changes in the HHS Guidelines. The 1994, 1998, and 2004 revisions to the HHS Guidelines differ substantially from the 1988 version of the HHS Guidelines, upon which the former rule was based.

The President of the United States designated HHS as the agency responsible for the Federal workplace drug testing program. HHS' SAMHSA is responsible for maintaining the HHS drug testing guidelines based on the most recent research and the accumulation of lessons learned from the Federal drug testing program, as well as others who are regulated. The NRC has historically relied on HHS to establish the technical requirements for urine specimen collection, testing, and evaluation, and has only deviated from HHS' guidelines for considerations that are specific to the nuclear industry. Updating Part 26 to be consistent with the most recent HHS Guidelines ensures that NRC regulations continue to be scientifically and technically sound.

Further, the HHS-certified laboratories that Part 26 requires licensees to use for drug testing are required by HHS to follow the HHS Guidelines in order to retain their certification. Basing Part 26 on older versions of the HHS Guidelines, or deviating from those Guidelines, increases the cost of drug testing for the nuclear industry. Therefore, updating Part 26 to increase consistency with the HHS Guidelines not only ensures that Part 26 is based on the best scientific and technical information available, but also avoids imposing an unnecessary and costly regulatory burden on the nuclear industry.

One example of an improvement from enhancing consistency with the HHS Guidelines is that several cutoff levels for detection of various drugs have been updated, including a revised lower cutoff level for the marijuana metabolite THC. The lower cutoff level will provide greater assurance that individuals who use marijuana are identified.

Additionally, a revision to the HHS Guidelines, published in the **Federal Register** on April 13, 2004 (69 FR 19643) as a final rule, includes requirements for specimen validity tests to determine whether a urine specimen has been adulterated, diluted, or substituted. This final rule adopts significant portions of the final HHS specimen validity testing provisions. The new validity testing requirements will substantially improve the effectiveness of the measures to guard against subversion of the testing process that are contained in former Part 26.

Several other provisions for drug testing are under consideration by HHS and were published as a proposed rule for public comment in the **Federal Register** on April 13, 2004 (69 FR 19672). One change to 10 CFR Part 26 that is included from the proposed HHS Guidelines is permission for licensees to use validity screening tests to determine whether a urine specimen must be

subject to further testing at an HHS-certified laboratory because it may have been adulterated, diluted, or substituted, in lieu of the instrumented validity testing required in the April 13, 2004, final version of the HHS Guidelines. Although the HHS Guidelines that would permit Federal drug testing programs to use validity screening tests for initial testing of urine specimens are not yet final, some NRC licensees desired the flexibility to use these testing methods. A technical basis for use of those methods is included in section VI. However, the NRC is not including other provisions in the proposed HHS Guidelines at this time. Those provisions include permitting the drug testing of specimens other than urine (*e.g.*, hair, saliva, sweat), requirements for split specimen procedures for all specimens, and HHS certification of instrumented initial test facilities, which would be analogous to licensee testing facilities. Should such provisions be included in final HHS Guidelines in the future, the NRC will consider incorporating them into 10 CFR Part 26 at that time.

In addition to the changes to 10 CFR Part 26 that incorporate the recent revisions to the HHS Guidelines, the DOT revised its Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR Part 40, 65 FR 41944; August 9, 2001) to include the use of oral fluids (*i.e.*, saliva) as acceptable specimens for initial alcohol screening tests. This final rule also reflects the new oral fluids testing technology to provide FFD programs with increased flexibility in administering initial alcohol tests.

Because the HHS Guidelines do not establish requirements for alcohol testing, NRC relies on the DOT regulations, in part, to ensure that the alcohol testing provisions of Part 26 remain scientifically sound and legally defensible. Because the DOT programs test a much larger number of individuals in comparison to the number of alcohol tests that are conducted under Part 26, basing the NRC's alcohol testing regulations on portions of the DOT regulations reflects the lessons learned from that larger population.

Goal 2—Strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue. This goal is central to this rulemaking activity. Subpart I, Managing Fatigue, adds clear and enforceable requirements for licensee management of worker fatigue to 10 CFR Part 26. The requirements reduce the potential for worker fatigue and therefore, strengthen the effectiveness of FFD programs at nuclear power plants and substantially increase the protection of public health and safety and the common defense and security. Section VI of this document discusses the specific reasons for each worker fatigue provision. Section IV.D provides a detailed discussion of the overall basis for establishing fatigue management requirements for FFD programs, and the benefits expected to result.

Goal 3—Improve the effectiveness and efficiency of FFD programs. The NRC has gained experience in the actual implementation of FFD programs since Part 26 was originally promulgated. The NRC is making many changes throughout Part 26 based on that experience in order to improve the industry's programs, specifically to increase both the effectiveness of the programs in achieving the goals of Part 26 and the efficiency of program operations. Increasing the effectiveness and efficiency of FFD programs will enhance the protection of public health and safety and the common defense and security.

One example of a change related to Goal 3 is the reduction in the period within which pre-access testing must be performed from 60 days, in former § 26.24(a)(1), to 30 days or less, in Subpart C [Granting and Maintaining Authorization]. This change improves the effectiveness of the pre-access test in detecting drug and alcohol use by individuals who are applying for authorization to have the types of access or perform the duties that require them to be subject to Part 26. Reducing the number of breath specimens required for alcohol testing from two each for initial and confirmatory testing, in former Section 2.4(g)(18) in Appendix A to Part 26, to one specimen for the initial test and one for the confirmatory test also increases the efficiency of FFD programs without compromising the accuracy and validity of alcohol test results.

Another example of rule changes related to Goal 3 is establishing a regulatory framework for the management of worker fatigue that appropriately balances the need for flexibility to manage plant exigencies with the need for more readily enforceable requirements and efficient NRC oversight of licensee compliance with the requirements and performance objectives of the rule.

Goal 4—Improve consistency between FFD requirements and the access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. Part 26 and the access authorization requirements each contain provisions that require establishing the trustworthiness and reliability of personnel before granting unescorted access to the protected areas of nuclear power plants. The NRC determined that, because both sets of requirements share this same goal, revising Part 26 was necessary to clarify the relationship between these requirements, particularly for licensee access authorization decisions regarding personnel who move between sites with some interruption in their status of having unescorted access to a nuclear power plant. In addition, some requirements in former Part 26 addressed the granting of temporary unescorted access. In response to the terrorist attacks of September 11, 2001, on the World Trade Center and the Pentagon, and the current threat environment, the Commission took action to curtail the use of temporary unescorted access at commercial nuclear power plants. Temporary unescorted access was eliminated by orders issued January 7, 2003, which imposed enhancements to existing access authorization programs. Therefore, it was necessary to revise the related provisions in Part 26.

Goal 5—Improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements. The final rule incorporates a number of changes to eliminate or modify unnecessary requirements. The experience NRC has gained over the years since Part 26 was promulgated has enhanced the agency's understanding of implementation issues experienced by the industry, and the NRC is now eliminating or modifying some provisions, while at the same time maintaining protection of public health and safety and the common defense and security.

For example, because of inconsistencies in how licensees interpreted the FFD and access authorization requirements for conducting employment inquiries, many licensees contacted an individual's previous employers twice—once to obtain the information required under Part 26 and once to obtain the information required for access authorization. The revisions to Part 26 clarify that licensees may obtain information to satisfy FFD suitable inquiry requirements and related access authorization requirements at the same time when conducting an employment inquiry.

Goal 6—Improve clarity in the organization and language of the rule. The final rule is organized to facilitate implementation, as compared to the former rule, which has generated many questions from licensees. Therefore, in the final rule, the NRC has substantially reorganized the requirements to eliminate redundancies, to group related requirements, and to present requirements in the order in which they apply to licensees' FFD processes. In addition, the NRC has made many language changes to improve clarity. This substantial reorganization, which substantially reduces the likelihood of variations in FFD programs across the industry through differing interpretations of the rule, improves the protection of public health and safety and the common defense and security. The final rule is clearer in both organization and language, and is expected to result in more uniform implementation, and, consequently, more consistency in achieving the Part 26 goals.

In contrast to certain NRC regulations, Part 26 includes a considerable number of detailed requirements. In the public meetings held during the development of the final rule, industry representatives indicated that they consider this level of detail necessary to help protect individual privacy and ensure consistency in implementing the requirements. Additionally, industry representatives indicated that this high level of detail can help to avoid unnecessary litigation between licensees and individual personnel regarding worker non-compliance with specific drug and alcohol testing performance steps. Such litigation would be more likely if those specific performance steps were not required by NRC rule. The level of detail and the enhanced clarity in the new language and organization included in Part 26 have eliminated the need for a guidance document for provisions pertaining to drug and alcohol testing. Industry representatives commented that a guidance document would not have the same weight as a rule, and that both licensees and individuals should be protected fully with rigor and specificity in a rule. Therefore, industry desired the rule to be more specific and detailed, in lieu of a guidance document.

Goal 7—Protect the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26. This goal was an implicit objective of the former rule, and the final rule continues to protect the privacy and other rights of individuals (including due process) who are subject to 10 CFR Part 26. The NRC, DOT, and HHS have all gained experience in implementing workplace drug and alcohol testing programs. This experience has led the DOT and HHS to modify many of their requirements for such testing to more clearly protect privacy and other rights of individuals. Many of the changes to Part 26 related to this goal are based on either DOT or HHS requirements. The NRC believes the protection of individual rights to be of the highest importance and is making changes to Part 26 to ensure that those rights are protected through rule language developed using the best available information. One example of such a change is that the final rule prohibits any testing of ''Bottle B, the second portion of a split urine specimen, or retesting an aliquot of a specimen'' without the donor's permission.

C. Overview of Final Rule

The final rule is divided into subparts that contain related requirements. Each subpart is assigned a descriptive title to aid users in locating rule provisions and to simplify cross-referencing within the final rule. By grouping related requirements and presenting them generally in the order in which they apply to licensees' and other entities' FFD processes, the final rule improves the ease of implementing the rule. For example, the final rule adds Subpart K [FFD Programs for Construction] to consolidate FFD requirements for new reactor construction. Also, the provisions that were contained in Subparts J [Recordkeeping and Reporting Requirements] and K [Inspections, Violations, and Penalties] of the proposed rule are now contained in Subparts N and O, respectively, of the final rule.

The major topics addressed in each subpart and the reasons that the NRC made major changes to the former rule are described below. A detailed cross-reference table between the former and final Part 26 provisions is included at the end of this notice.

Subpart A Administrative Provisions

The first subpart, Subpart A, replaces the General Provisions portion of the former rule, but continues to address the same subject matter. Thus, Subpart A addresses the purpose and scope of the rule, provides definitions of important terms used in the final rule, and updates former provisions related to requests for specific exemptions, interpretations of the rule, and communications with the NRC. The final rule also adds a section to Subpart A that consolidates FFD program applicability requirements for categories of individuals.

Subpart B Program Elements

Subpart B of the final rule reorganizes and amends former §§ 26.10 through 26.29. These sections of the former rule specified the performance objectives that FFD programs were required to meet and the FFD program elements that licensees and other entities were required to implement to meet the performance objectives. However, the final rule does not include former § 26.27 [Management actions and sanctions to be imposed] in Subpart B for two reasons. First, the final rule is reorganized to be consistent with the order in which licensees and other entities implement their programs. Because Subpart B is focused on establishing the framework of FFD programs, it would be premature to present requirements related to implementing the FFD program (i.e., imposing sanctions on an individual for violating the FFD policy) at this point in the rule. Second, the subject matter of former § 26.27 is sufficiently important and complex that a separate subpart is warranted. Therefore, the final rule presents requirements related to management actions and sanctions in Subpart D [Management Actions and Sanctions to be Imposed].

Subpart C Granting and Maintaining Authorization

Subpart C of the final rule substantially amends former FFD requirements related to the process that licensees and other entities must follow in determining whether an individual is trustworthy and reliable, as demonstrated by avoiding substance abuse, and can be expected to perform his or her job duties safely and competently. The final rule introduces the concept of (authorization(to Part 26 to refer to the status of an individual who the licensee or other entity has determined can be trusted to avoid substance abuse, and, therefore, may be permitted to have the types of access or perform the duties described in § 26.4 [FFD program applicability to categories of individuals], as a result of the process described in this subpart. For example, in the case of nuclear power plant personnel, a licensee may permit an individual who is ''authorized'' under Part 26 to have unescorted access to protected areas in nuclear power plants if the individual's job requires such access.

The NRC has published other requirements, such as 10 CFR 73.56, that establish additional steps that licensees and other entities must take as part of the process of determining whether to grant unescorted access to an

individual or permit an individual to maintain unescorted access to protected areas. These additional requirements focus on aspects of an individual's character and reputation other than substance abuse, and, among other steps, require the licensee or other entities who are subject to the rule to conduct a psychological assessment of the individual, perform a credit and criminal history check, and interview individuals who have knowledge of the applicant for authorization. However, historically there have been some inconsistencies and redundancies between the Part 26 requirements related to granting and maintaining unescorted access and the other related regulations, particularly the NRC's access authorization requirements for nuclear power plant personnel. The inconsistencies have led to many implementation questions from licensees, as well as inconsistencies in how licensees have implemented the requirements. The redundancies have imposed an unnecessary burden on licensees in other cases. Therefore, a central goal of adding Subpart C to the final rule is to eliminate those inconsistencies and redundancies to ensure that licensees and the other entities who are subject to the rule have clear and easily interpretable requirements to follow when determining whether to grant or maintain an individual's unescorted access under Part 26 and also under other, related requirements, including, but not limited to, the January 7, 2003 access authorization orders issued by the NRC to nuclear power plant licensees.

The requirements in Subpart C are based on several fundamental changes to the NRC's approach to the authorization requirements in former Part 26. The primary concern, which Subpart C is designed to address, is the necessity of increasing the rigor of the authorization process to provide reasonable assurance that any individual who is granted and maintains authorization is trustworthy and reliable, as demonstrated by avoiding substance abuse. The necessity for increased rigor in the authorization process is discussed in Section VI of this document with respect to § 26.23(a) in terms of the increased insider threat since the terrorist attacks of September 11, 2001. One change to former Part 26 authorization requirements that reflects this concern is the elimination of temporary access authorization requirements in the second sentence of former § 26.27(a)(4). Other changes are discussed in Section VI with respect to the specific provisions that incorporate them.

A second, related change to the NRC's approach to authorization requirements, which has informed Subpart C, is an increased concern with the sharing of information about individuals between licensees and other entities. At the time the former Part 26 was developed, the industry structure was different and personnel transfers between licensees (*i.e.*, leaving the employment of one licensee to work for another licensee) with interruptions in authorization were less common. Most licensees operated plants at a single site and maintained an FFD program that applied only to that site. When an individual left employment at one site and began working for another licensee, the individual was subject to a different FFD program that often had different requirements. Because some licensees were reluctant to share information about previous employees with the new employer, licensees often did not have access to the information the previous licensee had gathered about the individual and were required to gather the necessary information again. The additional effort to collect information that another licensee held created an unnecessary burden on both licensees. But, because few individuals transferred, the burden was not excessive.

However, since 1989, the industry has undergone significant consolidation and developed new business practices to use its workforce more efficiently. Industry efforts to better use expertise and staffing resources have resulted in the development of a large transient workforce within the nuclear industry that travels from site to site as needed, such as roving outage crews. Although the industry has always relied on C/Vs for special expertise and staff for outages, the number of transient personnel who work solely in the nuclear industry has increased and the length of time they are on site has decreased. Because the former FFD regulations were written on the basis that individual licensees would maintain independent, site-specific FFD programs and shared limited information, and that the majority of nuclear personnel would remain at one site for years, the former regulations did not adequately address the transfer of personnel between sites.

These changes in the industry have increased the need for information sharing among licensees and C/Vs. The increased insider threat since September 11, 2001, has also heightened the need for information sharing among licensees and C/Vs to ensure that licensees and other entities have information that is as complete as possible about an individual when making an authorization decision. To address this need, the access authorization orders issued by the NRC to nuclear power plant licensees on January 7, 2003, mandated increased sharing of information. In addition, Subpart C requires licensees and other entities to collect and share greater amounts of information than under the former rule, subject to the protections of individuals' privacy that are specified in § 26.37 [Protection of information]. As a result, individuals who are subject to the rule will establish a detailed ''track record'' within the industry that will follow them if they change jobs and move to a new position that requires them to be granted authorization by another licensee or entity who is subject to the rule. This increased information sharing contributes to providing reasonable assurance that individuals who are granted and maintain authorization under Part 26 are trustworthy and reliable when individuals move between FFD programs.

However, a consequence of increased information sharing is that one violation of any licensee's FFD policy has greater potential to end an individual's career. Although an individual who has an active substance abuse problem cannot be permitted to have unescorted access to protected areas, the NRC continues to affirm that individuals who pursue treatment, stop abusing drugs or alcohol, and maintain sobriety for an extended period of time should regain the public's trust. The length of time that an individual must maintain sobriety in order to demonstrate that he or she can again be trusted with the public's health and safety and the common defense and security has been a matter of debate since Part 26 was originally under development. However, the research literature continues to indicate that individuals who maintain sobriety past the first 3 years following treatment have substantially reduced recidivism rates (*i.e.*, relapsing into substance abuse) than during the first 3 years after treatment. There is also a further drop in recidivism rates after 5 years of sobriety.

Despite these research findings, some individuals who have had one confirmed positive test result have been prevented from working in operating nuclear power plants. The increased information sharing required under Subpart C has the potential to result in a greater number of these individuals being banned from working in the industry. Therefore, the NRC has added several requirements to Subpart C to

minimize these consequences for individuals who are able to demonstrate that they are effectively coping with a substance abuse problem. Additional requirements for protecting information to be gathered about individuals under Part 26 are specified in § 26.37. The detailed changes to former requirements are discussed in Section VI with respect to the specific provisions that incorporate these requirements.

In general, the authorization requirements in Subpart C are structured according to whether an individual who has applied for authorization has previously held authorization under Part 26. If an individual has not established a ''track record'' in the industry, the final rule requires licensees and other entities to meet an extensive set of requirements before granting authorization to the individual. If an individual has established a favorable track record in the industry, the amount of original information gathering that the final rule requires licensees and other entities to complete before granting authorization to the individual is reduced. The need for original information gathering in these instances is reduced because licensees and other entities will have access to all of the information that previous FFD programs have collected about the individual under the final rule.

For individuals who have established a favorable track record in the industry, the steps that licensees and other entities are required to complete in order to grant authorization to an individual also depends upon the length of time that has elapsed since the individual's last period of authorization was terminated and the amount of supervision to which the individual was subject during the interruption. (The term ''interruption'' refers to the interval of time between periods during which an individual holds authorization under Part 26.) In general, the more time that has elapsed since an individual's last period of authorization ended, the more steps that the final rule requires licensees and other entities to complete before granting authorization to the individual. However, if the individual was subject to behavioral observation under a Part 26 program or continued to be subject to random drug and alcohol testing during the interruption, the final rule requires licensees and other entities to complete fewer steps in order to grant authorization to the individual. There are several reasons that the final rule requires fewer steps in the authorization process for these individuals.

First, individuals who have established a favorable work history in the industry have demonstrated their trustworthiness and reliability from previous periods of authorization, so they pose less potential risk to public health and safety and the common defense and security than individuals who are new to the industry. Much is known about these individuals. Not only were they subject to the initial background screening requirements before they were initially granted authorization; but, while they were working under a Part 26 program, they were watched carefully through on-going behavioral observation, repeatedly attained negative results from random drug and alcohol tests, and demonstrated the ability to consistently comply with the many procedural requirements that are necessary to perform work safely at operating power reactor facilities.

Second, individuals who have established a favorable work history in the industry and whose authorization has been interrupted for only a short period are unlikely to develop an active substance abuse problem during the interruption. The shorter the period of time since the individual's last period of authorization ended, the less likely it is that the individual has developed an active substance abuse problem or undergone other significant changes in lifestyle or character that would diminish his or her trustworthiness, reliability, and ability to perform work safely and competently.

Further, if the individual was also subject to supervision under some elements of a Part 26 program (*e.g.*, behavioral observation, a requirement to report any arrests, random drug and alcohol testing) during the period that his or her authorization was interrupted, the higher the assurance that the individual does not have an active substance problem. And, it is less likely that the individual could have undergone significant changes in lifestyle or character that would be undetected.

Therefore, the final rule establishes categories of requirements for granting authorization to an individual that vary, based upon whether the individual has previously held authorization under Part 26; whether the individual's last period of authorization was terminated favorably or unfavorably; how long it has been since the individual last held authorization under Part 26; and whether the individual was subject to any elements of a Part 26 program during the interruption period. Section 26.55 [Initial authorization] establishes authorization requirements for individuals who have not previously held authorization under Part 26 and individuals who have not held authorization within the past 3 years. Section 26.57 [Authorization update] establishes authorization requirements for individuals who previously held authorization under Part 26, whose last period of authorization was terminated favorably more than 1 year ago but less than 3 years ago. Section 26.59 [Authorization reinstatement] establishes authorization requirements for individuals who previously held authorization under Part 26 and whose last period of authorization was terminated favorably within the past year. Section 26.69 [Authorization with potentially disqualifying fitness-for-duty information] defines the steps that licensees and other entities must take in granting authorization to an individual about whom potentially disqualifying FFD information has been disclosed or discovered.

The time periods used to establish these categories of authorization requirements are consistent with the categories established in the access authorization orders issued by the NRC to nuclear power plant licensees on January 7, 2003. Basing the requirements on elapsed time is consistent with the programs of other Federal agencies who have similar needs to control access to sensitive information and protected areas. In addition, these time periods have been used successfully within nuclear power plant access authorization programs since 1989 and have met the NRC's goal of ensuring that individuals who are granted unescorted access are trustworthy and reliable. Therefore, the final rule incorporates these time periods within Part 26.

In general, the steps that are required under this part to grant authorization to an individual who has recently held authorization and whose most recent period of authorization was terminated favorably are less extensive than the steps required for applicants for authorization who are new to the industry or those who have not recently held authorization. In addition, the NRC has strengthened the requirements for a rigorous evaluation process contained in the former § 26.27(e) that licensees and other entities are required to meet before granting authorization to an individual about whom potentially disqualifying FFD information has been disclosed or discovered (see § 26.69). The final rule requires licensees and other entities to obtain and review a written self-disclosure from the applicant and an employment history, and ensure that a suitable inquiry and pre-access drug and alcohol testing are completed before granting authorization to an individual,

with certain exceptions. The exceptions to the self-disclosure and employment history, suitable inquiry, and pre-access testing requirements are specified in §§ 26.61 [Self-disclosure and employment history], 26.63 [Suitable inquiry], and 26.65 [Pre-access drug and alcohol testing], respectively. The final rule also requires licensees and other entities to ensure that applicants are subject to random testing, as specified in § 26.67 [Random drug and alcohol testing of individuals who have applied for authorization].

Subpart D Management Actions and Sanctions

Subpart D of the final rule replaces former § 26.27(b) and (c) and divides the former provisions into two separate sections that specify requirements for responding to FFD policy violations in § 26.75 [Sanctions], and indications of impairment in § 26.77 [Management actions regarding possible impairment]. The final rule adds a new § 26.73 [Applicability] to specify the entities and individuals to whom the requirements of the subpart apply. The former rule has been reorganized to generally reflect the order in which the requirements apply to licensees' and other entities' FFD processes, and to group related requirements into separate sections. Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

In general, subpart D includes three significant changes from the related provisions in the former rule that are each intended to provide a stronger deterrent to engaging in the unwanted actions specified in the subpart. First, the final rule increases the severity of the minimum sanctions that are required if an individual violates a licensee's or other entity's FFD policy. The more stringent sanctions are necessary in order to strengthen the effectiveness of the rule in providing reasonable assurance that individuals who are subject to this part are trustworthy and reliable, as demonstrated by avoiding substance abuse, and by increasing the assurance that only individuals who are fit for duty are permitted to have the types of access or perform the duties listed in § 26.4.

Second, the final rule requires licensees and other entities who are subject to the rule to impose the same sanctions for an FFD violation involving the abuse of alcohol as required for the abuse of illegal drugs. Impairment caused by alcohol abuse creates a risk to public health and safety that is fundamentally similar to the risk posed by the use of illegal drugs. However, some licensees have imposed lesser sanctions for alcohol violations, an approach that is inconsistent with the NRC's intent. Therefore, the final rule rectifies this situation by explicitly requiring the same minimum sanctions for abuse of alcohol as formerly required for the use of illegal drugs.

Third, the final rule adds the sanction of permanent denial of authorization for any individuals who subvert or attempt to subvert the testing process. The former rule permitted licensees and other entities to have flexibility in establishing sanctions for actions such as refusing to submit to testing and attempting to subvert the testing process by submitting an adulterated or substitute specimen. As a result, different FFD programs imposed different sanctions and some individuals were granted authorization or permitted to maintain authorization when they committed such acts. However, acts to defeat the testing process indicate that an individual is not trustworthy and reliable, and suggest that the individual may be engaging in substance abuse that could pose a risk to public health and safety and the common defense and security. Therefore, the final rule establishes a minimum sanction that all FFD programs must impose to deter attempts to subvert the testing process, as well as provide reasonable assurance that individuals who are granted and maintain authorization can be trusted to comply with the rules and regulations to which they are subject.

These three changes have been made to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs. The NRC has made other changes to former § 26.27(b) and (c) in subpart D primarily to eliminate or modify unnecessary requirements and clarify the intent of former provisions.

Subpart E Collecting for Testing

Subpart E of the final rule reorganizes and amends the requirements related to collecting specimens for drug and alcohol testing that were contained in former § 26.24 [Chemical and alcohol testing] and interspersed throughout former Appendix A to Part 26. The subpart groups the related requirements and presents them in the order in which they would be implemented by FFD programs. The final rule also eliminates some redundancies in the provisions of the former rule that were related to specimen collections. The NRC has made these changes to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

In general, the procedures in this subpart are more detailed than those in Appendix A to the former rule and NRC regulations that are based on a risk-informed, performance-based approach, for several reasons. First, the more detailed procedures in subpart E will increase the consistency of Part 26 drug and alcohol specimen collection procedures with those of other Federal agencies and therefore, take advantage of the scientific and technical advances that have been made in workplace drug and alcohol testing programs since the former Part 26 was promulgated, as discussed in Section IV.B of this document. Second, the final rule permits FFD programs to accept and rely upon other FFD programs that are implemented under this part, as well as the programs of other Federal and State agencies, to a much greater extent than is permitted under the former rule. The permission to rely on other programs improves the effectiveness and efficiency of FFD programs (Goal 3 of the rulemaking) and improves the rule by eliminating or modifying unnecessary requirements (Goal 5 of the rulemaking). For example, under § 26.69(b)(6), the final rule permits licensees and other entities to rely on another Part 26 program's drug and alcohol followup testing of an individual who has violated an FFD policy and is consequently required to have at least 15 followup tests within the 3-year period following the violation, and is transferring from one licensee's site to another.

The final rule requires the receiving licensee or entity to continue the followup testing program. However, the final rule permits the licensee or other entity to accept the followup testing that was completed by the previous FFD program when determining the remaining number of followup tests to which the individual must be subject and the period of time during which the individual must continue to be subject to followup testing. Therefore, because the final rule permits this reliance on other programs, more detailed requirements for conducting the activities on which other FFD programs may rely, including drug and alcohol testing, are necessary to provide greater assurance that all Part 26 programs meet minimum standards. Third, the final rule incorporates a greater level of detail in the specimen collection procedures of the final rule for the reasons discussed in Section IV.B.

The NRC has made other major changes to the former rule's requirements for collecting specimens for drug and alcohol testing to incorporate specimen validity testing

requirements from the HHS Guidelines into Part 26 (Goal 1 of this rulemaking) and modify former alcohol testing requirements to improve the efficiency of FFD programs (Goal 3 of the rulemaking), while continuing to protect or enhance individuals' rights to privacy and due process under the rule (Goal 7 of the rulemaking).

Subpart F Licensee Testing Facilities

Subpart F of the final rule presents detailed requirements for conducting initial urine specimen validity and drug tests at licensee testing facilities, as permitted in § 26.24(d)(1) of the former rule and § 26.31(d)(3)(ii) of the final rule. The subpart is entitled, ''Licensee Testing Facilities,'' for brevity, but permits other entities who are subject to the rule to establish and operate drug testing facilities under the final rule.

The NRC has added this subpart to the final rule to group together in a single subpart the rule's requirements that are related to licensee testing facilities, which were intermixed with requirements related to drug testing at HHS-certified laboratories in Appendix A to Part 26 in the former rule. The final rule presents the requirements that are applicable to licensee testing facilities and HHS-certified laboratories in two separate subparts because the provisions of the former rule were not always clear with respect to which requirements applied to which type of testing facility. Also, the final rule includes the requirements that apply to both types of facilities in both subparts so that it is unnecessary for licensees and other entities who do not operate licensee testing facilities to be concerned with any provisions in subpart F. Although many of the requirements in this subpart are redundant with similar requirements in subpart G [Laboratories Certified by HHS], these changes meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The most important change in subpart F to the former requirements for licensee testing facilities is the addition of new requirements for licensee testing facilities to conduct initial urine specimen validity testing, based on similar provisions contained in the most recent revision to the HHS Guidelines (69 FR 19643; April 13, 2004). The reasons for requiring initial urine specimen validity testing are discussed with respect to § 26.31(d)(3)(ii). The NRC believes that it is necessary for licensee testing facilities to conduct specimen validity testing because Part 26 permits licensees and other entities to make authorization decisions based on initial drug test results from such facilities. Thus, the rule permits licensees and other entities to grant authorization to an individual who has negative initial test results from pre-access testing without further analysis of the urine specimen by an HHS-certified laboratory. If the initial test results from the licensee testing facility are inaccurate because the urine specimen was adulterated or substituted, the licensee or other entity could grant authorization to an individual who poses a risk to public health and safety and the common defense and security. Similarly, if an individual who has been selected for random testing submits an adulterated or substituted specimen that is not detected by initial tests at the licensee testing facility, the individual would be permitted to maintain authorization if the results of drug testing are negative. Therefore, in order to increase the likelihood that individuals who may be using drugs and attempting to defeat the testing process are detected, and to ensure that they are not permitted to be granted or maintain authorization, the NRC has concluded that it is necessary to require licensee testing facilities to conduct urine specimen validity tests.

However, in consideration of the increased costs and burden that are associated with instrumented initial validity testing, subpart F permits licensee testing facilities to use commercially available validity screening tests of urine specimens, which may be a less expensive alternative than the instrumented initial validity tests required in the current HHS Guidelines. As discussed in Section VI with respect to § 26.5 [Definitions], the final rule uses the term ''validity screening test'' to refer to these commercially available tests. The term ''initial validity test'' refers to instrumented validity testing.

At the same time that the HHS published its regulations to require specimen validity testing, which have been incorporated in the final rule, HHS also published a proposed revision to the Guidelines (69 FR 19673; April 13, 2004) that would permit the use of validity screening devices for the detection of substitution and the presence of adulterants in urine specimens. These devices include non-instrumented devices with visually-read endpoints as well as semi-automated or automated instrumented testing devices with machine-read end points. Specimen validity tests conducted with these devices use colorimetric assays, which is the same scientific principle as the initial tests conducted at HHS-certified laboratories. Non-instrumented specimen validity devices for urine testing have been shown to detect adulterants in urine specimens and creatinine concentrations on tests that were conducted on specimens that were spiked with drug analytes. However, the results from the preliminary studies are variable. Therefore, the proposed HHS Guidelines include extensive performance testing requirements for these devices, which subpart F also incorporates. Such performance testing is necessary to ensure that validity test results based on using these devices are accurate.

Subpart G Laboratories Certified by the Department of Health and Human Services

Subpart G presents together in a single subpart requirements related to the HHS-certified laboratories that are used by licensees and other entities who are subject to Part 26 for validity and drug testing. The requirements in this subpart group together the former requirements in Appendix A to Part 26 as they relate to HHS-certified laboratories. However, the final rule updates the former requirements to be consistent with the HHS Guidelines that were published in the **Federal Register** on April 13, 2004 (69 FR 19643). The most important changes to the former rule's requirements for HHS-certified laboratories are the incorporation of extensive requirements for urine specimen validity testing.

Subpart H Determining Fitness-for-Duty Policy Violations and Determining Fitness

Subpart H in the final rule reorganizes, clarifies, and enhances former requirements related to the decisions that medical review officers (MROs) and other healthcare professionals must make under Part 26 to provide input to licensees' and other entities' management decisions with respect to granting and permitting an individual to maintain authorization under Subpart C and also with respect to imposing sanctions and taking actions to prevent an individual from performing duties that require an individual to be subject to this part under Subpart D. The former requirements, which were interspersed throughout the rule, are grouped together in Subpart H to make them easier to locate within the final rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The subpart also makes several significant changes to the former requirements.

In general, Subpart H includes more detailed requirements for determining

FFD policy violations and conducting determinations of fitness than were included in the former rule. The NRC has added these more detailed requirements in response to implementation questions that the NRC has received from licensees since Part 26 was first promulgated, lessons learned from NRC inspections of FFD programs, and the experience of other Federal agencies that similarly require workplace drug and alcohol testing. However, the NRC's primary concern in establishing more detailed requirements is to enhance the consistency in how FFD policy violations and fitness are determined among Part 26 programs. The final rule permits licensees and other entities to rely on the determinations made by other Part 26 programs to a greater extent than the former rule. For example, § 26.63(b) of the final rule permits licensees and other entities to rely upon a previous licensee's or other entity's determinations of fitness, as well as their reviews and resolutions of potentially disqualifying FFD information, from previous periods of authorization. The reasons for adding these permissions were discussed previously in this section, with respect to Subpart C. However, to ensure that all licensees' and other entities' determinations of FFD policy violations and fitness can be relied upon by other FFD programs, it is necessary to enhance the former requirements and establish clear minimum standards for those processes. Therefore, the subpart includes greater detail to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Under the final rule, licensees and other entities continue to be prohibited from imposing sanctions on an individual who has a positive confirmatory drug test result from testing at the HHS-certified laboratory until the MRO has had an opportunity to discuss the result with the individual and determines that there is no legitimate medical explanation for the positive result(s). The final rule extends this requirement to the review of positive confirmatory validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed in Section VI with respect to § 26.31(d)(3)(I). An MRO review of adulterated or substituted validity test results from an HHS-certified laboratory before a licensee or other entity imposes sanctions on an individual is necessary for the same reasons that an MRO review is required of positive drug test results. That is, there may be legitimate medical reasons for the adulterated or substituted test result and the test result may not indicate that the donor has violated the FFD policy, which in this case would mean that he or she has not attempted to subvert the testing process. The NRC added a requirement for the MRO to review adulterated or substituted validity test results to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and ensure that the individuals are afforded accurate and consistent testing. The HHS Guidelines also require the MRO to review adulterated and substituted validity test results. Therefore, adding this requirement to the final rule also meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Another significant change that the final rule makes to former requirements is the establishment of a new position within FFD programs—the ''substance abuse expert'' (SAE). The SAE is responsible for performing a determination of fitness, which is determining whether there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties, in those instances in which an individual may not be fit for duty for reasons related to drug or alcohol abuse. The NRC has added the SAE position for several reasons.

First, some MROs who provide services under Part 26 have indicated that they do not feel qualified to assess the presence and severity of substance abuse disorders, make treatment recommendations, and determine when an individual who has had a substance abuse disorder may again be able to safely and competently perform duties under this part. The focus of MRO responsibilities under Part 26 and other Federal workplace drug testing programs is on the medical evaluation of positive, adulterated, substituted, or invalid test results, which requires a knowledge of substance abuse. However, some MROs do not have the extensive knowledge of substance abuse disorders that is necessary to make determinations of fitness and treatment recommendations as required under this part. Therefore, the final rule permits MROs to serve as SAEs if they meet the qualifications for this role that are established in this subpart. But, the rule requires licensees and other entities to rely on other healthcare professionals who have the necessary qualifications to conduct determinations of fitness if the MRO does not meet the SAE qualification requirements.

Second, the NRC believes that healthcare professionals other than licensed physicians may have the requisite knowledge and skills to serve as SAEs under the rule. Therefore, the final rule defines the position of SAE in terms of the knowledge and skills required, and permits healthcare professionals other than licensed physicians to serve in this role.

Third, under the final rule, FFD programs are permitted to accept determinations of fitness and treatment plans from other Part 26 programs, if an individual who has had a substance abuse problem will be granted authorization by another licensee or entity. Consequently, detailed requirements for the qualifications and responsibilities of the SAE are necessary to ensure consistency among FFD programs. Detailed requirements for the qualifications and responsibilities of the SAE are necessary because of the key role the SAE plays in assuring the common defense and security and public health and safety when making a determination of fitness on which licensees and other entities will rely when making authorization decisions. It is critical that SAEs understand the potential impact on the common defense and security and public health and safety when determining that an individual who has had an active substance abuse problem has resolved the problem and is again worthy of the public's trust. A sophisticated understanding of substance abuse problems and the types of adverse behaviors they may involve, including knowledge of the research literature and clinical experience, is necessary to inform the SAE's clinical judgments in these circumstances.

The NRC has adapted many of the provisions in the subpart from related DOT requirements regarding the ''substance abuse professional'' [49 CFR Part 40, subpart O; 65 FR 41944; August 9, 2001]. The SAE role is not defined in former Part 26.

Subpart I Managing Fatigue

Subpart I of the final rule strengthens the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue. Because the overall rationale for including Subpart I, Managing Fatigue, in Part 26, is detailed

and extensive, this discussion is presented separately in Section IV.D.

Subpart J [Reserved]

As a result of adding Subpart K [FFD Programs for Construction] to the final rule, several subparts of the proposed rule have been renumbered. The provisions contained in Subpart J of the proposed rule have been moved to Subpart N of the final rule.

Subpart K FFD Programs for Construction

As a result of reorganizating the final rule, the NRC has moved the provisions contained in Subpart K of the proposed rule [Inspections, Violations, and Penalties] to Subpart O of the final rule.

The final rule adds a new Subpart K to revise and increase the level of detail of FFD requirements contained in § 26.3(e) of the proposed rule pertaining to FFD programs for new reactor construction. The NRC has added this subpart to the final rule to clarify the requirements applicable to entities conducting construction activities in response to public comments that raised concerns with the proposed requirements. A detailed description of these public comments, as well as a summary of the features and objectives of Subpart K can be found in Section V of this document. A detailed section-by-section analysis of the provisions of Subpart K can be found in Section VI of this document.

Subpart L [Reserved]

Subpart M [Reserved]

Subpart N Recordkeeping and Reporting Requirements

As a result of reorganizing the proposed rule, the NRC has moved the provisions contained in Subpart J of the proposed rule [Recordkeeping and Reporting Requirements] to this subpart of the final rule. The NRC has added Subpart N to the final rule to reorganize the former rule's requirements for maintaining records and submitting reports to the NRC. The subpart combines and amends two sections of the former rule: Section 26.71 [Recordkeeping requirements] and § 26.73 [Reporting requirements], and incorporates the record retention requirements of former §§ 26.21(b), 26.22(c), and 26.80(c). The final rule adds a new § 26.709 [Applicability]. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule, by grouping related requirements together in the subpart.

Major changes to the former rule's requirements for recordkeeping and reporting reflect the addition of requirements for specimen validity testing to the final rule, the addition of requirements for managing worker fatigue at nuclear power plants, and a relaxation of the required frequency with which Part 26 programs must submit FFD program performance reports to the NRC from bi-annually to annually.

Subpart O Inspections, Violations, and Penalties

As a result of reorganizing the proposed rule, the NRC has moved the provisions contained in Subpart K of the proposed rule [Inspections, Violations, and Penalties] to this subpart of the final rule. The NRC added Subpart O to the final rule to combine into one subpart former §§ 26.70 [Inspections], 26.90 [Violations], and 26.91 [Criminal penalties]. The NRC has grouped these sections together in one subpart because they each establish requirements related to the NRC's oversight of the implementation of FFD programs. Section 26.821 [Inspections] retains the requirements in former § 26.70. Section 26.823 [Violations] retains the requirements in former § 26.90 [Violations]. Section 26.825 [Criminal penalties] retains the requirements in former § 26.91 [Criminal penalties].

D. Inclusion of Worker Fatigue Provisions in 10 CFR Part 26

The NRC has determined that the effectiveness of FFD programs in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security should be strengthened by establishing clear and enforceable requirements for the management of worker fatigue at nuclear power plants. Subpart I, Managing Fatigue, of the final rule includes these requirements and establishes an integrated approach to fatigue management for nuclear power plant workers, with fatigue prevention, detection, and mitigation as the fundamental components. The requirements in Subpart I provide a substantial increase in the protection of public health and safety and common defense and security. In establishing the provisions of this final rule, the NRC has taken into consideration the effects of fatigue; the specific work practices of the nuclear power industry that contribute to and mitigate fatigue; the inadequacy of the former regulatory framework; the excessive hours formerly worked by many nuclear power workers; and the practices of other industries and countries for regulating work hours. In addition, the NRC held many public meetings with the nuclear industry and the public to discuss provisions for the final rule.

The NRC has determined that an integrated approach is necessary to effectively manage worker fatigue because individuals experience fatigue for many reasons, including long work hours, inadequate rest, and stressful or strenuous working conditions. Shiftwork, home-life demands, and sleep disorders can all contribute to inadequate sleep and excessive fatigue. Individual differences in workers' tolerance of these conditions also influence worker fitness for duty. As a consequence, fatigue is a complex phenomenon that requires an integrated approach to manage effectively. The requirements in Subpart I were developed on the premise that fatigue management requires the collaboration of individual workers and licensees.

Each of the requirements in Subpart I is discussed in detail in Section VI. However, because Subpart I presents an integrated fatigue management approach, this section discusses the principal findings that led to the NRC's decision to include fatigue management provisions in Part 26, as well as supporting information on the causes and problems with worker fatigue in the nuclear power industry.

The Commission approved a rulemaking plan to include worker fatigue provisions for nuclear power plants in 10 CFR Part 26 on January 10, 2002, (SRM–SECY–01–0113), as described in Section I. Since that time, the NRC has continued to analyze the need for work-hour provisions in the final rule. The considerations listed in the numbered paragraphs that follow summarize the NRC's considerations concerning the appropriate regulatory action to address the potential for worker fatigue to affect public health and safety and the common defense and security. These considerations include:

(1) The research literature demonstrating the substantive effects of fatigue and decreased alertness on an individual's ability to safely and competently perform his or her duties;

(2) The conditions that contribute to worker fatigue in the U.S. nuclear power industry;

(3) With the exception of orders limiting the work hours of security personnel, the NRC's former regulatory framework did not include consistent or readily enforceable requirements to address worker fatigue;

(4) Reviews of industry control of work hours have repeatedly identified practices that were inconsistent with the NRC's Policy on Worker Fatigue, including excessive use of extended

work weeks and the overuse of work-hour limit deviations;

(5) The former regulatory framework included requirements that were inadequate and incomplete for effective fatigue management;

(6) Ensuring effective management of worker fatigue through rulemaking substantially enhances the effectiveness of FFD programs, but additional orders are not presently warranted to ensure adequate protection of public health and safety or the common defense and security; and

(7) Addressing the fatigue of workers in safety-critical positions through regulation is consistent with practices in foreign countries and other industries in the U.S.

Each of these considerations is discussed in greater detail below.

(1) Fatigue and decreased alertness can substantively degrade an individual's ability to safely and competently perform his or her duties.

The NRC previously noted in its ''Policy Statement on the Conduct of Nuclear Power Plant Operations,'' dated January 24, 1989 (54 FR 3424), that ''nuclear power plant operators on each shift must have knowledge of those aspects of plant status relevant to their responsibilities to maintain their working environment free of distractions, and using all their senses, be alert to prevent or mitigate any operational problems.'' The degradation in an individual's cognitive functioning resulting from inadequate rest includes, but is not limited to, a reduced ability to sustain attention; maintain situational awareness; make timely and conservative decisions; communicate; and work effectively as a team member. These degradations in performance, if exhibited by individuals performing risk-significant functions, can adversely affect the safety and security of a nuclear power plant.

The NRC evaluated the research available on the degradation of worker abilities that are important to safe plant operation. The research supports the fatigue management provisions in subpart I. Many of the specific research citations are listed in detail in section VI. The following is a discussion of the fundamental concerns associated with worker fatigue, and some of the overall research that forms the basis for the integrated fatigue management approach in Subpart I.

Many studies have shown that fatigue impairs human alertness and performance (e.g., Alluisi and Morgan, 1982; Rosa, 1991; Scott, 1990; Dinges, 1992; Dinges, 1995; Dawson and Reid, 1997; Bobko, et al., 1998; Harrison and Horne, 2000; Williamson and Feyer, 2000). The lack of adequate days off and extended workdays (overtime) can result in a cumulative sleep debt (i.e., the difference between the amount of sleep an individual needs and the amount of sleep that individual actually obtains) and performance impairment (Webb and Agnew, 1974; Baker, et al., 1994; Colquhoun, et al., 1996; Tucker, et al., 1999; Williamson and Feyer, 2000; Department of Transportation (DOT), May 2, 2000, 65 FR 25546). Across a broad range of industries, studies concerning extended work hours suggest that fatigue-induced personnel impairment can increase human error probabilities by a factor of more than 2 to 3 times (Hanecke, et al., 1998; Colquhoun, et al., 1996; Akerstedt, 1995; U.S. DOT, 49 CFR parts 350, et al., Final Rule, May 2, 2000; 65 FR 25544).

Studies of the nuclear power industry indicate that normal daily variations in alertness associated with human circadian rhythms (i.e., physiological processes that vary on an approximate 24-hour cycle) may be responsible for daily variations in the incidence of personnel errors at nuclear power plants (Bobko, et al., 1998; Dorel, 1996; Maloney, 1992). The findings of these studies are consistent with the results of a survey of more than 100 nuclear power plant shift supervisors—over 90 percent stated that they notice times of day, and days in the schedule, during which control room operators are less alert, less vigilant, or make more mistakes (Baker, et al., 1990 [EPRI NP–6748]). These studies suggest that despite controls, such as standardized work practices and independent verification, to ensure correct and reliable human performance, factors that influence alertness may increase the incidence of human errors in nuclear power plants.

Fatigue has generalized effects on human performance capabilities, and is associated with performance decrements at a base level, across a variety of tasks (Dinges, 1995). Fatigue can impair both physical and cognitive (i.e., mental) functioning.

Generally, cognitive task performance is affected more readily by fatigue than physical or psychomotor tracking performance (Krueger, 1989; 1991). General cognitive fatigue decreases an individual's ability to remain alert, process complex information, and correctly grasp a complex set of circumstances. Fatigue has been shown to cause memory problems, slowed responses, lapses and false responses (Williams, et al., 1959; Morgan, et al., 1974; Dinges, 1992; Dinges, 1995). Many of the cognitive tasks performed by nuclear power plant personnel that are important to the protection of public health and safety and the common defense and security rely on their ability to sustain attention, analyze problems, make rapid, accurate decisions, and communicate and work as a team. The following effects of fatigue on cognitive abilities are the primary focus of the fatigue management requirements:

(a) *Sustaining attention*—Vigilance and attention to detail are fundamental for plant safety, whether an individual is operating or maintaining equipment important to plant safety, performing surveillance procedures in the plant, monitoring system status in the control room, or monitoring plant security systems or barriers. Tasks requiring sustained attention (e.g., vigilance tasks) are among the most susceptible to fatigue-induced degradation (Monk and Carrier, 2003). The sensitivity to fatigue of vigilance tasks is one of the primary reasons that tests, such as the psychomotor vigilance task (Dinges, et al., 1997; Doran, et al., 2001), are standard measurement tools used in studies of the effects of sleep deprivation and fatigue. Of particular note are research findings showing that, in operational settings, individuals may experience periods of sleep up to a few seconds (called microsleeps), during which they fail to respond to external stimuli, and are completely unaware that these episodes have occurred (Cabon, et al., 2003; Priest, et al., 2001; Summala, et al., 1999).

(b) *Decision-making*—Conservative decision-making is central to safe nuclear power plant operations. Fatigue is associated with more risky strategies and decreases in the effort individuals exert in decision-making (Schellekens, et al., 2000). Furthermore, Harrison and Horne (2000) reviewed the impact of sleep deprivation on decision-making and reported that, contrary to popular belief, sleep deprivation impairs decision-making even if individuals try to compensate for lack of sleep when responding to heightened stimulation. As noted by Cabon, et al. (2003), studies have shown reductions in aircrew alertness, even during the critical descent phase. These findings suggest that the alerting stimuli of off-normal conditions (e.g., landing an airplane, acknowledging control room annunciators) may not fully negate the effects of fatigue on performance. The National Transportation Safety Board (NTSB) reviewed the performance of flight crews involved in 37 major accidents and found that those crew members who had been awake longer than 12 hours before their accidents made more errors overall, and specifically more tactical decision

errors, than did crew members who had been awake for less time (NTSB, 1994).

(c) *Problem solving*—Perseveration is a term used to describe poor problem solving performance, characterized by an individual or group of individuals maintaining a faulty diagnosis or mitigation plan despite contrary information. An example of perseveration from the nuclear power industry was the initial response by plant operators to events at Three Mile Island Unit 2 in 1979. The operators' initial response was based on a faulty diagnosis of the plant condition (the operators failed to recognize they were dealing with a loss of coolant accident), which the operators maintained throughout the first 2 hours of the event in the face of numerous conflicting indications. Many factors contributed to human performance problems during the Three Mile Island accident and the NRC is not suggesting that operator fatigue was a contributing factor. However, fatigue is one factor that has been found to contribute to this type of performance degradation (Harrison and Horne, 2000), which may have serious consequences for public health and safety. Sleep-deprived workers fail to appropriately allocate attention, set task priorities, or sample for sources of potentially faulty information (Hockey, 1970; Krueger, 1989). Mental fatigue also contributes to decreased originality and flexibility in problem solving and sub-optimal planning (Van der Linden, et al., 2003; Lorist, et al., 2000; Horne, 1988).

(d) *Communication and teamwork*—Fatigue affects skills important to written and oral communication and teamwork. Fatigue degrades speech articulation, verbal fluency, grammatical reasoning (the ability to process oral and written instructions), and memory (Harrison and Horne, 1997; 1998). Studies of individuals in simulated combat and command and control conditions have shown that fatigue slows the encoding, decoding, and transcription of information (Banderet, 1981; Angus and Heslegrave, 1985). Fatigued individuals also tend to be less communicative and have greater difficulty performing multiple tasks concurrently, as demonstrated in simulated aircraft cockpit tasks requiring monitoring and communications (Pascoe, et al., 1995; Harrison and Horne, 2000). These effects have been found in the analysis of incidents and accidents. In a study of major aircraft accidents, crews that had been awake longer (an average of 13.8 hours for captains and 13.4 hours for first officers) made significantly more procedural and tactical decision errors than crews that had been awake for a shorter period (an average of 5.3 hours for captains and 5.2 hours for first officers) (NTSB, 1994). Similar to control room personnel in nuclear power plants, aircraft cockpit crews make extensive use of secondary checks to verify that decisions and performance are correct, and to mitigate the consequences of errors. Although the difference was not statistically significant, analysis of the crew errors indicated that crews that had been awake longer made nearly 50 percent more errors in failing to challenge a faulty action or inaction by another crew member. These studies highlight how fatigue cannot only degrade the fitness of an individual, but also the overall performance of a crew.

Although fatigue has long been widely recognized as causing degraded performance, recent research has helped characterize the magnitude of these effects relative to a historical FFD concern: impairment from alcohol intoxication. Part 26 prohibited the use of alcohol on site and within several hours before a tour of duty, and established alcohol testing requirements for personnel on duty. The NRC established these requirements based on the recognition that alcohol can have significant adverse effects on a worker's ability to safely and competently perform his or her duties. Recent studies have shown that fatigue can cause performance degradations that are comparable to the levels observed from blood alcohol concentrations (BACs) in excess of those that would result in a positive breath alcohol test under the provisions of Part 26. In those studies, individuals who were awake for 17–19 hours had cognitive and psychomotor performance comparable to individuals with a BAC of 0.05 percent (Dawson and Reid, 1997; Williamson and Feyer, 2000). Part 26 establishes breath alcohol cutoff level below 0.05 percent. The NRC considers the insight that fatigue can impair a worker at levels comparable to those prohibited for alcohol to be particularly significant.

(2) Conditions that contribute to worker fatigue are prevalent in the U.S. nuclear power industry.

Fatigue may result from an individual remaining awake continuously for an excessive period of time, or from the individual obtaining an inadequate amount or quality of sleep, or both. Conditions that contribute to worker fatigue include:

(a) *Extended work shifts with five or more consecutive work days*—Although the effects of shift length on worker performance are influenced by the nature of the task, various studies have shown that task performance declines after 12 hours on a task (Rosa, 1991; Folkard, 1997; Dawson and Reid, 1997). Other studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Colquhoun, et al., 1996; Hanecke, et al., 1998; U.S. DOT, 49 CFR parts 350, et al., Final Rule; 65 FR 25544; May 2, 2000). The effects of extended working hours on worker performance can be exacerbated when many extended shifts are scheduled in succession. The National Institute for Occupational safety and Health published a report in 2004 (Caruso et al., 2004) that reviewed 52 recent reports examining the association between long work hours and illness, injuries, health behaviors, and performance. NIOSH reported that ''a pattern of deteriorating performance on psychophysiolgical tests as well as injuries while working long hours was observed across study findings, particularly when 12-hour shifts combined with more than 40 hours of work a week.''

The use of 12-hour shifts has become increasingly common at U.S. nuclear power plants. Schedules that include 5 or more 12-hour shifts in succession during routine operations are sometimes popular with workers because they allow a long sequence of days off. However, scheduling more than 4 consecutive 12-hour shifts is not a recommended means of managing fatigue (Baker, *et al.*, 1990 [EPRI NP–6748]; NUREG/CR–4248, ''Recommendations for NRC Policy on Shift Scheduling and Overtime at Nuclear Power Plants''). As noted in the 2000 Sleep in America Poll, ''waking up unrefreshed'' was more likely to be reported by individuals working more than 60 hours per week (58 percent vs. 42 percent of those working 41–60 hours per week and 39 percent of those working 31–40 hours) (National Sleep Foundation, 2000).

During the public meetings described in the preamble to the proposed rule, industry stakeholders noted that the use of 6 or more consecutive 12-hour shifts is now standard practice during plant outages. In SECY–01–0113, the NRC staff reported that more than 80 percent of the authorizations written by licensees to exceed the technical specification work-hour limits during outages were for exceeding 72 hours (e.g., six 12-hour shifts) in a 7-day period. The NRC's more recent review of deviations authorized at six plants for refueling outages during 2003 and 2004 also indicated that deviations from the limit of 72 hours in 7 days continue to account for more than 80 percent of the

deviations authorized. During the public meetings, industry stakeholders also reported that, during outages, some licensees have scheduled personnel for three or more weeks of consecutive 12-hour shifts without intervening days off.

(b) *Extensive Overtime*—Many research studies report that excessive working hours cause worker fatigue (Akerstedt, 1995b; Rosa, 1995; Buxton, et al., 2002). The U.S. nuclear power industry makes extensive use of overtime, creating a combined effect of long work hours with reduced break periods. As noted in SECY–01–0113, at approximately one-fourth of the sites, more than 20 percent of the personnel covered by working hour limits work more than 600 hours of overtime annually. This amount of overtime is more than two to three times the level permitted for personnel at some foreign nuclear power plants and more than twice the level recommended by an expert panel Commissioned by the NRC in 1985 (NUREG/CR–4248). In SECY–01–0113, the NRC also noted that some licensees authorized hundreds to several thousand deviations from the limits of 16 hours of work in any 24-hour period, 24 hours of work in any 48-hour period, 72 hours of work in a 7-day period, and from the minimum break requirement of 8 hours between work periods. The NRC also noted the continued excessive use of such deviations in its survey of six plants in 2004.

(c) *Shiftwork*—The nuclear power industry is a round-the-clock operation requiring individuals to be awake and working at times when they would normally be asleep. Although individuals can function in these circumstances, human alertness and task performance are cyclically affected by a daily biological clock, which runs on about a 24-hour (circadian) cycle, as it assists in timing numerous physiological and psychological phenomena (such as core body temperature, the daily release of various hormones, mood swings, and wake-sleep cycle) (Liskowsky, et al., 1991). The circadian trough, or lowest levels of function reflected in, for example, alertness, performance, subjective mood, and body temperature, occurs around 3 a.m. to 5 a.m., with many human functions showing reduced levels between 12 a.m. and 6 a.m. Sleepiness is most severe between 3 and 5 a.m., with a less marked but significant expression again between 3 and 5 p.m.

There is substantial scientific literature on circadian variations in alertness that clearly demonstrates the significant roles that worker fatigue, sleep loss, and circadian rhythms play in contributing to errors and accidents (Kryger, et al., 1994; Akerstedt, 1995a; Dinges, 1995; Folkard, 1997; Comperatore and Krueger, 1990; Miller and Mitler, 1997). These findings range from reduced response speed on a variety of tasks, to missing warning signals, to minor hospital incidents and accidents (Krueger, 1994). In addition, as previously described in this section, circadian variations have also been noted in studies of the incidence of personnel errors at nuclear power plants (Bobko, et al., 1998; Dorel, 1996; Maloney, 1992) and noted in observations by a large number of nuclear power plant shift supervisors (Baker, et al., 1990 [EPRI NP–6748]).

In addition to causing individuals to perform work at periods of depressed alertness, shiftwork also conflicts with circadian variations in alertness by requiring individuals to sleep during naturally occurring periods of increased cognitive arousal. Circadian rhythms, and naturally occurring tendencies for sleep and wakefulness, do not fully adapt to shiftwork schedules. In addition, daylight, noise and the ''regular day'' schedules of other family members challenge the ability of shiftworkers to obtain adequate rest. As a result, shiftworkers generally obtain less sleep, and report a higher incidence of sleepiness and sleep-related complaints. For example, in a survey of 1,154 U.S. adults, the National Sleep Foundation (NSF) found that shiftworkers, on average, get less sleep (6 hours, 30 minutes) than regular day workers (6 hours, 54 minutes). Almost half of the shiftworkers they surveyed obtained less than 6.5 hours of sleep per ''night'' during the work-week, 30–90 minutes less than recommended by most sleep experts. In comparison to regular day workers, shiftworkers were more likely to be sleepy at work 2 or more days per week (34 percent vs. 23 percent) (National Sleep Foundation, 2000). Many studies have demonstrated that decreased performance and increased errors and accidents are associated with night work and are affected by varying sleep schedules and durations of sleep periods (e.g., Balkin, et al., 2000).

The challenge for shiftworkers to remain alert during the early morning hours of a shift can be exacerbated by extended shift lengths, overtime, and the inability of many shiftworkers to obtain adequate sleep during the day (Hanecke, 1998). The powerful drive for sleep that is associated with circadian factors, and the fact that shiftwork is a daily influence on the alertness of all shiftworkers at nuclear power plants, has been demonstrated by a number of recent events. For example, there have been instances of operators falling asleep in the control rooms at the Pilgrim nuclear power station (2004) and the test and research reactor at the Massachusetts Institute of Technology (2003), as well as a security officer falling asleep at the Braidwood nuclear power plant while driving a patrol vehicle (2004), despite these individuals recognizing the potential safety and disciplinary consequences.

(d) *Early start times and extended commutes* —Although many plant personnel do not work rotating shifts, start times before 7 a.m. can interfere with a worker's ability to obtain adequate rest if the schedule is not aligned with his or her circadian cycle and naturally occurring tendency for sleep and wakefulness. Such start times typically cause workers to wake before 6 a.m., thereby reducing the amount of sleep that can be obtained between midnight and 6 a.m., the most effective time period for most people to sleep. In addition, long commutes to remote work sites such as nuclear power plants, which are frequently located in rural areas and distanced from major population centers, contribute to the potential for fatigue associated with early start times.

(e) *Sleep disorders*—Sleep disorders, such as sleep apnea, insomnia, and restless leg syndrome (i.e., a condition that is characterized by uncomfortable or unpleasant sensations in the legs, causing an overwhelming urge to move them, often contributing to difficulty in staying or falling asleep), are conditions that can significantly reduce the quantity and quality of sleep that individuals are able to obtain, affect an individual's ability to remain alert, and ultimately degrade an individual's ability to safely and competently perform his or her duties (Kryger, *et al.*, 1994; Lewis and Wessely, 1992). These factors are not effectively addressed by limits on working hours in the absence of other fatigue management practices. Although the NRC does not have data for the incidence of sleep disorders that are specific to U.S. nuclear power plant workers, in the general U.S. population, these conditions are not uncommon. For example, the prevalence of sleep apnea is estimated to be 4 percent for adult males and 2 percent for adult females (Strollo and Rogers, 1996). The incidence of sleep apnea may in fact be higher for shiftworkers at power plants, as this condition is more common in middle-age adult males than in the general population. A survey by the NSF of 1,154 adults living in households in the continental U.S.

found self-reports of sleep apnea were more common from shiftworkers than regular day workers (15 percent vs. 9 percent) (National Sleep Foundation, 2000). Similarly, the NSF found that shiftworkers reported a higher incidence of insomnia (66 percent vs. 55 percent) than regular day workers.

Although worker motivation can mitigate to a limited degree the effects of fatigue, fatigue has a physiological basis, including changes in glucose metabolism in the brain (Wu, et al., 1991; Thomas, et al., 2000). These changes are beyond the individual's control. In addition, several studies have suggested caution with regard to the abilities of individuals to self-monitor their capacity to safely and competently perform their duties when fatigued (Dinges, et al., 1997; Belenky, et al., 2003; Akerstedt, 2003). These studies note that individuals experience microsleeps without being aware of their lapses in attention and underestimate their propensity for uncontrolled sleep episodes. As a consequence, a worker's motivation to remain alert does not provide reasonable assurance that an individual will be able to safely and competently perform his or her duties.

Considering the above factors, fatigue can have a significant adverse effect on worker abilities. Further, the likelihood of a nuclear power plant worker being impaired from fatigue is not trivial, and potentially greater than the likelihood of impairment from drugs and alcohol, which the NRC requires licensees to address through their FFD programs. Therefore, the NRC believes that regulatory action is warranted to ensure that fatigue is adequately addressed through licensee FFD programs. Further, the NRC asserts that rulemaking is the appropriate regulatory action for the following reasons:

(3) With the exception of orders limiting the work hours of security personnel, the NRC's former regulatory framework did not include consistent or readily enforceable requirements to address worker fatigue.

The principal components of the former regulatory framework for matters pertaining to working hours and fatigue for non-security personnel were (a) NRC's Policy on Worker Fatigue, as issued on June 15, 1982, in GL 82–12, and (b) plant technical specifications related to this policy statement, and (c) certain limited requirements of 10 CFR Part 26.

As part of the assessment of PRM–26–2, in which Barry Quigley petitioned for rulemaking to establish enforceable requirements addressing fatigue of workers at nuclear power plants, the NRC reviewed and assessed the implementation and enforceability of the NRC's former regulatory framework applicable to worker fatigue, including licensee technical specifications for the administrative control of work hours. This review was documented in detail in Attachment 1 to SECY–01–0113. The NRC continued this evaluation during development of this final rule, and the principal findings include:

(a) *NRC's Policy on Worker Fatigue*—NRC guidance documents do not prescribe requirements. Guidance documents establish policy or provide advice on meeting a regulatory requirement. As a result, a policy is enforceable only to the extent that the guidelines have been incorporated into a license condition or technical specifications. For the three nuclear power plant sites that have not incorporated the guidelines from the NRC's Policy on Worker Fatigue into a license condition or technical specification, the guidelines are unenforceable. These plant sites have implemented the concept using other administrative controls that the NRC has determined to be adequate. However, had the NRC determined that the controls were inadequate, it would have had no basis for taking enforcement action.

(b) *Technical Specifications*—For those licensees who have incorporated the NRC's Policy on Worker Fatigue into a license condition or technical specifications, consistent enforcement has been complicated by the following factors:

—The language in plant technical specifications is largely advisory (e.g., an individual should not be permitted to work more than 16 hours straight) and key terms have not been defined. This deficiency has resulted in inconsistent interpretation and implementation of technical specifications by licensees, as well as difficulty for the NRC in enforcing the requirements. For example, many technical specifications use the terms, ''routine heavy use of overtime,'' ''unforeseen problems,'' and ''temporary basis.'' The NRC has not defined any of these terms and has not consistently pursued enforcement on the basis of the amount or frequency of overtime authorized.

—The technical specifications have inconsistent levels of detail from one nuclear power plant licensee to another. Only three-quarters of the licensees' technical specifications include the quantitative work-hour limit guidelines of the NRC's Policy on Worker Fatigue.

—The technical specifications contain varying scopes of requirements. Some plant technical specifications require periodic reviews of overtime approvals to ensure that excessive hours have not been assigned, while other technical specifications contain no equivalent requirements. Although the observed variability in the controls does not by itself present a safety concern, such variability is inconsistent with establishing a uniform level of assurance that personnel are not in a fatigued condition that could significantly reduce their mental alertness and decision-making capabilities.

—Licensees have inconsistently interpreted the scope of personnel who must be subject to the technical specification work-hour limits. The NRC's Policy on Worker Fatigue applies to personnel who are performing safety-related functions. The NRC's review of work-hour data gathered by NEI regarding the work hours of personnel subject to the technical specifications (Nuclear Energy Institute, 2000) identified variation in the numbers and types of personnel covered by these controls. A limited number of sites may not have been applying work-hour controls to all personnel performing safety-related functions. At least two nuclear plant sites do not apply the work hour controls to any maintenance personnel even though GL 83–14, ''Definition of 'Key Maintenance Personnel' (Clarification of GL 82–12),'' issued March 7, 1983, defined key maintenance personnel to include individuals who work on safety-related equipment.

—The basic measure used to determine whether an individual's work hours are within or above the technical specification limits has not been implemented consistently from one nuclear power plant to another. Work hours included within the limits at some nuclear power plants have not been included at others, effectively creating substantively different work-hour limits among plants.

(c) *10 CFR Part 26, ''Fitness for Duty Programs''*—The general performance objectives of former § 26.10 required that licensees provide ''reasonable assurance that nuclear power plant personnel * * * are not * * * mentally or physically impaired from any cause, which in any way adversely affects their ability to perform their duties.'' Although former 10 CFR Part 26 contained specific requirements pertaining to alcohol and drug usage, it did not include prescriptive

requirements regarding fatigue. Rather, former § 26.20 used general, non-mandatory language to state that the FFD policy ''should'' address other factors that can affect a worker's ability to safely and competently perform his or her duties, ''such as mental stress, fatigue, and illness.'' As a result, it has been difficult for the NRC to justify a violation of the regulation based on a licensee's failure to limit overtime hours. In addition, without a numerical limit on overtime hours, or a provision limiting overtime, a range of overtime practices could be viewed as ''reasonable,'' and therefore in compliance with the regulation.

In summary, the broad and non-prescriptive provisions of Part 26, and the technical specifications and license conditions pertaining to fatigue, in the absence of clearly defined terms or measures of fatigue, have made it difficult for the NRC to enforce worker fatigue requirements and work-hours limits in an effective, efficient, and uniform manner that ensures that all licensees provide reasonable assurance that workers are able to safely and competently perform their duties. The NRC believes that a consistent fatigue management program and its uniform implementation across the industry is essential, and the most effective regulatory mechanism is to incorporate worker fatigue requirements into 10 CFR Part 26.

(4) Reviews of industry control of work hours have repeatedly identified practices that were inconsistent with the NRC's Policy on Worker Fatigue, including excessive use of work hours and work hour limit deviations.

The policy states, in part, ''Enough plant operating personnel should be employed to maintain adequate shift coverage without routine heavy use of overtime.'' Surveys and expert panels have suggested that tolerance for overtime is generally limited to 300–400 hours of overtime per year (ADAMS Accession No. ML05270310; NUREG/CR–4248). Baker, et al. (1994) reviewed the hours worked by nuclear power plant operations, technical, and maintenance personnel during 1986, four years after the NRC issued its policy. Based on a sample of 63 percent of U.S. nuclear power plants operating at that time, Baker and colleagues found that operations personnel averaged more than 500 hours of overtime annually at 20 percent of the plants, and more than 700 hours of overtime at 9 percent of the plants. Technical personnel averaged more than 500 hours of overtime annually at 30 percent of the plants, and more than 700 hours of overtime at 18 percent of the plants. Maintenance personnel averaged more than 500 hours of overtime annually at 80 percent of the plants and more than 700 hours of overtime at 14 percent of the plants.

The NRC's Policy on Worker Fatigue included provisions for licensees to authorize deviations from the NRC's work and rest guidelines for individual workers in ''very unusual circumstances.'' On June 10, 1991, following several NRC inspections noting concerns related to licensee work hour control, the NRC issued Information Notice (IN) 91–36, Nuclear Power Plant Staff Working Hours, to alert licensees of potential problems resulting from inadequate controls to prevent excessive working hours. The conditions cited in the notice included an event attributed to fatigue, excessive use of deviations and overtime, and overtime deviations authorized after the fact. Subsequent NRC reviews completed in 1999 and 2001 identified continued problems with industry control of work hours. In 1999, the NRC reviewed licensee event reports and NRC inspection reports from January 1994 through April 1999. The NRC found that only a few events of limited risk significance had been attributed to fatigue. However, the staff found several instances each year in which licensee use of overtime appeared to be inconsistent with the general objectives or specific guidelines of the NRC's Policy on Worker Fatigue.

NEI conducted a survey in the summer of 2000 concerning industry control of work hours for personnel subject to the technical specifications (letter dated August 29, 2000, from J. W. Davis, NEI, to G. M. Tracy, NRC, ADAMS Accession No. ML003746495). Forty-seven sites responded to the survey, providing data from 1997–1999. The NRC staff's review of the data is documented in Attachment 1 to SECY–01–0113. The NRC evaluated the results of the survey concerning overtime and found that 8 of 36 sites providing data had more than 20 percent of the personnel covered by the policy working in excess of 600 hours of overtime per year. Considering all plants that provided data, the percentage of personnel working in excess of 600 hours of overtime per year increased from 7 percent in 1997 to 11 percent in 1999. The percentage of licensed operators working in excess of 600 hours of overtime per year increased from 13 percent in 1997 to more than 16 percent in 1999. The NRC considers these percentages to represent excessive use of overtime in the nuclear industry.

The NRC also reviewed the data collected by NEI concerning deviations, which showed that approximately one-third of the respondents were authorizing more than a thousand, to as many as 7,500, deviations in a year to exceed the policy guidelines. The frequency of deviations did not appear to be consistent with either the specific guidelines or the general objective of the policy. As previously described in this section, the policy permits deviations from the guidelines in ''very unusual circumstances.''

Subsequent to the Commission's decision to initiate rulemaking for worker fatigue, the NRC staff also obtained data from six sites in 2004. Those data indicated that between 95 and 603 deviations, with an average of 311 deviations, were issued for individuals. The data were provided by the six sites for each plant's most recent refueling outage and one month of power operation, and therefore do not reflect the total number of deviations issued for individuals during all of 2004, except for one of the six sites that provided its deviation data (101 deviations) for all of 2004. Data on the deviations from 2004 in this sample are reported in detail in Appendix 3 of the Regulatory Analysis. The NRC believes that licensee use of deviations and overtime at some sites has been excessive, and has been inconsistent with the intent of the NRC's Policy on Worker Fatigue.

In addition to excessive work hours and work-hour guidelines deviations, the NRC has recently identified other concerns related to licensee policies and practices applicable to worker fatigue. On May 10, 2002, the NRC issued Regulatory Issue Summary (RIS) 2002–007, ''Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declaration of Fitness-for-Duty.'' The NRC issued the RIS following several allegations made to the NRC regarding the appropriateness of licensee actions or policies related to individuals declaring they are not fit due to fatigue. These concerns indicate a need to ensure that individuals and licensees clearly understand their responsibilities with respect to self-declarations of worker fatigue. The final rule establishes requirements to address this need.

(5) The former regulatory framework included requirements that were inadequate and incomplete for effective fatigue management.

(a) The NRC's Policy on Worker Fatigue did not establish clear expectations for the control of work hours. As previously noted in this section, the NRC did not define key terms of the policy, and, as a

consequence, implementation has been varied across the industry.

(b) Certain policy guidelines and technical specifications were inadequate to provide reasonable assurance that individuals remain capable of safely and competently performing their duties. For example, the requirement for an 8-hour break between work periods has been revised to a 10-hour break. The basis for this revision to increase the length of this break period is described in detail in Section VI with respect to § 26.205(d)(2)(i).

In addition, although the policy established an objective of a nominal 40-hour work week, the specific work hour guidelines of the policy and most technical specifications for the administrative control of work hours have principally focused on acute fatigue. These guidelines did not adequately address the longer term control of work hours and the cumulative fatigue that can result from prolonged periods of extended work hours. Acute fatigue results from restricted sleep, sustained wakefulness, or continuous task demands over the past 24 hours or more. Cumulative fatigue results from inadequate rest over consecutive sleep-wake periods when the worker obtains less sleep than he or she requires. An individual incurs a sleep debt for each day during which the worker obtains insufficient sleep. If the individual continues to obtain insufficient sleep, this debt accumulates over successive days, resulting in increasing fatigue and impairment (Belenky, et al., 2003).

The inadequacy of the former regulatory framework for addressing cumulative fatigue became particularly apparent in the months following the terrorist attacks of September 11, 2001. The NRC received numerous allegations from nuclear security officers that certain licensees required them to work excessive amounts of overtime over long periods due to the post-September 11, 2001, threat environment. These individuals questioned their readiness and ability to perform their required job duties due to the adverse effects of cumulative fatigue. The NRC reviewed the actual hours worked by security personnel and determined that, in the majority of cases, individual work hours did not exceed the guidelines specified in the NRC's Policy on Worker Fatigue, but the review confirmed that individuals had been working up to 60 hours per week for extended periods. The concerns expressed by individuals regarding their FFD, in light of work schedules that did not exceed the specific guidelines of the policy, as well as relevant technical research supporting the basis for cumulative fatigue, led the NRC to conclude that the work hour guidelines of the policy were inadequate for addressing cumulative fatigue. The NRC obtained additional worker feedback supporting this conclusion through a review of worker fatigue concerns and work hours during a long-term outage at the Davis Besse nuclear plant (NRC Inspection Report 05000346/2004003, dated March 31, 2004, ADAMS Accession No. ML040910335).

The comprehensive fatigue management approach in Subpart I, Managing Fatigue, establishes controls to address cumulative fatigue. Limits to mitigate cumulative fatigue for nuclear power plant security personnel were implemented by Order EA–03–038. The final rule codifies, with changes, these requirements. Changes to those limits that have been imposed by this rule are discussed in detail in Section VI, which also includes a detailed discussion of the limits and other controls to mitigate cumulative fatigue for other personnel who perform safety-related duties at nuclear power plants.

(c) The former regulatory framework did not effectively ensure that fatigue from causes other than work hours was addressed. Work hour controls are necessary, but not sufficient, to effectively manage worker fatigue. As a consequence, training and fatigue assessments are essential. Worker fatigue, and its effects on worker alertness and performance, can result from many causes in addition to work hours (e.g., stress, sleep disorders, daily living obligations) (Rosa, 1995; Presser, 2000). In addition, there are substantial individual differences in the abilities of individuals to work for extended periods without performance degradation from fatigue (Gander, 1998; Van Dongen, et al., 2004a; Van Dongen, et al., 2004b; Jansen, et al., 2003). Subpart I, Managing Fatigue, requires a comprehensive fatigue management program. One example is the strengthening of FFD training requirements concerning worker fatigue. The training requirements will improve the effectiveness of behavioral observation and the assessment of worker fatigue, self-declaration as a means for early detection of fatigue, worker self-management of fatigue, the ability of workers to obtain adequate rest on a shiftwork schedule, and licensee use of effective fatigue countermeasures.

(6) Ensuring effective management of worker fatigue through rulemaking will substantially enhance the effectiveness of FFD programs, but additional orders are not presently warranted to ensure adequate protection of public health and safety or the common defense and security.

Adequate protection of public health and safety and the common defense and security were ensured under the former regulatory framework, including Order EA–03–038 (for security personnel), the NRC's Policy on Worker Fatigue, and licensee technical specifications. Licensee FFD programs included behavioral observation programs to identify individuals whose behavior indicates they may not be fit to safely and competently perform their duties, and ensure that those individuals are removed from duty until any question regarding their fitness has been resolved. The former work-hour controls, in conjunction with licensee behavioral observation programs, automatic reactor protection systems and other administrative controls on worker activities (e.g., post-maintenance testing, peer checks, independent verifications) ensured adequate protection of public health and safety and the common defense and security. However, there were substantial limitations to the former regulatory framework, as detailed in this section. Therefore, although the previous regulatory framework provided adequate protection, including work-hour controls in 10 CFR Part 26 provides a substantial increase in public health and safety and the common defense and security. The NRC has incorporated worker fatigue provisions in Part 26 in light of the substantial increase in safety and security that is expected to result.

(7) Addressing fatigue of workers in safety-critical positions through regulation is consistent with practices in foreign countries and other industries in the U.S.

The NRC reviewed the limits on work hours for nuclear plant workers in eight other countries, as well as six other industries in the United States and Canada. These are summarized in Attachment 1 of SECY–01–0113. Although many factors influence specific regulatory limits, and requirements for other industries should be considered in context, the NRC found that the NRC's former guidelines are the least restrictive among those reviewed.

The work hours of nuclear power plant personnel in other countries are largely based on labor laws or union agreements that apply to multiple industries. With the exception of Spain, which has limits consistent with the NRC's Policy on Worker Fatigue, each of the other eight countries has more stringent requirements. The more stringent requirements have largely

preempted the need in those countries for regulation of work hours based on nuclear safety concerns.

The Department of Transportation (DOT) has established regulatory limits on the work hours of pilots, air traffic controllers, and maintenance personnel in the commercial aviation industry (14 CFR parts 121 and 135); in the maritime industry (46 U.S.C. 8104; 46 CFR parts 15.705, 15.710 and 15.111); in the rail industry (49 U.S.C. 211; 49 CFR Part 228); and for drivers of heavy trucks in the commercial trucking industry (49 CFR Part 395). The DOT recognized that fatigue can substantively degrade the ability of individuals to perform these duties and, therefore, promulgated regulatory requirements for each of these modes of transportation in keeping with the department's mission to protect public safety. In the late 1980s and early 1990s, the National Transportation Safety Board (NTSB) identified equipment operator fatigue as a significant issue affecting all transportation modes (Beal and Rosekind, 1995). As a result, DOT classified operator fatigue management as a DOT ''Flagship Initiative'' and several proactive fatigue management activities ensued across the transportation industries (e.g. U.S. DOT, 1995; Rogers, 1996, 1997; Hartley, 1998; Carroll, 1999).

In 1999, the NTSB evaluated DOT's decade of efforts on operator fatigue (NTSB, 1999). Not satisfied that enough was being done, NTSB subsequently offered DOT three recommendations: (1) expedite a coordinated research program on the effects of fatigue, sleepiness, sleep disorders, and circadian factors on transportation safety; (2) develop and disseminate educational materials for transportation industry personnel and management regarding shift work, work rest schedules, and proper regimens of health, diet, and rest; and (3) review and upgrade regulations governing hours of service for all transportation modes to assure they are consistent and incorporate the results of the latest research on fatigue and sleep issues (NTSB, 1999).

On April 28, 2003, the DOT issued revised hours-of-service regulations to require motor carriers to provide drivers with better opportunities to obtain sleep. Among other provisions, the regulations (1) increase the required off-duty time from 8 to 10 consecutive hours; (2) limit driving time to 11 cumulative hours following 10 consecutive hours off duty; (3) prohibit work after the end of the fourteenth hour after the driver began work; and (4) require long break recovery periods to prevent cumulative fatigue (68 FR 22456–22517; April 28, 2003, as amended by 70 FR 50071; August 25, 2005).

Nuclear power plant licensees in the U.S. have sometimes asserted that the characteristics of the work tasks in nuclear power plants differ from other occupations that have work hour controls (e.g. transportation equipment operators); therefore information from other occupations may not be applicable. In addition, licensees have suggested that the level of automation in nuclear power plants provides an important barrier to human errors resulting from fatigue, and that the amount of control room crew interaction and oversight of operators' actions assures that fatigue-induced errors will be detected and corrected before they have an opportunity to impact plant operations. The NRC concurs that requirements for other industries should be considered in context. Nevertheless, the fact that other Federal agencies with a safety mission have established regulations to address fatigue is relevant for several reasons.

First, the human need for sleep and the deleterious effects of sleep deprivation have a physiological basis (e.g., changes in brain glucose metabolism) that is independent of the nature of the work being performed (Wu, et al., 1991). Second, circadian variations in alertness and performance, and the underlying changes in physiological processes, have been observed in individuals performing a wide range of tasks across many industries (Kecklund, et al., 1997). For all individuals, time since awakening, the time of day, and the amount of prior sleep that an individual obtains relative to his or her sleep needs are primary determinants of fatigue and the need for sleep.

The NRC acknowledges that task characteristics and time on task may exacerbate the effects of fatigue on the ability of individuals to remain alert. For example, a concern for task-specific effects is reflected in the DOT hours-of-service regulations for commercial truck drivers, which establish a daily limit on driving time of 11 hours per day. This limit is in addition to the requirements prohibiting driving after 14 hours on duty and mandating minimum 10-hour break periods, which reflect the human physiological need for rest that is necessary to maintain performance (68 FR 22456–22517; April 28, 2003).

By comparison to driving a truck, the characteristics of some jobs in nuclear power plants (e.g., reactor operator) permit greater freedom of movement and social interaction, which may serve to temporarily mitigate the effects of fatigue on alertness. However, there is no evidence to indicate that worker motivation or the stimulating effects of the job or environment alter the underlying physiological processes. Although crew interactions and other job characteristics may serve to bolster worker alertness temporarily, environmental stimulation only masks individuals' physiological need for sleep. Removing the stimulation (e.g., transitioning from the activity of shift turnover to monitoring steady state plant operations during a night shift) will increase the potential for lapses in attention and uncontrolled sleep episodes among individuals who may be partially sleep deprived or otherwise fatigued.

Another consideration regarding the relevance of other regulations limiting work hours is that adverse fatigue effects are observed across a broad range of cognitive functions in addition to alertness. Whereas crew interactions may help sustain alertness, sleep deprivation and sustained periods of wakefulness continue to degrade other cognitive functions (e.g., memory and decision making) and elements of performance that are important to safe nuclear plant operations, such as communications and following written and oral instructions. For example, as discussed earlier in this section, studies of crew performance in critical phases of commercial aircraft flight (e.g., take-off and landings) and in simulated battle command station operations have shown fatigue-related degradations in performance despite the stimulation of the interactions, the intense level of activity, and the implications of degraded performance for the loss of human life. Regulations limiting work hours in other industries that use operating crews (e.g., aviation) and allow greater freedom of movement than trucking (e.g. maritime) are consistent with this understanding of the broad effects of fatigue on cognitive performance. There is no reason to believe that nuclear power plant workers' physiological processes and the adverse effects of fatigue on their abilities to perform their tasks would differ. In addition, the notion that human performance practices in the nuclear industry prevent fatigue-related performance decrements from resulting in human errors is not supported by studies that have shown circadian variations in performance at nuclear power plants (Bobko, et al., 1998; Dorel, 1996; Maloney, 1992).

The NRC acknowledges that the nuclear power industry is perhaps unique, relative to many other

industries, in its use of automated safety systems to protect against the consequences of equipment failure and human error. Nevertheless, reliable human performance remains an essential element in the protection of public health and safety and the common defense and security. NRC requirements, such as the minimum onsite staffing requirements of 10 CFR 50.54(m) and minimum security staffing requirements in site security plans, are predicated on the expectation that all personnel in these positions are fit for duty and are able to safely and competently perform their duties. As a consequence, the NRC does not consider the use of automated safety systems to be an appropriate basis for permitting conditions that could allow fatigue to degrade the important line of defense of reliable human performance. Further, despite automated systems, the contribution of human error to risk in operating events continues to be notable (NUREG/CR–6753, ''Review of Findings for Human Error Contribution to Risk in Operating Events'').

Because the NRC concurs that task characteristics are an appropriate consideration, the final rule differs from other Federal agencies' requirements with respect to specific work hour requirements and requires licensees to consider task characteristics when authorizing any waiver from the work hour controls. Nevertheless, the NRC believes that it remains relevant that other Federal agencies with public safety missions have chosen to address worker fatigue through regulation.

In summary, the NRC believes that the requirements in Subpart I will provide a substantial increase in the protection of public health and safety and common defense and security. In determining the provisions of this final rule, the NRC has taken into consideration the effects of fatigue on human performance, the specific work practices of the nuclear power industry that both mitigate and contribute to fatigue, the inadequacy of the former regulatory framework, the excessive hours formerly worked by many nuclear power plant personnel, and the relevant research and practices of other industries and countries for regulating work hour limits. In addition, many public meetings were held with the nuclear industry and the public to discuss draft provisions for the final rule. The specific basis for each provision of the fatigue management portions of the final rule are discussed in Section VI.

The requirements for managing fatigue will provide a substantial increase in the protection of public health and safety and common defense and security by:

(1) Establishing specific, integrated, comprehensive, and enforceable requirements for the effective prevention, detection, and mitigation of worker fatigue;

(2) Ensuring that personnel who perform functions that are significant to the protection of public health and safety or the common defense and security are subject to appropriate work hour controls, including: individuals performing risk significant operations or maintenance duties; health physics, chemistry, and fire brigade duties important to emergency response; and individuals performing security duties important to maintaining the security of the plant;

(3) Establishing work hour controls that provide increased assurance that workers will have adequate opportunity for rest and that deviations from the work hour limits will only be authorized as necessary for plant safety or security and following appropriate assessment of the worker's ability to safely and competently perform his or her duties;

(4) Ensuring that work hour deviations are only permitted when necessary for plant safety or security, and following assessment of the worker's ability to safely and competently perform his or her duties;

(5) Establishing controls to prevent cumulative fatigue that can result from consecutive weeks of extended work hours;

(6) Ensuring workers are provided with sufficient break periods to provide for adequate opportunity for sleep to mitigate acute and cumulative fatigue;

(7) Ensuring that, in addition to work hours, other factors that can affect worker fatigue and the ability of workers to remain alert are adequately addressed through licensee FFD programs;

(8) Encouraging effective fatigue management by permitting licensees to use alternate measures for prevention and mitigation of fatigue; and

(9) Strengthening FFD training requirements concerning worker fatigue. This will improve behavioral observation and assessment of worker fatigue; self-declaration as a means for early detection of fatigue; worker self-management of fatigue; the ability of workers to obtain adequate rest on a shiftwork schedule; and licensee use of effective fatigue counter-measures.

E. Subsequent Rulemakings

On August 28, 2007 (72 FR 49352), the Commission issued a final rule amending its regulations by revising the provisions, particularly 10 CFR Part 52, applicable to the licensing and approval processes for future nuclear power plants. The Part 52 final rule also clarified portions of the former Part 26 to explicitly extend the applicability of sections of the former Part 26 to a combined license holder after the date that the NRC makes the finding under § 52.103(g), a combined license holder before the date that the NRC makes the finding under § 52.103(g), a manufacturing license holder under Subpart F of 10 CFR Part 52, and a person authorized to conduct the construction activities under § 50.10(e)(3). The Part 52 final rule accomplished this by:

(1) Revising the former § 26.2(a) to refer to combined license holders after the date that the NRC makes the finding under § 52.103(g);

(2) Revising the former § 26.2(c) to refer to a holder of a combined license before the date that the NRC makes the finding under § 52.103(g), a holder of a manufacturing license under Subpart F of Part 52, and a person authorized to conduct the activities under § 50.10(e)(3);

(3) Revising the former § 26.10(a) to refer to the personnel of a holder of a manufacturing license and those authorized to conduct the activities under § 50.10(e)(3); and

(4) Revising the former Appendix A to Part 26, paragraph 1.1(1) to include a reference to a holder of a combined license after the date that the NRC makes the finding under § 52.103(g).

The Part 52 final rule changes to Part 26 went into effect on September 27, 2007. Each of the Part 26 provisions revised by the Part 52 final rule has been modified by this final rule, as discussed in section VI of this document.

On October 9, 2007 (72 FR 57416), the Commission issued a final rule amending its regulations applicable to limited work authorizations (LWAs), which allow certain construction activities on production and utilization facilities to commence before a construction permit or combined license is issued. The LWA final rule modified the scope of activities that are considered construction for which a construction permit, combined license or LWA is necessary, specified the scope of construction activities that may be performed under a LWA, and changed the review and approval process for LWA requests. By making these changes in the LWA final rule, the Commission also revised the scope of Part 26 by clarifying which entities could be subject to Part 26. The extent to which the LWA final rule impacted

Part 26 is discussed in section VI in this document.

V. Summary of Public Comments Submitted on Proposed Rule

Description of Public Comments and Public Meetings

The NRC received 81 written public comments on the proposed Part 26 published on August 26, 2005. The NRC also considered six comments submitted on a previous working draft of the proposed rule that NRC posted on its Web site on May 19, 2005, but which were received too late to consider at that time. These 87 written comments contained more than 350 pages of material. The stakeholders who submitted these 87 comments are as follows: 25 (29 percent) from nuclear energy industry representatives, including several substantive comments from NEI; five (6 percent) from other organizations; seven (8 percent) from unions; 21 (24 percent) from individuals who work in the nuclear energy industry (i.e. operators, maintenance workers); 15 (17 percent) from other individuals; and 14 (16 percent) from anonymous commenters.

The NRC considered comments contained in the transcript of a public meeting held on September 21, 2005, in which 28 individuals, including NRC staff, spoke. Four written comments were submitted anonymously at this meeting. The NRC also considered comments from several other public meetings: November 7 and 9, 2005 (ADAMS Accession No. ML052990048) to provide clarification on the proposed rule; and December 15, 2005 (ADAMS Accession No. ML053400002) regarding NEI's proposed alternative approach to the work-hour portions of the proposed rule.

The written comments received on the proposed rule addressed many issues that were of stakeholder concern. The NRC analyzed all of these comments as part of the process for developing this final rule. In particular, commenters raised several important concerns relating to fatigue management, the application of FFD requirements to entities involved in new plant construction and manufacturing activities, and validity testing of urine specimens. These concerns are discussed in some detail below. As discussed in Section VI, commenters also raised numerous other smaller issues that led the NRC to modify many final rule provisions. Finally, many comments resulted in minor changes to the proposed rule to improve clarity in the rule's organization and language, consistent with Goal 6 of this rulemaking. Virtually all of the comments supported the objectives of the proposed rule.

Public Comment on Subpart I

The NRC has reorganized the overall structure of the proposed rule and renumbered several subparts. This necessitated renumbering the affected sections of Subpart I [Managing Fatigue].

Subpart I contains requirements for the management of worker fatigue at nuclear power plants. Most comments recommended modifications to Subpart I to address specific concerns with the proposed rule language or certain provisions of the rule. However, the vast majority of the stakeholders commenting on Subpart I expressed their general support for the NRC's objective of establishing a set of clear and enforceable requirements to address the management of worker fatigue at nuclear power plants. Commenters supported the fatigue provisions for various reasons. In particular, commenters expected that the rule would increase the clarity of work hour requirements, reduce forced overtime, provide reasonable assurance that the risk of fatigue-related events is managed, increase staffing levels, and prevent worker injuries. Those who opposed the rule asserted that it would place an unnecessary burden on licensees, reduce worker income, and make it more difficult for licensees to attract supplemental workers during outages.

The NRC received several substantive comments that addressed specific provisions in proposed § 26.199 [Work hour controls]. This section would have established requirements for the control of work hours for a limited scope of personnel at a nuclear power plant. In general, the individuals who would have been subject to these requirements perform functions that most directly affect the protection of public health and safety and common defense and security. The provisions that were the subject of these comments were proposed § 26.199(d)(2)(ii), which would have required a minimum 24-hour break in any 7-day period; proposed § 26.199(d)(2)(iii), which would have required a minimum 48-hour break in any 14-day period; and proposed § 26.199(f) [Collective work hour limits], which would have required licensees to control the average work hours of specified duty groups (e.g., operations, security). The NRC also received substantive comments on the reporting requirements in Subpart I of the proposed rule. Specifically, the comments concerned the proposed § 26.197(e) [Reporting] which would have required licensees to provide information concerning the implementation of certain work hour requirements as part of an annual FFD program report.

Proposed Requirements for a Minimum 24-Hour Break in Any 7-Day Period

Section 26.199(d)(2)(ii) of the proposed rule would have required a minimum 24-hour break in any 7-day period. Commenters noted that licensees who currently use 8-hour schedules often include periods of 7 consecutive work days in their schedules. These schedules limit the frequency of shift rotations and enable licensees to conduct training on a Monday-through-Friday schedule. The commenters also asserted that the requirement for a minimum 24-hour break in any 7-day period would substantially reduce licensee flexibility in scheduling 8-hour shifts and would cause them to switch to 12-hour shifts. The NRC agrees that the proposed requirement for a minimum 24-hour break in any 7-day period would have adversely affected licensee scheduling of 8-hour shifts as described in the comments and has revised the maximum number of work days that the rule permits between breaks.

Section 26.205(d)(2)(ii) of the final rule replaces proposed § 26.199(d)(2)(ii) and requires a minimum 34-hour break in any 9-day period. In revising the requirement, the NRC considered that, although the final rule permits more consecutive work shifts for 8-hour and 10-hour shift schedules, the additional flexibility allows licensees to more readily optimize their 8-hour shift schedules to minimize the transitions between day, evening, and night shifts that can lead to worker fatigue. Although this relaxation also allows more consecutive shifts for individuals on 10-hour shifts, these individuals typically do not work a rotating schedule and therefore do not experience the disruption of their circadian cycle that exacerbates the cumulative fatigue effects of consecutive work shifts. The rule also establishes minimum day of requirements in § 26.205(d)(3) that effectively limit within each shift cycle the number of times individuals can work the 8 consecutive work days allowed by § 26.205(d)(2)(ii). The scheduling of 12-hour shifts is unaffected by this requirement because § 26.205(d)(1)(iii) effectively limits the scheduling of 12-hour shifts to not more than 6 consecutive days. The final rule also provides the licensee with sufficient flexibility to accommodate other

practical considerations, such as scheduling training on a Monday-through-Friday basis, and allows a contingency day for 8-hour shift schedules that include a series of seven consecutive 8-hour shifts.

The final rule also revises the minimum duration of the break period from 24 hours, as specified in § 26.199(d)(2)(ii) of the proposed rule, to a minimum of 34 hours. The revision more clearly reflects the NRC's intent to require a periodic ''day off'' in which individuals have the opportunity for two consecutive sleep periods without an intervening work period. The 34-hour break duration provides this opportunity, supports use of forward rotating and fixed shifts, and allows for the possibility that individuals may work 26 hours in a 48-hour period contiguous to the break.

Proposed Requirement for a Minimum 48-Hour Break in Any 14-Day Period and Collective Work Hour Limits

Section 26.199(d)(2)(iii) of the proposed rule would have required a minimum 48-hour break in any 14-day period. This requirement would have provided periodic breaks to prevent and mitigate cumulative fatigue. Although this requirement would have also been applicable when a reactor was operating, the NRC considered it particularly important for the control of work hours during outages. During these periods, successive weeks of extended work hours (i.e., up to 72 hours per week) are common. However, the NRC received substantive comments regarding this provision.

Several commenters expressed concern that a mandatory 48-hour break would limit the ability of licensees to provide adequate coverage for unplanned maintenance (e.g., to quickly restore inoperable equipment). Several commenters also stated that the break requirements would encourage supplemental workers to seek jobs in other industries that offer more overtime. Therefore, commenters were concerned that this unintended consequence of the break requirements would harm the licensees' ability to attract and retain qualified workers. Other commenters stated that, although the recovery concept is scientifically supported, the approach used to prevent cumulative fatigue should consider existing work schedules and scheduling practices. Commenters also asserted that a 48-hour break during a series of night shifts would adversely affect the circadian cycle of those workers who had adjusted to the night shift. These commenters stated that for workers on the night shift, having 1 day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, thus reducing the risk of accidents on the job. However, two days off may interfere with a worker's sleep cycle, requiring the individual to readjust to the night shift after a 2-day break. Commenters also asserted that a 1-day break in any 7-day period is more than adequate when combined with other rule provisions to address cumulative fatigue.

The NRC considered public comments on the proposed 48-hour break requirement in conjunction with public comments on the collective work hour limits of the proposed rule. The collective work hour limits in proposed § 26.199(f) would have required licensees to control the average work hours of specified groups of personnel that perform the same job function. In general, this provision would have required licensees to ensure that the collective work hours of individuals within each group did not average more than 48 hours per week, when averaged over a period of up to 13 weeks. The objective of the collective work hour limits, like the 48-hour break requirement, was to prevent cumulative fatigue. In contrast to the 48-hour break requirement, the collective work hour limits would typically have been applicable only when a reactor was operating. Thus, the 48-hour break requirement in conjunction with the 24-hour break requirement of proposed § 26.199(d)(2)(i) would have been the principal mechanism to address cumulative fatigue during outages, and collective work hour limits would have been the principal means of preventing cumulative fatigue while a plant was operating.

Some commenters stated that the collective work hour limits would be an ineffective means for addressing fatigue because it is experienced on an individual basis. That is, the collective work hour limits could not ensure that each individual would be protected from cumulative fatigue. One commenter stated that the collective work hour controls would allow licensees to force individuals to work overtime. Other commenters stated that licensees may be able to manipulate the collective work hour calculations. Still other commenters asserted that the collective work hour controls were unnecessary to mitigate the effects of cumulative fatigue and that they would limit licensee flexibility to increase work hours for a job-duty group based on operational needs. These commenters stated that other rule provisions, such as the work scheduling requirement, individual work hour limits, individual break requirements, and the provisions concerning fatigue assessments and the self-declaration process, adequately address the possibility of cumulative fatigue.

The NRC agrees, in part, with certain comments on the proposed 48-hour break requirement and the collective work hour limits of the proposed rule, and has revised the final rule accordingly. To address cumulative fatigue during periods when a plant is operating, the NRC replaced the proposed rule requirement for a minimum 48-hour break in § 26.199(d)(2)(iii) and the collective work hour limits in § 26.199(f) with the requirements in § 26.205(d)(3) of the final rule. This section requires that each individual subject to the work hour requirements has a minimum average number of days off per week while the plant is operating. This provision addresses comments on the proposed 48-hour break requirement and collective work hour limits as follows:

- The minimum day-off requirements of § 26.205(d)(3) address cumulative fatigue on an individual basis. In contrast to the proposed collective work hour limits, the final rule provides more uniform assurance of worker FFD and addresses the concern that, although duty groups could have met the collective work hour requirements, individuals in those groups may have worked excessive hours.
- The minimum day-off requirements of § 26.205(d)(3) establish limits that in most circumstances are tailored to the duration of the shifts that individuals work (e.g., individuals on 8-hour shifts must average at least 1 day off per week; individuals on 10-hour shifts must average 2 days off per week). As a consequence, in contrast to the single set of break requirements in the proposed rule, the final rule provides a better correlation between the number of hours an individual works and the amount of restorative rest required by the rule.
- The minimum day-off requirements of § 26.205(d)(3) establish a flexible approach to addressing cumulative fatigue. This provision requires a minimum average number of days off per week, averaged over a shift cycle of up to 6 weeks. Accordingly, the rule does not require that individuals meet the average each week, but does ensure that individuals receive a minimum number of days off over the course of the shift cycle. As a consequence, the NRC has established a requirement that accommodates a wide range of scheduling practices and short-term fluctuations in workload. The

requirement also allows licensees considerable flexibility in accommodating individual worker preferences concerning the timing and distribution of days off.

• The minimum day-off requirements of § 26.205(d)(3) establish limits that are practical and likely to impose less administrative burden on licensees than would have been required by the collective work hour limits in the proposed rule.[1] By establishing limits that require the control of work hours on an individual basis, licensees need not define and track membership in duty groups. In addition, the requirements in the final rule largely adopt an approach proposed by NEI as an industry-recommended alternative to the group work hour controls. Thus, the NRC expects that licensees will consider the administrative requirements of this work hour control method to be less burdensome.

To address cumulative fatigue during periods when a plant is in a unit or planned security system outage, the NRC has replaced the proposed rule requirements for a minimum 48-hour break (§ 26.199(d)(2)(iii)) and the collective work hour limits applicable to security personnel during outages (§ 26.199(f)(2)(i)) with the requirements in § 26.205(d)(4) and (d)(5) of the final rule. Section 26.205(d)(4) requires that licensees provide individuals who perform the operations, health physics or chemistry, and fire brigade duties described in § 26.4(a)(1) through (a)(3) of the final rule a minimum of 3 days off in each successive 15-day period of a unit outage. Section 26.205(d)(4) also requires that licensees provide individuals who perform the maintenance duties described in § 26.4(a)(4) at least 1 day off in any 7-day period. Section 26.205(d)(5) applies to individuals who perform the security duties described in § 26.4(a)(5) of the final rule and requires a minimum of 4 days off in each successive 15-day period of a unit outage or planned security system outage. These final rule provisions address those comments on the 48-hour break and collective work hour requirements applicable to outage periods as follows:

• The minimum day-off requirements of § 26.205(d)(4) do not mandate that licensees schedule 2 consecutive days off as would have been required by the 48-hour break requirement. As a result, licensees are better able to establish schedules that minimize the potential for disrupting the circadian cycle of individuals who are on fixed night shifts.

• The minimum day-off requirements of § 26.205(d)(4) allow licensees substantial flexibility in scheduling the required days off within the 15-day outage periods. As a result, licensees are able to implement a range of scheduling options to meet known outage schedule demands and have the flexibility to revise schedules as necessary to address emergent needs.

• The minimum day-off requirements of § 26.205(d)(4) allow licensees to use a predictable, repeating schedule. The requirements permit a schedule of four consecutive 12-hour shifts followed by 1 day off. This 5-day sequence can repeat three times in each 15-day period creating a schedule that is predictable and repeatable, characteristics typically desired by workers and schedulers. This schedule limits the number of consecutive work shifts to prevent cumulative fatigue and includes sufficient periodic days off to mitigate fatigue. For individuals performing the maintenance duties described in § 26.4(a)(4) the requirement permits a predictable, repeating schedule of 6 consecutive work days followed by 1 day off.

• The minimum day-off requirements of § 26.205(d)(4), in conjunction with the other requirements in § 26.205 [Work hours], allow a maximum workweek of 72 hours and an average workweek of 67.2 to 72 hours for a period of up to 60 days. As a result, the requirements allow licensees to offer substantial amounts of overtime within these limits to attract supplemental workers for outage activities. The NRC acknowledges that some individuals may want to work more than 72 hours, or even more than 84 hours, per week. However, the NRC notes that the work hour limits of § 26.205 apply only to those duties that the agency believes have the most direct impact on the protection of public health and safety and common defense and security. As a result, the requirements do not prevent individuals from working more than 72 hours per week, unless those individuals are performing (1) duties on structures, systems, and components (SSCs) that a risk-informed evaluation process has shown to be significant to public health and safety, (2) critical emergency or fire response duties, or (3) duties as members of the site security force that are necessary for the execution of the site security plan.

• Several commenters recommended that the 8-week exclusion period be extended to 10 weeks to accommodate extended outages for activities such as reactor vessel head and steam generator replacements. In conjunction with these comments, industry stakeholders asserted at public meetings held for this rulemaking that cumulative fatigue was not a concern during these extended outages because individuals often had periods when they were not required to work the extended work hours typically associated with outages. In response to this comment, the NRC includes a provision in § 26.205(d)(6) of the final rule which allows licensees to extend the 60-day exception for individuals by 1 week for each 7-day period the individual worked not more than 48 hours during the outage. Thus, the rule allows the outage exception to be extended when directly justified by an individual's actual work history. In light of the significant work hours allowed by the requirements, as discussed in the preceding paragraph, the NRC considers this approach to be better justified for the management of worker fatigue than the proposal for a blanket extension of the outage exclusion to 10 weeks.

Section 26.205(d)(5) of the final rule applies to individuals who perform the security duties described in § 26.4(a)(5) and requires a minimum of 4 days off in each successive 15-day period of a unit outage or planned security system outage. This minimum days-off requirement is comparable to the work hour limits imposed for security personnel by order EA–03–038 and the 60-hour collective work hour average that the proposed rule would have required. The NRC replaced the collective work hour limits for security personnel with the requirements in § 26.205(d)(5) of the final rule for the following three reasons:

(1) In addition to other commenters, security personnel expressed concerns about the effectiveness of the collective work hour controls to fully protect against impairment from fatigue for all personnel in a group.

(2) Elimination of the 48-hour break requirement sets aside a key requirement for preventing an excessive number of consecutive work days that would have otherwise been allowed under the collective work hour limits. As a result, the NRC concluded that the collective work hour limits, absent the 48-hour break requirement, would not provide reasonable assurance that nuclear power plant security personnel would be protected from cumulative fatigue from excessive work hours.

(3) Revision of the outage requirements to a minimum of 4 days off in a 15-day period avoids the potential confusion and additional

[1] Although the NRC believes that the minimum day off requirements of § 26.205(d)(3) will impose less administrative burden on licensees than the collective work hour limits of the proposed rule, the NRC has conservatively retained the administrative burden estimate of the collective work hour limits for § 26.205(d)(3) of the final rule.

burden of two different approaches and accounting systems (i.e., minimum day off requirements and collective work hour limits) for the control of personnel work hours at a site.

The NRC believes that the minimum day-off requirements of § 26.205(d)(3) through (d)(6) of the final rule address the range of comments on the rule, several of which expressed opposing views regarding the need to relax the requirements or to make them more restrictive.

The NRC does not agree with the comments that asserted that the proposed requirements to address cumulative fatigue were unnecessary and that a 1-day break in any 7-day period is more than adequate when combined with the other rule provisions (e.g., self-declaration and training) to address cumulative fatigue. The NRC has concluded that, given a broad range of considerations, a 1-day break in any 7-day period is an appropriate requirement for individuals performing the maintenance duties described in § 26.4(a)(4) for a limited time period during unit outages. The NRC has also concluded that additional days off are necessary for individuals performing other duties described in § 26.4(a) to ensure that those individuals are not impaired by the cumulative fatigue that would result if they routinely worked the maximum work hours that would otherwise be allowed by the requirements in § 26.205(d)(1) and (d)(2). Accordingly, the final rule requires more than a 1-day break in any 7-day period for individuals performing the duties described in § 26.4(a)(1) through (a)(3) and (a)(5) during unit outages. For periods when the plant is operating, the final rule requires that all individuals working 10 or 12-hour shifts receive on average more than one day off per week. The rule requires only one day off per week on average for individuals working 8-hour shifts because individuals on 8-hour shifts could not be practically scheduled at the maximum work hours allowed by the requirements in § 26.205(d)(1) and (d)(2).

The NRC acknowledges the important role of self-declaration and training in fatigue management, as noted by some commenters, but also recognizes the inherent limitations of these provisions to effectively address fatigue, particularly during periods of outage schedule conditions. As noted by Michael T. Coyle, NEI, comment letter #49, and supported by several other commenters, ''for many supplemental workers the availability of overtime is a key factor in where they decide to work.'' The NRC also recognizes that outages are periods when individuals may perceive increased schedule pressure and is aware that at least one site offered bonuses for perfect attendance during outages. Self-declaration would likely cause individuals to forfeit a portion of that overtime and possibly a bonus. As a result, despite the best efforts of licensees to emphasize safety and worker FFD, the NRC anticipates that self-declaration and training in methods to obtain adequate rest may not be implemented as effectively or consistently during outage periods as during periods of routine plant operation, and therefore, they are not a substitute for work hour controls that effectively prevent cumulative fatigue.

In asserting that a 1-day break is more than adequate to address cumulative fatigue, industry stakeholders have cited the basis for the Federal Motor Carrier Safety Administration's (FMCSA) minimum 34-hour break provision for commercial motor vehicle (CMV) operators. The NRC reviewed the FMCSA regulations (49 CFR Part 395), associated statements of considerations (65 FR 25540 (May 2, 2000); 70 FR 49978 (Aug 25, 2005), the findings of an expert panel commissioned by the FMCSA (Belenky et al., 1998), a petition for review of the final rule (Brief of Public Citizen, et al., Owner-Operator Independent Drivers Ass'n, Inc. v. Federal Motor Carrier Safety Admin., 494 F.3d 188 (D.C. Cir. July 24, 2007) (No. 06–1035) (''FMCSA'')), and the decision of the court with regard to the petition. FMCSA. The NRC concluded that, for a limited range of conditions, the studies cited by FMCSA support a 34-hour break as an appropriate minimum rest period. However, the NRC staff does not agree that the basis cited by the FMCSA supports a requirement that would routinely allow 72 hours of work for all nuclear power plant workers performing functions important to the protection of public health and safety before such a break is required. The NRC notes that:

(1) The FMCSA regulations for CMV operators include requirements that prohibit driving after 60 hours of duty in 7 days. By contrast the NEI proposal would allow 72 hours of work in a 7-day period, excluding turnover.

(2) The statement of considerations for the FMCSA regulation establishes that long work weeks with minimum break periods are the exception for CMV operators. The FMCSA sets forth this information as a premise for the adequacy of the 34-hour break. By contrast, application of the industry proposed requirement to the control of work hours during unit outages would allow licensed operators [2] and other plant personnel to work regularly occurring periods of multiple consecutive 72-hour work weeks with minimum break periods. The NRC notes that a federal appeals court vacated the 2005 provision of the FMCSA requirements that would have permitted a 34-hour break to restart the weekly limits. Among the reasons cited by the court was that FMCSA's operator-fatigue model did not ''account for cumulative fatigue due to the increased weekly driving and working hours permitted by the 34-hour restart provision.'' FMCSA at 206.

(3) Contrary to the NEI assertion that a 34-hour break is ''more than adequate'' the expert panel commissioned by the FMCSA described the 34-hour break as ''absolutely minimal.'' Further, the expert panel noted that a fundamental assumption for the adequacy of the 34-hour break is that it will provide two consecutive nights of uninterrupted sleep between midnight and 6 a.m. Given common outage scheduling practices, the NRC believes that no workers on night shifts and few workers on day shifts would meet this assumption.

In addition, the NRC does not agree with industry stakeholder comments that an opportunity for 8 hours of sleep between shifts prevents cumulative fatigue. This argument is contrary to common experience in that it implies workers should be able to work 12 hours per day, without degradation in their performance, for an unlimited number of days. To the contrary, the National Institute for Occupational Safety and Health (NIOSH) found that ''up to five consecutive 12/14-hour shifts * * * creates the potential for excessive fatigue, even when 8 hours of sleep per day are obtained'' (2000 NIOSH 3). Similarly, the NRC notes that it has received increased reports of excessive fatigue following extended periods of 12-hour shifts, such as in the months following the terrorist attacks of September 11, 2001, and during the extended head replacement outage at Davis Besse (NRC Inspection Report 05000346/2004003, dated March 31, 2004, ADAMS Accession No. ML040910335). The NRC found that workers typically did not average more than 60 work hours per week during these periods. As a result, even if a 34-hour break was adequate to mitigate cumulative fatigue from 72 or more hours of work, the 1 day off in a 7-day

[2] At multi-unit sites with common control rooms, all licensed operators would be subject to the limits applicable to unit outages, including operators responsible for operating units.

period that the industry's proposed would not ensure that breaks would be provided on a sufficient frequency to prevent weekly occurrences of cumulative fatigue. A NIOSH review (Caruso, et al., 2004) of 52 recent reports examining the association between long work hours and illness, injuries, health behaviors, and performance, reported ''a pattern of deteriorating performance on psychophysiological tests as well as injuries while working long hours was observed across study findings, particularly when 12-hour shifts combined with more than 40 hours of work a week.''

Considering the limitations of the technical basis cited by the industry and its applicability to outage scheduling practices and operating experience and technical literature indicating that 1 day off in 7 days is not adequate for recovery when individuals are working in excess of 60 hours per week, the NRC concluded that the industry proposal would not effectively prevent cumulative fatigue for individuals performing the operations, health physics, chemistry, fire brigade and security duties described in § 26.4(a)(1) through (a)(3) and (a)(5) for multiple consecutive weeks of extended work hours. The NRC considers the minimum day off requirements of the final rule provide adequate flexibility to accommodate emergent work and a range of scheduling practices while supporting reasonable assurance of worker FFD. By limiting the use of the maximum work hours and minimum break guidelines to a ''temporary basis,'' the requirements of § 26.205(d)(3) through (d)(6) are consistent with the NRC's long-standing ''Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors.''

Proposed Reporting Requirements

Many comments addressed the reporting requirements for the fatigue provisions. Section 26.197(e) of the proposed rule would have required licensees to submit, as part of the annual FFD program report required under § 26.717 [Fitness-for-duty program performance data] of the final rule, information concerning the licensee's implementation of the work hour controls and management of worker fatigue. The proposed rule would have required the annual report to include a summary of the waivers the licensee approved during the calendar year, information pertaining to instances of job duty groups exceeding a collective work hour average of 48 hours in any averaging period during the calendar year, and information pertaining to instances of fatigue assessments conducted during the calendar year.

Several commenters from industry asserted that the reporting requirements in the proposed § 26.197(e) should be deleted from the rule because they would not provide new or unique information to the NRC, would be unnecessary to protect public health and safety, would be unnecessary to facilitate NRC oversight of the revised rule, and would be unduly burdensome. One commenter further stated that the NRC's proposed FFD rule and supporting materials did not demonstrate that the industry would fail to comply with the requirements of the revised rule without the imposition of these reporting requirements. The commenter asserted that the existing regulatory process is adequate to ensure compliance with the rule. Some commenters believed that the reporting requirement would create a significant duplication in licensee efforts, noting that proposed § 26.199(j) required periodic reviews by licensees to assess the effectiveness of the work hour controls, and that these reviews are documented and trended under the licensee's corrective action program which is periodically inspected by the NRC.

Some commenters stated that the reports the rule would require would not be a meaningful indicator of licensee performance in managing work hours because a number of valid conditions may warrant waivers of work hour controls. Two commenters suggested that the rule require licensees to report the number of workers covered under § 26.199(a) [Individuals subject to work hour controls] of the proposed rule to provide appropriate context for the annual reporting of waivers.

Several commenters from industry also stated that the NRC did not meet its obligation under the Paperwork Reduction Act with respect to the information collection requirements proposed in § 26.197(e). They argued that the NRC failed to adequately justify the need for these provisions to achieve the objectives of the proposed FFD rule and failed to objectively support its estimate of the burden placed on affected licensees. The commenters asserted that the annual report would require at least 30 clerical hours to develop and 20 management hours to review.

In response to public comments on the reporting requirements, the NRC revised certain requirements for the inclusion of fatigue management information in the annual FFD program report. The NRC also made conforming changes to the reporting requirements as part of changes to other provisions of the rule.

Section 26.203(e) [Reporting] of the final rule presents the reporting requirements associated with licensee implementation of Subpart I. This section does not retain the requirements in proposed § 26.197(e)(2) for the reporting of information pertaining to the control of collective work hours because the final rule does not include collective work hour controls. In addition, the agency revised the requirements in proposed § 26.197(e)(1) and (e)(2) in response to comments that the required information would not provide a meaningful indication of licensee performance in managing work hours because a number of valid conditions may warrant waivers of work hour controls. Through its review of authorized waivers from the work hour limits in plant technical specifications, the NRC has found that waivers are most frequently associated with outage activities. Accordingly, the NRC has revised the final rule to require licensees to report whether a waiver of the work hour requirements in § 26.205 was associated with an outage activity.

As a result of these revisions, the NRC will be better able to interpret a licensee's changes in waiver use over time and understand why certain annual reports for a given licensee may indicate a heightened level of waiver use relative to the licensee's previous reports. The NRC recognizes that outages are not the only cause of waivers; however, the agency expects that most other causes of waiver use will be for substantially shorter periods of time or involve smaller groups of workers and that these other conditions would not have a substantive effect on overall waiver use. For unique causes that may have more substantive effects (e.g., licensee response to hurricanes), the NRC is likely to be aware of or able to identify these conditions if they were to significantly affect waiver use. The NRC notes that the frequency of waiver use (i.e., how often individuals exceed the work hour limits while performing functions important to safety and security) indicates the potential for worker fatigue to affect the performance of these functions, regardless of whether a waiver is the result of an activity associated with an outage or a cause that is beyond the licensee's control.

In addition to requiring an indication of whether a waiver was associated with an outage activity, the NRC revised the annual report requirement to require a frequency distribution of waivers for each of the five duty groups described in § 26.4(a) of the final rule. As a result, the annual report would include, for

example, a table that shows the number of operators who received just one waiver during the year, the number of operators who received two waivers during the year, and so on. The NRC incorporated this requirement in the final rule in response to comments that the rule should also require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide an appropriate context for the annual reporting of waivers. The NRC understood that the intent of this comment was to provide a basis for evaluating the number of waivers from the work hour controls relative to the number of individuals subject to those controls. The NRC chose not to require licensees to report the number of individuals covered under § 26.4(a) of the final rule because that number will vary throughout the course of the reporting period, particularly when the reporting period includes a unit outage. In addition, the NRC believes that the required distribution of waivers more effectively provides context to the waiver use information by indicating whether the waivers were concentrated among individuals performing a certain duty and whether the waiver use in a duty group was associated with relatively few individuals or distributed among many individuals.

The NRC does not agree with comments that the requirements for including fatigue management information should be deleted from the rule because they would not provide new or unique information to the NRC, would be unnecessary to protect public health and safety, would be unnecessary to facilitate NRC oversight of the revised rule, and would be unduly burdensome. In choosing to retain reporting requirements for waiver use, the NRC considered several aspects of the work hour requirements in the final rule. First, the NRC established the work hour limits in the final rule at levels such that the potential for fatigue is substantive for individuals working in excess of those limits. Second, the rule permits licensees to authorize waivers of the limits only for circumstances in which the additional work hours are necessary to prevent or mitigate a condition adverse to safety or security. Finally, the rule only requires a waiver if the individual is operating or maintaining an SSC that a risk-informed evaluation process has shown to be important to the protection of public health and safety or if the individual is performing specified functions that are essential to an effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers indicates (1) the number of hours worked on risk-significant activities by individuals who are at increased potential for impairment, and (2) how often a licensee must mitigate or prevent a condition adverse to safety while relying on individuals who are at increased potential for impairment. The NRC considers this unique information, not otherwise reported, to be relevant to the agency's mission.

The NRC similarly considered the need to retain reporting requirements regarding fatigue assessments and any management actions in response to the fatigue assessments. The NRC concluded that the fatigue assessment information that would have been reported under the requirements of the proposed rule is more the purview of a licensee's corrective action program, and would have been more detailed than the program performance data for drug and alcohol testing required under § 26.717(c) of the final rule. Accordingly, the final rule requires licensees to report a summary of corrective actions, if any, resulting from the licensee's analysis of waiver and fatigue assessment data. As a consequence, the required reports will provide information that will focus more on licensee performance in managing worker fatigue and will enable NRC to review licensee reporting of waivers in the context of associated corrective actions.

The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of the implementation of the requirements through the following means:

• Consistency, efficiency, and continuity of NRC oversight—Information provided through the annual FFD program performance reports concerning fatigue management will enable the NRC to achieve a higher level of consistency and efficiency in the oversight of the implementation of the requirements in Subpart I and in the enforcement of those requirements. Without the reporting requirements, the NRC's inspection of licensee FFD programs would likely be limited to individual inspectors evaluating licensee fatigue management for a sample of workers at a site for a limited time period. These assessments would necessarily be conducted without the benefit of broader contextual information from the site or the industry normative information that would be available through the annual reports. In contrast, the annual reports will help ensure a common perspective and maintain consistency among inspectors conducting the oversight process. In addition, the annual reports can enhance the efficiency of the NRC inspection process by providing information necessary to allow the agency to focus inspection resources on duty groups (e.g., security or maintenance) that may warrant review. The reports will enable the NRC to be better focused in preparing for the inspection, reduce the burden of onsite inspection hours, and potentially reduce the total number of hours required for a baseline inspection. Further, the annual reporting will also help to achieve a more complete and continuous assessment of licensee performance because the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.

• Evaluation of rule implementation for lessons learned—Although the NRC and stakeholders have made extensive efforts to ensure clear and enforceable requirements that are effective and practical for the management of worker fatigue, the rule introduces the potential for unintended consequences and lessons learned. In addition, changes in the size and composition of the nuclear industry may have unforeseen implications for site staffing and fatigue management. The NRC expects that the site-specific and normative information obtained through the annual reports can provide important insights regarding opportunities to amend the rule to improve its effectiveness or reduce unnecessary burden. The NRC notes that information provided by the FFD program performance reports was the basis for reducing the random testing rate for drugs and alcohol required in a previous amendment to Part 26.

• Consistent interpretation of waiver criterion—The final rule provides licensees the discretion to use waivers to exceed the work hour limits, thereby allowing levels of work hours that could adversely affect worker FFD. The principal basis for allowing waivers is to reduce the additional staffing burden that licensees would otherwise incur if waivers were not available to address exigent circumstances. The annual reporting of waiver use in conjunction with the corrective action summaries will enable the NRC to ensure that licensees use this discretion in a manner consistent with the objectives of the rule and not as a means to compensate for a lack of adequate staffing. Further, although the use of waivers is limited to conditions when the work hours are ''necessary to prevent or mitigate a condition adverse to safety or security,'' the NRC recognizes the potential for licensees to develop different

interpretations regarding this criterion. Some industry commenters on the proposed rule took exception to the NRC's characterization of high levels of waiver use at some sites as abuse. These commenters suggested that differences in licensee waiver practices could be attributed to the policy being subject to a number of interpretations during the many years that it has been in effect. Regardless of the cause of the differences in licensee use of work hour control waivers, the NRC considers it prudent to address, through rulemaking, the lessons learned from past implementation of the policy and provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criteria in the future.

In addition to the reasons cited in the preceding paragraphs explaining the need for reporting requirements to ensure the effective and efficient oversight of the implementation of the rule, the NRC considers the reporting requirements to be justified and beneficial for the following additional reasons:

• Consistency with other Part 26 requirements and performance objective—The final rule retains the requirement of the former rule that licensees must report the results of drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 [Reporting requirements] and 26.23(b) of the final rule). In addition, several studies discussed in detail in Section IV.D of this document have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above the levels permitted by this rule. Further, given the frequency of worker concerns regarding fatigue and the work scheduling practices that are common during outages, the incidence of impairment from fatigue is likely to be greater than the very low incidence of drug and alcohol use that is detected through testing. Therefore, the NRC considers the reporting of information pertaining to licensee management of worker fatigue to be consistent with the requirements for reporting information pertaining to drug and alcohol testing, the performance objective of this rulemaking for licensees to implement a comprehensive FFD program, and the NRC's belief that the management of worker fatigue is no less important to worker FFD than the effective detection and deterrence of drug and alcohol use.

• Public confidence—Public interest groups such as the UCS and the Project on Government Oversight have commented at public meetings that relevant information regarding worker fatigue is withheld to either protect alleger identity or, in the case of security personnel, plant security. In addition, several public media articles have been published during the past 2 years reporting instances of guards sleeping and guards fearing repercussions for refusing forced and excessive overtime. Information submitted by licensees in the annual reports will be publicly available and will reassure public stakeholders that the NRC is appropriately cognizant of licensee actions regarding fatigue management and that the NRC's oversight of these activities is transparent to all stakeholders.

• The burden is limited and justified—Section 26.203(e) of the final rule requires licensees to report information concerning fatigue management as part of the annual FFD program report. As a result, the burden associated with this reporting requirement is an incremental change to the reporting requirement for drug and alcohol testing. In addition, the fatigue management information required by § 26.203(e) of the final rule is largely information that licensees will have already generated to demonstrate compliance with other provisions of Subpart I. As a result, the burden associated with the report will be largely associated with compiling the information in an appropriate form and reviewing that compilation. The NRC has reviewed the public comments suggesting that the agency underestimated the number of clerical and management hours associated with this requirement and has taken these comments into consideration in estimating the burden of the reporting requirements in § 26.203(e) of the final rule. Nevertheless, the NRC considers the burden associated with the annual reporting requirements to be justified for the reasons described in this and the preceding paragraphs.

The NRC also considered comments that the reporting requirement ignores significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires licensees to periodically review and assess the effectiveness of the work hour controls and that the licensee's corrective action program, which is routinely inspected by the NRC, will document and trend these reviews. However, as noted previously, the NRC considers the annual reports to be a limited burden that will enable the NRC to provide more effective and consistent oversight and achieve other objectives for the effective implementation of the requirements in Subpart I.

Public Comments on FFD Programs for Construction and Manufacturing

In response to substantive public comments and industry efforts to develop guidance on the subject, the NRC has added Subpart K to the final rule to clarify § 26.3(e) of the proposed rule, which contained requirements for combined license holders, combined license applicants, construction permit holders, construction permit applicants, as well as manufacturing license holders under Part 52.

Subpart K's FFD program is intended to provide reasonable assurance that individuals involved in the construction of a nuclear power plant who perform specified duties at the site are fit for duty, trustworthy, and reliable, commensurate with the potential risks to public health and safety and the common defense and security that their activities and access to certain information would pose.

Proposed § 26.3(e) would have retained and updated the requirements of § 26.2(c) of the former rule. However, proposed § 26.3(e) would not have revised the basic approach taken in former § 26.2(c). The former rule specified the regulations in Part 26 that applied to licensees holding permits to construct a nuclear power plant. Section 26.2(c) of the former rule required each construction permit holder with a plant under active construction to comply with §§ 26.10 [General performance objectives], 26.20 [Written policy and procedures], 26.23 [Contractors and vendors], 26.70 [Inspections], and 26.73 [Reporting requirements] of the former rule. This provision also explained that permit holders with plants under active construction were required to implement a chemical testing program, including random tests, and make provisions for employee assistance programs (EAPs), imposition of sanctions, appeals procedures, the protection of information, and recordkeeping.

Proposed § 26.3(e) would have explicitly reflected the NRC's combined licensing procedure for nuclear power plants under 10 CFR Part 52, ''Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants.'' It would have specified the entities that are regulated by the NRC (specifically, combined license holders before the Commission has made the finding under § 52.103 [Operation under a combined license], combined license applicants who have received authorization to construct under § 50.10(e)(3), construction permit

holders under Part 50, ''Domestic Licensing of Production and Utilization Facilities,'' construction permit applicants who have received authorization to construct under § 50.10(e)(3), and holders of manufacturing licenses under Part 52) who would be responsible for meeting certain Part 26 requirements. (The Part 52 final rule amended § 26.2(c) of the former rule to include in § 26.2(c) combined license holders before the date that the Commission makes the finding under § 52.103(g), holders of manufacturing licenses, and persons authorized to conduct the activities under § 50.10(e)(3).)

The proposed rule would have replaced the cross-references to other sections of the former rule with updated cross-references to the related sections in the proposed rule (i.e., §§ 26.23 [Performance objectives], 26.41 [Audits and corrective action], and 26.189 [Determination of fitness]). The proposed rule would also have stipulated that the specified entities should implement a drug and alcohol testing program, including random testing, and make provisions for EAPs, imposition of sanctions, procedures for the objective and impartial review of authorization decisions, protection of information, and recordkeeping. However, the proposed rule did not specify in detail how the FFD programs of the entities listed in proposed § 26.3(e) were to address these topics or the categories of workers who would be subject to the programs.

Some comments received during the public comment period stated that the proposed rule did not clearly describe the type of FFD programs the NRC expected under proposed § 26.3(e). Commenters stated that because the proposed rule required FFD programs for construction to comply with a few specific sections of the rule, it would have imposed virtually all of the rule's requirements on FFD programs for construction, because it would be difficult to ensure compliance with the referenced sections of the rule without applying the entire rule. Other comments received from industry representatives during the public comment period indicated that the NRC should not require FFD programs for construction that are more rigorous than industrial safety programs implemented during construction of other large, commercial facilities because construction activities do not pose risks to public health and safety or the common defense and security until nuclear fuel arrives on site. In response to these comments, the NRC staff gathered additional information about FFD programs for construction in other industries, developed a new Subpart K, ''FFD Programs for Construction,'' and revised other sections of the rule to clarify the scope of requirements for construction activities.

The results of the NRC staff's benchmarking activities indicated that, as a result of the higher incidence of substance problems among construction workers than other occupational groups, pre-employment, for-cause, and post-accident drug and alcohol testing are increasingly common at large, commercial construction projects and some labor union coalitions have implemented drug and alcohol testing and substance abuse treatment-referral programs for their members. In addition, the staff also identified several private-sector entities in the petrochemical and steel manufacturing industries that require drug and alcohol testing, including random testing, for construction workers on large projects, as well as employment history evaluations and other background checks. Where safety and/or security during construction are critical, large construction projects initiated by some Federal agencies (e.g., the Department of Energy) require drug and alcohol testing, including random testing, extensive background checks, and continuous behavioral observation for the most sensitive construction tasks. The NRC concluded that (1) implementing FFD requirements for new nuclear power plant construction activities is consistent with the practices of other industries, and (2) taking a graded approach to FFD requirements, by imposing requirements that are commensurate with the potential risks to public health and safety and the common defense and security that the results of construction activities may pose when a plant begins operations, is consistent with the approach implemented by other government agencies when constructing facilities that have the potential to affect public health and safety or the common defense and security.

The NRC also determined that some of the requirements in proposed § 26.3(e) would be difficult to implement. For example, much of the nuclear power plant construction workforce will likely be transient and rapidly changing. As a result, it may be challenging to conduct random drug and alcohol testing in a manner that would meet all of the random testing requirements Part 26 includes for operating plants. In addition, some new reactors will be constructed near an operating plant that has readily accessible FFD program resources, such as a specimen collection and alcohol testing site, a licensee testing facility, an FFD training program, and expert staff (e.g., a substance abuse expert, MRO, or EAP representative). However, other new reactors may be constructed at locations that are distant from the FFD program resources of an operating plant. Therefore, the NRC concluded that applying some of the requirements in the proposed rule would be overly burdensome, such as requiring random testing of all construction workers, the requirement for all nuclear power plant construction workers to have access to an EAP, and the proposed requirement for a determination of fitness process performed by a substance abuse expert under § 26.189 of the final rule.

To streamline administration of the FFD program for construction, add flexibility, and implement an approach that is commensurate with the potential risks resulting from new plant construction, the final rule requires two different levels of FFD requirements for workers in different job roles. Because of their important oversight responsibilities, the first category of workers, specified in § 26.4(e), includes any individual whose duties, once construction activities begin, require him or her to perform the following activities at the location where the nuclear power plant will be constructed and operated: serve as security personnel required by the NRC; perform quality assurance, quality control, or quality verification activities related to safety- and security-related construction activities; based on a designation under § 26.406 by a licensee or other entity, monitor the fitness of the individuals specified in § 26.4(f); witness or determine inspections, tests, and analyses certification required under Part 52; supervise or manage the construction of safety- or security-related SSCs; or direct or implement the licensee's or other entity's access authorization program. These individuals must be subject to a full FFD program that meets the same requirements as FFD programs for operating plants (including random drug and alcohol testing at the 50 percent annual rate, behavioral observation training, and a suitable inquiry/employment history check but excluding the requirements of Subpart I) when they are performing duties at the location where the nuclear power plant is being constructed and will operate. However, individuals who serve as security personnel required by the NRC must meet the requirements applicable to security personnel in § 26.4(a)(5) at the time the licensee or other entity

receives special nuclear material in the form of fuel assemblies.

A new definition of ''supervises or manages'' in § 26.5 explains that these terms mean the exercise of control over work activity by an individual who is not directly involved in the execution of the work activity, but who either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity. The reference to security personnel is modified by the addition of the words ''required by the NRC'' to clarify that the FFD requirements are meant to apply to security personnel who perform duties specified by NRC regulations and orders, while other security personnel, if any, are not covered by the requirements.

By contrast to the requirements for those individuals listed under § 26.4(e), § 26.4(f) provides that the FFD program in Subpart K applies only to individuals who are constructing or directing the construction of safety- or security-related SSCs. Section 26.5 explains that ''construction or construction activities'' means the tasks involved in building a nuclear power plant that are performed at the location where the nuclear power plant will be constructed and operated, and that these tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs and the installation of their foundations, including the placement of concrete. At a minimum, these individuals must be subject to an FFD program that meets the requirements of Subpart K, which emphasizes performance objectives and does not incorporate all of the requirements of Part 26, unless the licensee or other entity chooses to subject them to an FFD program that meets the Part 26 requirements for operating plants, except the fatigue management requirements in Subpart I of the final rule. The rule adds new definitions of ''safety-related SSCs'' and ''security-related SSCs'' (described further in Section VI.A of this SOC) that clarify the intended coverage of § 26.4(f).

If a licensee or other entity specified in § 26.3(c) of the final rule chooses to implement an FFD program for construction under Subpart K, the entity must submit to the NRC a description of the FFD program and its implementation as part of the license, permit, or limited work authorization application. The description must include a written FFD policy that will be given to all individuals covered by the program and FFD procedures. The program must include pre-assignment, for-cause, and post-accident drug and alcohol testing. Subpart K requires an FFD program for construction to include sanctions for FFD policy violations, a system of files and procedures to protect personal information, and procedures for reviewing determinations that an individual has violated the FFD policy. The entity who elects to implement a program under Subpart K must conduct periodic audits, maintain records, provide reports to the NRC, and develop and apply procedures for suitability and fitness evaluations to determine whether to assign individuals to constructing safety- and security-related SSCs. The program description will be evaluated as a part of the application for the license, permit, or limited work authorization and the NRC's finding on the application will include a finding on the FFD program description. Before work begins on the foundations, including placement of concrete, for the safety- or security-related SSCs under the license, permit, or limited work authorization, the entity will be required to implement the FFD program that it has described in its application.

To detect and deter substance abuse by individuals who are constructing safety- and security-related SSCs, Subpart K of the final rule permits a licensee or other entity listed in § 26.3(c) of the final rule to subject these individuals either to random testing for drugs and alcohol or a fitness monitoring program. Subpart K also permits FFD programs for construction to—

(1) Collect specimens other than urine for drug testing and/or rely on collection sites at local hospitals or clinics that conduct testing under U.S. DOT procedures, rather than those specified in Subpart E, ''Collecting Specimens for Testing,'' of Part 26;

(2) Rely on healthcare professionals other than a substance abuse expert to evaluate an individual's fitness;

(3) Designate the persons who will perform fitness monitoring, if the entity elects this option, and adjust the number of fitness monitors performing monitoring and the frequency of monitoring to accommodate the stage of construction and local conditions; and

(4) Establish the random testing rate and limit the selection of individuals for testing to only those who are present and constructing safety- or security-related SSCs on a given day, if the entity elects this option.

In the course of its analysis and development of Subpart K of the final rule, the NRC published a Federal Register notice (71 FR 13782; March 17, 2006) that described the NRC's alternative concepts for FFD programs during construction and announced a meeting to obtain stakeholder feedback. The concepts described included a requirement for FFD policies and procedures on a limited set of topics; pre-access drug and alcohol testing, for-cause drug and alcohol testing, and post-event testing for accidents; requirements for protection of information; requirements for collecting specimens and conducting alcohol tests; the option to test specimens at a licensee testing facility; initial and confirmatory testing of urine specimens for drugs and validity at an HHS-certified laboratory; a review of drug test results by an MRO; and annual reports of FFD program performance. The notice listed fatigue management requirements, random drug and alcohol testing, the requirement for an EAP, and the determination of fitness process described in the proposed Part 26 rule as concepts the NRC was not currently pursuing for FFD programs for construction. These concepts, along with draft guidance for construction programs being prepared by nuclear industry representatives, were discussed at the public meeting held on March 29, 2006.

On October 24, 2006, the NRC published the entire draft final rule text of 10 CFR Part 26 on the NRC's rulemaking Web site and, on November 7, 2006, held a second public meeting with stakeholders to present the technical basis for Subpart K and to describe the fitness monitoring option included in Subpart K as an alternative to random drug and alcohol testing of construction workers. The NRC staff described four primary reasons for imposing regulatory requirements for FFD programs during construction: (1) The quality of work could be adversely affected by construction workers who are impaired by substance abuse where studies indicate that members of this group have the highest rates of substance abuse problems among occupational groups in the U.S. (e.g., SAMHSA's NHSDA covering the years 2000–2001 and SAMHSA's National Survey on Drug Use and Health covering the years 2002–2004), (2) individuals who have become addicted to illegal drugs are susceptible to coercion and will interact with others involved in the drug trade, (3) past experience has demonstrated that errors during construction can adversely affect subsequent plant operations (NUREG/CR–6819, Vols. 1–4, ''Common-Cause Failure Event Insights,'' (May 2003) and NUREG–1837, ''Regulatory Effectiveness Assessment of Generic Issue 43 and Generic Letter 88–14,'' (October, 2005)), and (4) quality assurance by design uses

a sampling process. The staff stated that, despite having a high degree of confidence in the effectiveness of quality assurance/quality control programs (required under 10 CFR Part 50) and the inspections, tests, analyses, and acceptance criteria (ITAAC) programs (required under 10 CFR Part 52) to detect construction errors, it is prudent to require an FFD program during construction to provide reasonable assurance that impaired construction workers do not introduce faults in safety- or security-related SSCs that may cause the SSCs to fail when the plant is operational. In addition, the staff expressed concern that some construction personnel who have substance abuse problems will have access to sensitive information that could be useful to an adversary, as well as physical access to safety- and security-related SSCs that may provide opportunities for malicious acts.

The staff acknowledged, in part, that the full defense-in-depth approach of the FFD program for operating plants is not appropriate for all construction workers because many construction activities do not have the potential to impact subsequent plant operations, and, before fuel arrives on site, do not impose immediate radiological risks. The staff stated that, therefore, the rule's requirements for construction require a full FFD program for only a limited number of personnel who have critical oversight responsibilities for verifying that safety- and security-related SSCs are constructed properly. For workers who will construct the safety- and security-related SSCs, the FFD program requirements in Subpart K are less stringent. For example, Subpart K does not require a suitable inquiry/employment history check for these workers. In addition, the staff acknowledged the many complex logistical challenges associated with implementing FFD requirements during construction. Therefore, the Subpart K requirements provide a licensee or other entity listed in § 26.3(c) of the final rule greater flexibility in implementing FFD programs for construction than the rule permits for FFD programs at operating plants.

The staff also stated that the NRC has decided to defer adopting requirements for reactor manufacturing facilities in the final rule. Although proposed § 26.3(e) would have covered these facilities, and the Part 52 final rule amended § 26.2(c) of the former rule to include holders of manufacturing licenses, the NRC has concluded that it needs additional information before proceeding with FFD requirements for these facilities.

Stakeholder responses to the staff's presentation varied. Industry stakeholders asserted that Part 26 requirements during nuclear power plant construction are not warranted until shortly before fuel arrives on site. Some industry commenters indicated that, because there are no immediate radiological risks to public health and safety or the common defense and security during the construction of new plants, the NRC should not require FFD programs for construction that are more rigorous than the industrial safety programs implemented during construction of other large, commercial facilities. Industry stakeholders also asserted that NRC requirements for FFD programs during construction are unnecessary because the NRC-mandated quality assurance processes will detect any errors in construction and are adequate to protect public health and safety and the common defense and security, and the industry will voluntarily implement FFD programs during construction for industrial safety and business reasons. Industry stakeholders also commented that the fitness monitoring program, which is permitted under Subpart K in lieu of random drug and alcohol testing of workers who are constructing safety- and security-related SSCs, is an unfamiliar concept and asked several implementation questions. The staff indicated that it will work with stakeholders to develop a guidance document that would provide examples of acceptable means to implement an FFD program under Subpart K, including fitness monitoring.

A representative from a public interest group stated that the Subpart K requirements are necessary for FFD during construction. However, this representative questioned the staff's concerns about construction workers having unfettered access to sensitive information as partial justification for the FFD requirements before fuel receipt. This individual stated that safety considerations alone, independent of any potential security concerns, warrant regulations for FFD programs for construction before fuel receipt.

Based on the staff's assessment of the potential risks to public health and safety and the common defense and security that the results of construction activities may pose when a plant begins operations, the staff concluded that—

(1) Relying on voluntary FFD programs would not ensure that all workers who construct safety- and security-related SSCs or provide oversight of those construction activities are subject to a program;

(2) Relying on voluntary FFD programs that include only pre-employment, for-cause, and post-accident testing would not provide the on-going detection and deterrence of substance abuse that is achieved by either random testing or a fitness monitoring program;

(3) The extensive programs required for operating plants are not warranted for all nuclear power plant construction activities, but consistent implementation of FFD programs that provide on-going detection and deterrence of substance abuse is warranted; and

(4) Public confidence in new plant construction will be enhanced by a program to provide reasonable assurance that individuals who construct safety- and security-related SSCs are fit for duty.

The NRC believes that the requirements for FFD programs for construction in Subpart K of the final rule (1) provide reasonable assurance that individuals who are responsible for constructing and assuring the quality of safety- and security-related SSCs are fit for duty, trustworthy, and reliable, commensurate with the potential risk to public health and safety and the common defense and security, (2) permit licensees and other entities the flexibility to implement programs that are appropriate for local circumstances and the challenges created by a large and transient workforce, and (3) ensure that the privacy and other rights (including due process) of individuals who are subject to the requirements will be protected.

Public Comment on Drug and Alcohol Testing Provisions

The NRC received several detailed comments on the drug and alcohol testing provisions contained in Subparts E, F, and G. Most significantly, no comments disagreed with NRC's proposed inclusion of specimen validity testing of all urine specimens collected under Part 26 provisions. Most comments related to improving the clarity and intent of the proposed rule. Many comments received were of a technical nature and addressed inconsistencies between the NRC's proposed rule and requirements in other federal testing programs, mainly the HHS's Mandatory Guidelines for Federal Workplace Drug Testing and DOT drug and alcohol testing regulations (49 CFR Part 40). The NRC, in large part, agrees with many of the comments and has made clarifying revisions to the final rule.

Stakeholder commenters raised several concerns relating to the drug and

alcohol provisions of the proposed rule. First, numerous comments were received on the validity testing provisions for screening and initial validity tests conducted at licensee testing facilities. Some stakeholders disagreed with the NRC's proposal to permit licensee testing facilities to use point-of-collection type tests to conduct validity screening tests. The NRC considered the comments, but has retained in the final rule the proposed provision to allow licensee testing facilities to use point-of-collection type tests to conduct validity screening tests. However, in response to the comments received, the NRC has revised the performance testing provisions in § 26.137 to ensure that the functional capabilities of the performance testing of screening tests meet the criteria of the final rule. In addition, another set of comments pointed out that the proposed rule did not afford licensee testing facilities the opportunity to conducting specific gravity testing on specimens, which is a required component of reporting specimens as dilute, substituted, or invalid. The NRC continues to believe that any specimen that has a creatinine concentration below 20 mg/dL must be forwarded for additional testing at an HHS certified laboratory (including specific gravity testing). Finally, the NRC received numerous comments on the use of the term ''non-negative.'' Some commenters believed that the term created significant confusion with respect to understanding specimen test results. The NRC agrees with the commenters and has replaced the term ''non-negative test result'' in the final rule with the term ''positive'' (for drug test results) and the term ''adulterated, substituted, and invalid'' (for validity test results). In addition, the NRC has replaced the term ''non-negative test result'' with the new term ''questionable validity'' for licensee testing facility test results that indicate that a specimen may be adulterated, substituted, dilute, or invalid.

VI. Section-by-Section Analysis of Substantive Changes

The final rule is organized into twelve subparts that are comprised of related requirements, as follows:

Subpart A—Administrative Provisions
Subpart B—Program Elements
Subpart C—Granting and Maintaining Authorization
Subpart D—Management Actions and Sanctions to be Imposed
Subpart E—Collecting Specimens for Testing
Subpart F—Licensee Testing Facilities
Subpart G—Laboratories Certified by the Department of Health and Human Services
Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness
Subpart I—Managing Fatigue
Subpart J—[Reserved]
Subpart K—FFD Programs for Construction
Subpart L—[Reserved]
Subpart M—[Reserved]
Subpart N—Recordkeeping and Reporting Requirements
Subpart O—Inspections, Violations, and Penalties

A detailed cross-reference table between the former and final Part 26 provisions is included at the end of this document.

The NRC has deleted Appendix A of the former rule and moved the detailed requirements for conducting drug and alcohol testing that were contained in Appendix A to 10 CFR Part 26 to Subpart E [Collecting Specimens for Testing], Subpart F [Licensee Testing Facilities], and Subpart G [Laboratories Certified by the Department of Health and Human Services] of the final rule.

Subpart A—Administrative Provisions

Section 26.1 Purpose

Section 26.1 of the final rule amends the language of the corresponding section of the former rule. The final rule deletes the term ''certain aspects'' and adds the term ''implementation'' to the phrase in the former rule which stated, ''for the establishment and maintenance of * * * fitness-for-duty programs,'' in order to convey more accurately that the final rule includes requirements for implementing FFD programs, in addition to requirements for establishing and maintaining such programs. The NRC has moved the portion of former § 26.1 that referred to the entities who are subject to the rule to § 26.3 [Scope] in order to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the final rule, by consolidating related requirements into one section.

Section 26.3 Scope

The NRC has reorganized, renumbered, and amended § 26.3 relative to both former § 26.2 [Scope], as modified by the Part 52 final rule, and proposed § 26.3 [Scope] based upon the NRC's consideration of issues raised by public comments on the proposed rule. In general, the final rule retains and clarifies most of the provisions pertaining to the scope of the former and proposed rules. However, one public comment stated that the proposed rule was confusing with regard to the entities and individuals who are subject to the different requirements of this part. Therefore, the final rule amends this section of the proposed and former rules and adds a new § 26.4 [FFD program applicability to categories of individuals], as discussed with respect to that section, to clarify the rule text. Also, the final rule makes a substantive change to the proposed rule by adding § 26.3(c), which modifies the requirements of proposed § 26.3(e) pertaining to combined license holders and applicants and construction permit holders and applicants. As in § 26.3(e) of the proposed rule, § 26.3(c) of the final rule specifies the requirements to which these entities are subject. However, the final rule modifies these requirements and moves them to a new Subpart K [FFD Programs for Construction]. These changes are discussed in more detail with respect to § 26.3(c).

Section 26.3(a) of the final rule specifies that licensed nuclear power reactor operators and combined license holders after the Commission has made the finding in § 52.103(g) shall comply with the requirements of this part, with the exception of Subpart K. The Part 52 final rule modified former § 26.2(a) to expressly require combined license holders after the Commission has made the finding in § 52.103(g) to comply with the requirements of Part 26.

The final rule clarifies that the regulations contained in Subpart K do not apply to the licensees and other entities specified in § 26.3(a) because only entities specified in § 26.3(c) are permitted to implement an FFD program under the more flexible program requirements in Subpart K. The final rule also adds a requirement that licensees who receive their operating license under § 50.57 after the date of publication of the final rule in the **Federal Register** and holders of a combined license under Part 52 after the Commission has made the finding in § 52.103(g) must implement an FFD program meeting all of the requirements of Part 26 except Subpart K before receipt of special nuclear material in the form of fuel assemblies. The NRC believes that once fuel assemblies have arrived on site, the full range of potential risks to public health and safety and the common defense and security that Part 26 is designed to avert are possible. Therefore, the NRC believes that a more rigorous FFD program must be in place at this time.

Section 26.3(b) of the final rule combines § 26.3(b) and (c) of the proposed rule. This section retains the requirement in the first sentence of former § 26.2(a) that licensees who are authorized to possess, use, or transport formula quantities of are subject to the regulations in this part. Section 26.3(b) also retains the requirements of former

§ 26.2(d) and specifies that corporations and entities other than a corporation are subject to the regulations of this part because there may be entities who are organized as firms, partnerships, limited liability companies, or associations who may also obtain a certificate or approved compliance plan under Part 76 and elect to engage in activities involving formula quantities of SSNM.

However, the entities specified in this paragraph are not subject to the requirements contained in Subpart I [Managing Fatigue] for the reasons that are discussed with respect to § 26.201 [Applicability]. With respect to the proposed rule, the final rule adds a specification that the entities listed in § 26.3(b) are not subject to the requirements contained in Subpart K, because the requirements of Subpart K apply only to the entities specified in § 26.3(c). The provision also eliminates the cross reference to § 26.25(a)(3) of the proposed rule because the final rule has moved the proposed provisions in § 26.25 to § 26.4 of the final rule for increased clarity in the rule's organization.

Section 26.3(c) of the final rule retains but modifies the provisions of former § 26.2(c) and proposed § 26.3(e). Proposed § 26.3(e) would have retained and updated the requirements of § 26.2(c) of the former rule before Part 26 was amended by the Part 52 final rule. However, proposed § 26.3(e) did not revise the basic approach taken in former § 26.2(c), and specified the regulations in Part 26 that applied to the entities listed in proposed § 26.3(e). Section 26.3(c) of the final rule specifies that the entities listed are subject to the requirements of Part 26, except Subpart I.

The NRC received a public comment, discussed in detail in Section V of this document, that argued that proposed § 26.3(e) was unclear regarding the type of FFD program the NRC expected from the licensees specified in this paragraph. The NRC acknowledged these concerns, and for the reasons discussed in Section V of this document, the final rule amends the requirements of proposed § 26.3(e) and moves them to a separate Subpart K. The specific requirements applicable to the entities specified in § 26.3(c) are discussed in this document with respect to Subpart K.

Like the proposed rule, the final rule specifies the requirements that are applicable to combined license holders before the Commission has made the finding under § 52.103(g) and to construction permit holders. Section 26.3(c)(2) and 26.3(c)(4) specifies that combined license holders before the Commission has made the finding under § 52.103(g) and construction permit holders, respectively, are subject to the requirements of Part 26, except for Subpart I.

The final rule, however, to be consistent with the LWA final rule, amends the proposed rule with respect to combined license applicants and construction permit applicants. Section 26.3(c)(1) and (c)(3) addresses combined license applicants and construction permit applicants, respectively. Although the proposed rule specified combined license applicants and construction permit applicants who have ''received the authorization to construct under § 50.10(e)(3),'' revisions to Part 50 in the LWA final rule have changed the content and applicability of § 50.10(e)(3). As a result, the Part 26 final rule specifies combined license applicants and construction permit applicants who ''have been issued a limited work authorization under § 50.10(e), if the limited work authorization authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related [SSCs] under the limited work authorization.'' Similarly, in § 26.3(c)(5), the final rule, with respect to the proposed rule, adds a new specification for early site permit holders ''who have been issued a limited work authorization under § 50.10(e), if the limited work authorization authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the limited work authorization.'' (The final rule contains definitions of safety- and security-related SSCs in § 26.5, and those definitions are discussed with respect to that section.)

The LWA final rule modified the scope of activities that are considered construction for which a construction permit, combined license, or LWA is necessary, and specified the scope of construction activities that may be performed under an LWA. Under an LWA, entities are allowed to perform some or all of the following activities: driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, and installation of the foundation, including placement of concrete, any of which are for an SSC of a production or utilization facility for which either a construction permit or combined license is otherwise required under 10 CFR 50.10(c).

The NRC has concluded that if the entity is authorized under the LWA to perform only the driving of piles, subsurface preparation, or placement of backfill, concrete or permanent retaining walls within an excavation for safety- and security-related SSCs, it will not be required to comply with Part 26. Entities who are authorized under the LWA to perform installation of the foundation, including placement of concrete, for safety- or security-related SSCs, however, will be required to comply with Part 26 and establish either an FFD program under Subpart K of Part 26 or an FFD program that complies with all of Part 26 except Subparts I and K.

The NRC based its decision to distinguish the installation of the foundation, including placement of concrete, from the other activities listed under § 50.10(d)(1) on the following considerations. First, until the NRC broadened the concept of construction because of its early interpretation of the National Environmental Policy Act, construction requiring NRC approval in the form of a construction permit was defined in § 50.10 as ''pouring the foundation for, or the installation of, any portion of the permanent facility on the site.'' Thus, installation of the foundation has in the past been identified by the agency as a key step in construction.

Second, the NRC concluded that installation of the foundation is different in kind from the other activities listed under § 50.10(d)(1). A common meaning of ''foundation'' is the underlying base or support for a building or the substructure of a building. Therefore, the foundation is an integral component of the fabric of a safety- or security-related SSC, while piles, backfill, and retaining walls are not. The foundation must be installed properly on the first attempt, as any flaws in the foundation or voids or concrete will be difficult to detect and impossible to correct without complete re-installation of the foundation. The individuals who install foundations for safety- and security-related SSCs must therefore be fit-for-duty and trustworthy and reliable. Thus, the installation of foundations has a closer and more significant nexus with public health and safety and common defense and security, and the individuals who construct or direct the construction of such SSCs should be subject to an FFD program.

Third, the public can be expected to view installation of foundations as different from, and more important than, other activities under an LWA because of the integral nature of foundations with the SSCs and the nexus with public health and safety and common defense and security. An FFD program that provides reasonable

assurance that the individuals who perform installation of foundations of safety- or security-related SSCs are trustworthy and reliable and fit to perform their duties will enhance public confidence in the NRC's regulatory processes and the safety and security of newly constructed nuclear power plants.

Further, § 26.3(c) of the final rule explains that if the licensees and other entities specified in § 26.3(c)(1) through (5) receive special nuclear material in the form of fuel assemblies, then those entities must comply with all of the requirements of Part 26. This requirement is consistent with the requirement in § 26.3(a) that licensees who receive their operating license under § 50.57 after the date of publication of the final rule in the **Federal Register** and holders of a combined license under Part 52 after the Commission has made the finding in § 52.103(g) must comply with the requirements of Part 26, except Subpart K, before the receipt of special nuclear material in the form of fuel assemblies. Under both § 26.3(a) and (c), no later than when fuel arrives on site, the applicable licensees and other entities must implement an FFD program that complies with the requirements of Part 26 for the reasons discussed with respect to § 26.3(a).

The NRC has decided to defer adopting requirements for reactor manufacturing facilities. Although these facilities would have been covered under proposed § 26.3(e) and were temporarily included in the former § 26.2(c) as amended by the Part 52 final rule, the agency has concluded that it needs additional information before going forward with FFD requirements for such facilities, particularly when FFD requirements are closely linked to issues of access authorization and physical security. The NRC is considering, but has not yet completed, regulatory requirements on those subjects for reactor manufacturing facilities. Any industry stakeholders with a potential interest in pursuing a license for a reactor manufacturing facility should ensure that they engage in early discussions with the NRC so that suitable requirements can be developed in a timely manner.

Section 26.3(d) of the final rule retains the meaning of a portion of former § 26.23(a)(1), but amends some of the terminology used in the former rule. Like the proposed rule, the final rule requires that a C/V FFD program must meet the standards of Part 26 if licensees and other entities specified in paragraphs (a) through (c) of § 26.3 rely upon the C/V's FFD program or program elements to meet the requirements of Part 26. The provision adds C/Vs to the list of entities who are subject to Part 26 in § 26.3 to more clearly convey that C/Vs may be directly subject to NRC inspection and enforcement actions than the former rule language implied. The former rule text presented the applicability of the rule's requirements to a C/V's FFD program in terms of the contractual relationship between a licensee and the C/V. For example, former § 26.23(a)(1) stated, ''The contractor or vendor is responsible *to the licensee* [emphasis added] for adhering to the licensee's fitness-for-duty policy, or maintaining and adhering to an effective fitness-for-duty program; which meets the standards of this part.'' This paragraph, and others in the former rule, could be interpreted as implying that a C/V is accountable to the licensee but not to the NRC, should significant weaknesses be identified in the C/V's FFD program upon which a licensee relies. However, this interpretation would be incorrect. Therefore, § 26.3(d) of the final rule includes C/V FFD programs and program elements upon which the licensees and other entities specified in paragraphs (a) through (c) of this section rely within this section to convey more accurately that C/Vs are directly accountable for meeting the applicable requirements of Part 26, not only through their contractual relationships with the licensees and other entities who are subject to the rule. This clarification also is necessary to maintain the internal consistency of the final rule because some provisions of the rule apply only to C/Vs, including, but not limited to § 26.717(g). The final rule makes this change to meet Goal 6 of the rulemaking to improve the clarity in the organization and language of the rule.

The phrases ''program elements'' and ''licensees and other entities specified in paragraphs (a) through (c) of this section'' are used in § 26.3(d) of the final rule because C/Vs need only meet the requirements of Part 26 for those FFD program elements upon which licensees and other entities rely to meet the requirements of the rule. For example, a C/V may choose to implement all of the program elements that are required for a full FFD program under the final rule except drug and alcohol testing. In this case, the final rule does not require the C/V to address drug and alcohol testing in the C/V's FFD policy, procedures, and training program; establish contracts with drug-testing laboratories; collect specimens for drug and alcohol testing; or meet any other requirements in the final rule that relate to conducting drug and alcohol testing. However, if a C/V chooses to conduct drug and alcohol testing under some or all of the conditions specified in § 26.31(c) [Conditions for testing], such as for cause testing, and a licensee or other entity specified in § 26.3(a) through (c) relies upon the results of the C/V's tests in determining whether to grant authorization to an individual (see Subpart C [Granting and Maintaining Authorization]), then the use of these phrases in the provision would be correctly interpreted to mean that the C/V's drug and alcohol testing program element must meet the final rule's requirements related to drug and alcohol testing when conducting the tests on which the licensee or other entity relies. In contrast, if a C/V implements an FFD program element that is addressed in this part, but that program element is not relied upon by a licensee or other entity specified in paragraphs (a) through (c) of this section, then the provision does not require the C/V to meet the applicable Part 26 requirements for that FFD program element. Section 26.3(d) requires C/Vs to meet the requirements of Subpart I of the final rule, if any nuclear power reactor licensees specified in § 26.3(a) through (c) rely upon a C/V's fatigue management program element to meet the requirements of Subpart I. The applicability of Subpart I to C/Vs is discussed with respect to § 26.201.

The NRC has either eliminated or moved to other places of the final rule other provisions of former § 26.23 [Contractors and vendors]. The NRC has moved the former requirement for licensees to retain written agreements with C/Vs in the second sentence of § 26.23 to Subpart N [Recordkeeping and Reporting Requirements] of the final rule. The NRC has moved the requirement in former § 26.23(a)(1) to Subpart C of the final rule. That provision requires that individuals who have violated an FFD program must not be assigned to work within the scope of this part without the knowledge and consent of the licensee. The NRC has addressed the audit requirement contained in former § 26.23(b) in § 26.41(d) [Contracts] of the final rule. By moving the former requirements to different sections of the final rule and grouping related requirements together in one section or subpart that addresses similar topics, the NRC has met Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has amended and moved the requirements of proposed § 26.3(e) to

§ 26.3(c) and Subpart K of the final rule. The requirements contained in proposed § 26.3(e) are discussed in this document with regard to those sections.

Section 26.3(e) of the final rule, like the proposed rule, retains the second sentence of former § 26.2(b) and addresses entities who are not subject to the rule. The NRC has moved the first sentence of former § 26.2(b), which addressed individuals who are not subject to the rule, to § 26.4(i) of the final rule for organizational clarity.

Section 26.4 FFD Program Applicability to Categories of Individuals

In the proposed rule, the NRC moved the provisions in former § 26.2 that specified the individuals whose duties require them to be subject to the rule and exempt certain other individuals to § 26.25 [Individuals subject to the fitness-for-duty program]. However, the NRC has deleted § 26.25 from the final rule, and has amended, reorganized, and moved all of the provisions in proposed § 26.25 to a new § 26.4 to group related applicability requirements together in one section.

The provisions moved into new § 26.4 include the second sentence of former § 26.2(a), the first sentence of former § 26.2(b), and the portion of the second sentence of former § 26.2(d) that pertained to personnel. The NRC determined that separating into two different sections the requirements that address the entities who are subject to the rule and the requirements that address the individuals who must be subject to the rule makes the two sets of provisions easier to locate within the final rule without compromising the intended meaning of these provisions. Also, moving the applicability requirements for individuals into Subpart A [Scope] from Subpart B [Program Elements], where they were located in the proposed rule, is appropriate because some categories of individuals who are subject to the rule are not subject to Subpart B of the final rule. The applicability requirements in § 26.4 clearly specify the categories of individuals who are subject to Part 26. The NRC determined that grouping all of the applicability requirements into one subpart of the final rule increases the ease of locating these provisions, consistent with Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.4(a) of the final rule retains portions of proposed § 26.25(a)(1). Proposed § 26.25(a)(1) amended portions of former § 26.2(a) and (d) and described the individuals whose duties require them to be subject to Part 26. The final rule specifies that the persons who are granted unescorted access to nuclear power reactor protected areas by the licensees and other entities in § 26.3(a) and (c), as applicable, and who perform the duties in § 26.4(a)(1) through (a)(5) shall be subject to an FFD program that meets the requirements of this part, except Subpart K but including Subpart I. The NRC has moved the categories of individuals specified in § 26.199(a)(1) through (a)(5) of the proposed rule to § 26.4(a)(1) through (a)(5) of the final rule in order to group together all related applicability requirements for individuals in one section. This change is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. Additional concerns regarding the reasons why individuals performing these duties shall be subject to the fatigue management provisions of Subpart I are discussed with respect to § 26.205(a) [Individuals subject to work hour controls]. The final rule clarifies that these individuals may not be subject to the more flexible FFD program described in Subpart K because they may be granted unescorted access by the licensees in § 26.3(a), to whom all of the requirements of this part, except Subpart K, apply, and entities in § 26.3(c), as applicable, to whom all of the requirements of this part apply.

Section 26.4(b) of the final rule retains portions of and amends proposed § 26.25(a)(1). The final rule adds § 26.4(b) to clarify that individuals who are granted unescorted access to nuclear power reactor protected areas by the licensees and other entities in § 26.3(a) and (c), as applicable and who do not perform the duties described in § 26.4(a), shall be subject to an FFD program that meets all of the requirements of Part 26, except § 26.205 [Work hours] through § 26.209 [Self-declarations] and Subpart K. Section 26.4(b) does not permit these individuals to be subject to an FFD program that meets the more flexible requirements of Subpart K because they may be granted unescorted access to protected areas by the licensees in § 26.3(a), to whom all of the requirements of this part, except Subpart K, apply, and the entities in § 26.3(c), as applicable, to whom all of the requirements of this part apply. This paragraph does not require the individuals in this paragraph to be subject to an FFD program that meets the requirements of § 26.205 through § 26.209 for the reasons discussed with regard to § 26.205(a).

Section 26.4(c) of the final rule retains and amends proposed § 26.25(a)(2). Proposed § 26.25(a)(2) amended portions of former § 26.2(a) and (d) and described the individuals whose duties require them to be subject to Part 26. Section 26.4(c) of the final rule states that all persons who are required by a licensee or other entity in § 26.3(a), and, as applicable, (c) to physically report to the licensee's Technical Support Center or Emergency Operations Facility shall be subject to an FFD program that meets all of the requirements of this part, except § 26.205 through § 26.209 and Subpart K. Section 26.4(c) of the final rule does not permit these individuals to be subject to an FFD program that meets the more flexible requirements of Subpart K because they may be granted unescorted access by the licensees in § 26.3(a), to whom all of the requirements of this part, except Subpart K, apply, and the entities in § 26.3(c), as applicable, to whom all of the requirements of this part apply. This paragraph also does not require the specified individuals to be subject to an FFD program that meets the requirements of § 26.205 through § 26.209 for the reasons discussed with regard to § 26.205(a).

Section 26.4(d) of the final rule retains and amends portions of proposed § 26.25(a)(3). Proposed § 26.25(a)(3) amended the portions of former § 26.2(a) and (d) and described the individuals whose duties require them to be subject to Part 26. Section 26.4(d) of the final rule specifies that any individual whose duties for the licensees and other entities in § 26.3(b) require him or her to have the types of access or perform the activities in paragraphs (d)(1) through (d)(5) shall be subject to an FFD program that meets all of the requirements of this part, except Subparts I and K. Section 26.4(d) of the final rule does not require these individuals to be subject to an FFD program that meets the requirements of Subparts I or K, which is consistent with the provisions of the proposed rule.

The NRC has added § 26.4(e) to the final rule to specify that individuals whose duties when construction activities begin require them to have the types of access or perform the activities specified in § 26.4(e)(1) through (e)(6) at the location where the nuclear power plant will be constructed and operated must be subject to a rigorous FFD program that complies with the requirements of Part 26, except for the requirements of Subparts I and K. These individuals have direct responsibility for assuring the quality and security of construction activities and, thereby, the safety and security of the completed nuclear power plant. The NRC considers

it prudent that these personnel are verified to be trustworthy and reliable, as demonstrated by the avoidance of substance abuse, and fit for duty with an FFD program that is equivalent to the program required for an operating plant, which includes a 50 percent random testing rate and a suitable inquiry and employment history check. These individuals include all individuals whose duties at the location where the nuclear power plant will be constructed and operated require them to: (1) Serve as security personnel required by the NRC, until the licensee or other entity receives special nuclear material in the form of fuel assemblies, at which time individuals who serve as security personnel required by the NRC must meet the requirements applicable to security personnel in § 26.4(a)(5); (2) perform quality assurance, quality control, or quality verification activities related to safety- and security-related construction activities; (3) based on a designation under § 26.406 by a licensee or other entity, monitor the fitness of the individuals specified in § 26.4(f) (and thus has also received fitness monitoring training); (4) witness or determine inspections, tests, and analyses certification required by Part 52; (5) supervise or manage the construction of safety- or security-related SSCs; or (6) direct, as defined in § 26.5, or implement the access authorization program. Section 26.4(e)(5) specifies that an individual who ''supervises or manages the construction of safety- or security-related SSCs'' must be subject to an FFD program that complies with the requirements of Part 26, except the requirements of Subparts I and K. The NRC has added this provision based upon information from stakeholders at public meetings at which the conceptual framework for Subpart K was discussed. The NRC has included a definition of ''supervises or manages'' in the final rule, which means ''exercises control over a work activity by an individual who is not directly involved in the execution of the work activity.'' The final rule specifies that this requirement applies only to those individuals who supervise or manage the construction of safety- or security-related SSCs ''at the location where the nuclear power plant will be constructed and operated'' (i.e., only those individuals whose activities at the site where the nuclear power plant will be constructed and operated may negatively impact public health and safety and the common defense and security).

Section 26.4(e)(6)(i) through (e)(6)(vii) specifies that individuals who direct or implement the licensee's or other entity's access authorization program during construction must be subject to an FFD program that complies with the requirements of Part 26, except the requirements of Subparts I and K. The NRC expects that, in the absence of an order or regulation requiring a specific access authorization program during construction, an access authorization program during construction would require individuals to perform the same duties and activities as would a licensee's access authorization program under § 73.55 and § 73.56 when the plant is operating. These duties and activities include having access to the information used by the licensee or other entity to make access authorization determinations, including information stored in electronic format, as specified in (e)(6)(i); making access authorization determinations, as specified in (e)(6)(ii); issuing entry-control picture badges in accordance with access authorization determinations, as specified in (e)(6)(iii); conducting background investigations or psychological assessments used by the licensee or other entity to make access authorization determinations, as specified in (e)(6)(iv); adjudicating reviews or appeals of access authorization determinations, as specified in (e)(6)(v); auditing the access authorization program, as specified in (e)(6)(vi); or performing any of the activities or having any of the duties listed in § 26.4(e)(6) for any C/V upon whom the licensee's or other entity's access authorization program will rely, as specified in (e)(6)(vii). Section 26.4(e)(6)(iv) includes the following exception for individuals who conduct background investigations or psychological assessments used by the licensee or other entity to make access authorization determinations: ''He or she shall be subject to behavioral observation only when he or she is present at the location where the nuclear power plant will be constructed and operated, and licensees and other entities may rely on a local hospital or other organization that meets the requirements of 49 CFR Part 40, 'Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs' (65 FR 41944; August 9, 2001) to collect his or her specimens for drug and alcohol testing.'' The requirements for persons conducting background checks and psychological assessments are relaxed for reasons similar to requirements for MROs and certain FFD program personnel, as described in detail with respect to § 26.31(b)(1)(v) and (b)(2). The NRC has added the requirements of § 26.4(e)(6) in accordance with Goal 1 of this rulemaking, which is to update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.4(e)(1) includes the phrase ''until the licensees or other entities receive special nuclear material in the form of fuel assemblies, at which time individuals who serve as security personnel required by the NRC must meet the requirements applicable to security personnel in paragraph (a)(5) of this section'' to clarify that, once fuel is received on site, security personnel must be subject to all the requirements of this part, except the requirements of Subpart K, and including the requirements of Subpart I. The individuals listed in § 26.4(e)(2) through (6), once construction activities begin and until a licensee or other entity specified in § 26.3(a) or (c) grants them unescorted access to the nuclear power plant protected areas, must be subject to the requirements of this part, except the requirements of Subparts I and K. However, once the individuals listed in § 26.4(e)(2) through (6) are granted unescorted access to the nuclear power plant protected areas, they must be subject to the requirements of § 26.4(b), which require them to be subject to the requirements of this part, except those in (§§ 26.205 through 26.209 and Subpart K.

The NRC has added § 26.4(f) to the final rule to specify the individuals involved in the construction of a new reactor plant who, at the licensee's or other entity's discretion, must be subject to either a more flexible FFD program under Subpart K, or a more rigorous FFD program that meets the requirements in the other portions of Part 26, except Subparts I and K. These individuals include any individual who is constructing or directing the construction of safety- or security-related SSCs at the location where the nuclear power plant will be constructed and operated. However, if and when a licensee or entity specified in § 26.3(a) or (c) grants these individuals unescorted access to the nuclear power plant protected area, these individuals must be subject to the requirements of § 26.4(a) or (b), as applicable. As specified by the definition of (constructing or construction activities' in § 26.5, these tasks include fabricating, erecting, integrating, and testing safety- or security-related SSCs and the installation of their foundations, including the placement of concrete. The final rule also contains a definition of ''directing'' in § 26.5, which means

the exercise of control over a work activity by an individual ''who is directly involved in the execution of the work activity.'' This definition is distinguished from the term ''supervises or manages,'' used in § 26.4(e)(5), which means the exercise of control over a work activity by an individual ''who is not directly involved in the execution of the work activity.'' The NRC determined that it is necessary to impose FFD requirements on individuals who are constructing or directing the construction of safety- or security-related SSCs because (1) the quality of work could be adversely affected by construction workers who are impaired by substance abuse where studies indicate that members of this group have the highest rates of substance abuse problems among occupational groups in the U.S. (e.g., SAMHSA's NHSDA covering the years 2000–2001 and SAMHSA's National Survey on Drug Use and Health covering the years 2002–2004), (2) individuals who have become addicted to illegal drugs are susceptible to coercion and will interact with others involved in the drug trade, (3) past experience has demonstrated that errors during construction can adversely affect subsequent plant operations (NUREG/CR–6819, Vols. 1–4, ''Common-Cause Failure Event Insights,'' (May 2003) and NUREG–1837, ''Regulatory Effectiveness Assessment of Generic Issue 43 and Generic Letter 88–14,'' (October 2005)), and (4) quality assurance by design uses a sampling process. Despite having a high degree of confidence in the effectiveness of quality assurance and ITAAC programs to detect construction errors, the NRC believes it is prudent to require an FFD program during construction to provide reasonable assurance that impaired construction workers or individuals directing construction workers do not introduce faults in safety- or security-related SSCs that may cause the SSCs to fail to perform their intended functions when the plant is operating. In addition, the NRC is concerned that some construction personnel who have substance abuse problems will have access to sensitive information that could be useful to an adversary, as well as physical access to safety- and security-related SSCs that may provide opportunities for malicious acts. Therefore, the NRC is requiring individuals who are directly involved in constructing safety- and security-related SSCs to be subject to an FFD program.

Section 26.4(g) of the final rule contains the provisions in proposed § 26.25(a)(4). Proposed § 26.25(a)(4) clarified the NRC's original intent that FFD program personnel must be subject to the FFD program. Although former Section 2.3 in Appendix A to Part 26 required licensees to carefully select and monitor individuals who are responsible for administering the drug and alcohol testing program based upon the highest standards of honesty and integrity, some licensees' testing programs did not include all of the FFD program personnel who the NRC originally intended to be subject to testing. The final rule clarifies the NRC's original intent because the actions of these individuals have an ongoing effect on public health and safety and the common defense and security as a result of their responsibility to ensure that FFD programs are effective. In addition, these individuals' actions affect the confidence that the public, management, and individuals who are subject to testing have in the integrity of the program and the accuracy and reliability of test results. Individuals who are involved in the day-to-day operations of an FFD program are in a position to permit substance abusers to remain undetected. For example, specimen collectors could inadvertently commit errors when testing others as a result of being impaired from drug or alcohol abuse or intentionally omit testing an individual because of motives associated with maintaining a collector's substance abuse or empathy with an abuser. Further, several reported incidents have confirmed the need to assure that FFD program personnel meet the highest standards of honesty, integrity, reliability, and trustworthiness. For example, one licensee added specimen collectors to the testing pool after investigating an allegation and determining that two collectors were substance abusers. In another instance, a contracted MRO who was not in the testing pool was reported to be an alcoholic and an abuser of prescription drugs. Some MROs who provide their services to other Federally regulated industries also have been identified as substance abusers. Therefore, the revision to former § 26.2(a) fulfills the NRC's original objective and requires licensees and other entities to extend their programs to include FFD personnel who (1) can link test results with the individual who was tested before an FFD policy violation determination is made, including, but not limited to, the MRO, as specified in § 26.4(g)(1); (2) make determinations of fitness, as specified in § 26.4(g)(2); (3) make authorization decisions, as specified in § 26.4(g)(3); (4) are involved in selecting or notifying individuals for testing, as specified in § 26.4(g)(4); or (5) are involved in the collection or on-site testing of specimens, as specified in § 26.4(g)(5).

Although job titles and responsibilities may differ among different Part 26 FFD programs, examples of FFD program personnel who are subject to Part 26 under the final rule include, but are not limited to, the following: The FFD program manager under § 26.4(g)(1) through (g)(5); the MRO and MRO staff under § 26.4(g)(1); the licensee's or other entity's reviewing officials under § 26.4(g)(3); specimen collectors under § 26.4(g)(5); SAEs who are under contract to or employed by the FFD program under § 26.4(g)(2); and licensee testing facility personnel under § 26.4(g)(5). In some cases, information technology personnel who design and implement software programs for selecting individuals for random testing also may be subject to the rule under § 26.4(g)(4) if such personnel have knowledge of who was selected for random testing before the individual is notified or the ability to affect the selection of specific individuals for random testing.

Section 26.4(g) of the final rule amends the proposed rule to clarify the requirements that the FFD programs specified in this paragraph must meet. The section specifies that FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees or other entities, and whose duties require them to have the types of access and perform the activities in § 26.4(g)(1) through (g)(5) shall be subject to an FFD program that meets all of the requirements of Part 26, except Subparts I and K, and at the licensees's discretion, Subpart C. The final rule clarifies that the procedures referenced are those of the licensees and other entities specified in § 26.3(a) through (c) and, as applicable, (d). Licensees may use different FFD program personnel for a Subpart K program, in which case, those FFD program personnel would be subject to a full program under the rule. However, individuals specified in § 26.4(i)(1) are not subject to an FFD program under Part 26. The term ''as applicable'' in this provision specifies that entities listed in § 26.3(d) must subject FFD program personnel to all of the requirements of this part if they perform the activities specified in § 26.4(g). The final rule also clarifies that the FFD programs for FFD program personnel performing the listed activities in § 26.4(g) must meet all the requirements of Part 26, except Subparts

I and K, which is consistent with the provisions of proposed rule. The final rule clarifies that the licensees and other entities may subject FFD program personnel to an FFD program that meets the requirements of Subpart C, for the reasons discussed with respect to § 26.31(b). These clarifications are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.4(h) retains and amends the requirements contained in proposed § 26.25(d). Proposed § 26.25(d) clarified that individuals who have applied for authorization or perform duties that require them to be subject to Part 26 also would be subject to some provisions of Part 26. The former Part 26 required an applicant for authorization to provide a written statement related to his or her past activities under this part in former § 26.27(a)(1); provide permission to the licensee to conduct a suitable inquiry in former § 26.27(a)(2); and submit to pre-access testing in former § 26.24(a)(1). Although the proposed rule used general terms, such as ''applicable requirements of this part'' and ''applicable protections of this part,'' the final rule clarifies the requirements to which the individuals specified in this paragraph are subject. The final rule requires that individuals who have applied for authorization to have the types of access or perform the activities described in § 26.4(a) through (d) shall be subject to the requirements in §§ 26.31(c)(1), 26.35(b), 26.37, 26.39 and the applicable requirements of Subparts C, and E [Collecting Specimens for Testing] through H [Determining Fitness-for-Duty Violations and Determining Fitness]. These clarifications ensure the internal consistency of the final rule and meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.4(i)(1) through (i)(3) contains the provisions of proposed § 26.25(b)(1) through (b)(3). The final rule groups together in one paragraph the former rule's provisions that identify individuals who would not be subject to the rule. This change has been made to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.4(i)(1) to the final rule as a result of extensive discussions with industry stakeholders at the public meetings mentioned in the Section I.D of this document. Industry stakeholders expressed strong concern that the related language in the affirmed rule (which was discussed in the preamble to the proposed rule) that delineated the FFD program personnel who must be subject to Part 26 was too broad. Stakeholders agreed that FFD program personnel who work on site and are involved in the day-to-day operations of the FFD program should be subject to the rule. However, the stakeholders noted that the language used in the affirmed rule was so vague that it could be interpreted as requiring, for example, that offsite human resources staff at a licensee's or other entity's corporate offices, who may have access to some FFD information about individuals, must be covered, as well as any medical or treatment personnel and their managers, at a hospital or substance abuse treatment facility who provide an occasional FFD program service. These interpretations of the intent of the affirmed rule provisions would be incorrect.

The stakeholders also strongly disagreed with the requirement in the affirmed rule that some FFD program personnel who maintain offices at locations other than a licensee's or other entity's facilities and are not involved in day-to-day program operations, such as EAP counselors and some contract MROs, should be subject to the rule. The stakeholders indicated that they believe the honesty and integrity of such off-site personnel is maintained through their professions' oversight and standards, with the result that requiring these individuals to be subject to the rule would create a significant and unnecessary regulatory burden. Stakeholders stated that the regulatory burden would result from the significant logistical difficulties involved in ensuring that these individuals are subject to behavioral observation and drug and alcohol testing, and excessive costs to hire additional MRO(s) to review any positive, adulterated, substituted, or dilute drug test results from MRO(s) who serve the FFD program.

Based on the stakeholders' input, lessons learned from FFD program experience since the rule was first implemented, the experience gained by other Federal agencies and their regulated industries, and the continuing need to ensure that FFD program personnel meet the highest standards of honesty and integrity, the NRC added § 26.4(i)(1) to the final rule. The provision excludes from the rule individuals who may be called upon to provide an FFD program service to a licensee or other entity in special circumstances and who meet all of the following criteria:

(1) They are not employed by the licensee or other entity;

(2) They do not routinely provide services to the licensee's or other entity's FFD program; and

(3) They do not normally work at a licensee's or other entity's facility.

Examples of individuals who are not subject to the rule under this provision may include, but are not limited to, a nurse at a local hospital who collects a single specimen for a post-event test from an individual who has been injured, and a counselor at a residential substance abuse treatment facility who performs behavioral observation of a patient while the individual is in residence. Personnel who meet the three criteria specified in the paragraph are excluded from the FFD program because the limited nature of their involvement with the FFD program makes it unlikely that they would be subject to coercion or influence attempts to subvert the testing process and the NRC is not aware of any reports indicating that these types of individuals have been involved in any adverse incidents.

However, § 26.4(g) of the final rule requires MROs and SAEs to be subject to Part 26 (see the discussion of § 26.187 [Substance abuse expert] in Section VI of this document for a detailed description of the SAE's roles and responsibilities under the FFD program), as well as any EAP counselor who serves as the SAE for a licensee's or other entity's FFD program. Individuals who serve in these positions play the key roles of determining whether a positive, adulterated, or substituted drug test result is an FFD policy violation (i.e., the MRO under § 26.185) and whether an individual is fit to safely and competently perform the duties that require the individual to be subject to this part (i.e., the SAE). Although the NRC recognizes the significant logistical difficulties and costs that may be associated with covering these individuals, the NRC concluded that MROs and SAEs play such critical roles in the effective functioning of an FFD program that ensuring their continuing honesty and integrity by requiring them to be subject to the rule is warranted.

Section 26.4(i)(2) and (i)(3) retains the first sentence of former § 26.2(b) but divides it into two paragraphs. This organizational change makes it easier to locate these requirements within the rule text and to support cross-referencing to these paragraphs from other portions of the rule. The NRC has moved the second sentence of former § 26.2(b) to § 26.3(e) of the final rule, rather than retain it in this provision, because it addressed entities who would not be subject to the rule, rather than individuals. The NRC has made these

changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule adds a new § 26.4(i)(4), which specifies that FFD program personnel of a program that is regulated by another Federal agency or State upon which a licensee or other entity relies to meet the requirements of this part, as permitted in § 26.4(j), § 26.31(b)(2), and § 26.405(e)(3) are not subject to a licensee's or other entity's program if the FFD program personnel are not employed by the licensee or other entity and their normal workplace is not at the licensee's or other entity' facility.

Section 26.4(j) contains the provisions of proposed § 26.25(c). This provision provides that persons who are covered by a program regulated by another Federal agency or State need not also be covered by duplicate elements of a licensee's or other entity's FFD program. Duplicate testing and training requirements applicable to an appreciable number of individuals working at nuclear facilities have become an increasing problem as the facilities have implemented the DOT's drug and alcohol testing requirements [49 CFR Part 40, 65 FR 41944, August 9, 2001]. This revision reduces the burden on some individuals who are currently subject to Federal and State programs with requirements that duplicate those of Part 26. Minor differences in specific program requirements for conducting drug and alcohol testing would be unlikely to adversely affect the ability of a licensee's or other entity's FFD program to meet the performance objectives of this part. The licensee or other entity continues to be responsible for implementing any Part 26 program elements that may not be addressed by the alternate Federal or State program. These program elements may include, but are not limited to, providing behavioral observation and initiating for cause testing, if necessary, when an individual who is covered by an alternate program is on site at a licensee's or other entity's facility and is performing the duties that require the individual to be subject to the rule, as well as immediate removal from duty of persons whose fitness may be questionable.

Section 26.4(j)(1) through (j)(5) of the final rule contains the provisions in proposed § 26.25(c)(1) through (c)(4) and (c)(6). The final rule lists the necessary characteristics of an alternative Federal or State program that, under the final rule, licensees and other entities may rely upon to satisfy the requirements of this part for an individual who is subject both to Part 26 and an alternative program. Paragraphs 26.4(j)(1) and (j)(3) permit licensees and other entities to rely on the alternative program to meet the final rule's drug testing requirements if the alternative program tests for the drugs and drug metabolites that are specified in the final rule at or below the cutoff levels established in the final rule and an HHS-certified laboratory conducts the program's specimen validity and drug testing. Similarly, § 26.4(j)(2) permits licensees and other entities to rely on the alternative program to meet the final rule's alcohol testing requirements if the alternative program's alcohol testing procedures and devices meet the final rule's requirements and the alternative program uses cutoff levels that are at least as stringent as those specified in § 26.103(a). Section 26.4(j)(4) permits the licensee or other entity to rely on an alternative program's FFD training if that training addresses the knowledge and abilities listed in § 26.29(a)(1) through (a)(10). If the licensee or other entity relies on the alternative program, § 26.4(j)(5) requires the licensee or other entity to ensure that the alternative program informs the licensee or other entity of any FFD violations.

The final rule deletes the provision that was contained in proposed § 26.25(c)(5). The proposed provision allowed individuals subject to Part 26 and to a Federal agency- or State-regulated program to be covered only by those elements of an FFD program that are not included in the Federal agency or State program if an impartial and objective procedure is provided for the review and reversal of any findings of an FFD policy violation. The NRC has deleted this provision because it recognizes that it would be impractical to require a licensee to ensure that a Federal agency or State program would include an impartial and objective procedure for the review and reversal of any findings of an FFD policy violation. Such assurance would be beyond the licensee's ability to obtain or provide because the licensee would not control the Federal agency or State program. Therefore, this change is consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

These provisions are consistent with the former and final rules' approaches to permitting licensees and other entities to rely on C/V FFD programs and program elements to meet the requirements of this part if the C/V's program or program element meets the requirements of this part, as discussed with respect to § 26.21 [Fitness-for-duty programs]. In general, permitting licensees and other entities to rely on FFD programs and program elements that are implemented by others, when those programs or program elements meet the requirements of this part, fulfills the rule's performance objectives and improves Part 26 by eliminating or modifying unnecessary requirements, which is Goal 5 of this rulemaking. However, an important difference between the final rule's permission for licensees and other entities to rely on the programs of other Federal and State agencies, compared to the final rule's permission for licensees and other entities to rely on C/V programs, is that the final rule does not require licensees and other entities to audit the alternate Federal and State programs under § 26.41 [Audits and corrective action]. Auditing Federal and State programs is unnecessary because these programs are subject to other, equally effective audit and inspection requirements. Relieving licensees and other entities who are subject to this part from an audit requirement also is in keeping with Goal 5 of this rulemaking.

Section 26.5 Definitions

Section 26.5 amends former § 26.3 [Definitions] to (1) clarify some definitions; (2) make the listed terms and their definitions more consistent with those used by other Federal agencies (including SAMHSA and DOT); (3) define new terms used in other sections of the rule; and (4) move definitions into this section from former Section 1.2 in Appendix A to 10 CFR Part 26, which contained definitions of important terms used in Appendix A to Part 26. The rule also eliminates six terms in former § 26.3 and Section 1.2 in Appendix A to Part 26 because they are fully defined in the provisions of the final rule or are not used in the final rule. In addition, the rule eliminates redundant definitions of some terms, which appear in both former § 26.3 and Section 1.2 in Appendix A to Part 26. Finally, the NRC has revised some definitions to make them simpler and easier to understand, consistent with the NRC's commitment to using plain language. For example, some definitions in the former rule included requirements that were also contained in other sections of the rule. In these instances, the final rule eliminates the embedded requirements from within the definitions, but retains the definitions in this section. The NRC has moved these requirements to the related sections of the final rule for organizational clarity.

The final rule modifies several definitions of the proposed rule due to public comment or to increase clarity in the language of the rule, consistent with Goal 6 of the rulemaking. These changes

are discussed below. Otherwise, the final rule adopts the definitions of this section as proposed, without change.

The NRC has made the majority of the changes to this section as a result of adding new requirements for urine drug testing, including specimen validity testing, to the rule. The rule incorporates advances in the science and technology of urine drug testing that are based on the most recent revision to the HHS Guidelines, as published in the **Federal Register** on April 13, 2004 (69 FR 19643). These changes require adding terms to § 26.5, modifying a number of the terms that were used in the former rule, and revising the definitions of some terms in the former rule that are also used in the final rule, as described in the following paragraphs.

The final rule modifies several terms that are used in the former and proposed rules to describe the results of drug and alcohol testing, in order to reduce the number of terms, increase consistency with terms used by other Federal agencies, and address the addition of urine specimen validity testing requirements. The final rule has deleted the term ''non-negative'' from the proposed rule. The NRC has added the term ''non-negative'' to the proposed rule to refer to any adverse test result from the different types of urine testing that are required under the final rule. However, the NRC received a public comment that requested clarification of ''non-negative'' with respect to ''positive''' in the proposed rule. Therefore, the NRC has deleted ''non-negative'' from the final rule and replaced it with more specific terminology. The final rule uses the term ''positive'' to refer to results from drug and alcohol testing indicating the presences of drugs or drug metabolites in a urine specimen or the presence of alcohol above the cutoff levels established in this part in breath or oral fluids specimens. The final rule uses the terms ''adulterated, dilute, substituted, or invalid,'' as appropriate, to refer to results of validity tests of urine specimens indicating that the specimen may not be normal human urine. Consequently, the NRC has replaced the term ''non-negative'' in the following definitions in this section: ''confirmed test result,'' ''cutoff level,'' and ''Medical Review Officer (MRO).''

The final rule, with respect to both the former and proposed rules, adds the term ''positive result'' to specify what positive results mean for drug and alcohol testing. The definition clarifies that, when the laboratory has conducted the special analysis permitted in § 26.163(a)(2), a result reported by an HHS-certified laboratory that a specimen contains a drug or drug metabolite below the cutoff concentration is also a positive result.

The final rule also changes the former term ''confirmed positive test'' to ''confirmed test result'' to clarify that this term refers to the results of the MRO's review of both drug and validity tests of urine specimens, rather than to a type of testing. The final rule also removes the reference to testing of blood specimens for alcohol that is contained in the former definition of ''confirmed positive test'' from the definition of ''confirmed test result'' because blood specimens are no longer collected at the donor's request for confirmatory alcohol testing, as discussed with respect to § 26.83(a). With respect to the proposed rule, the final rule specifies that a confirmed test result demonstrates that an individual has used drugs ''and/or'' alcohol. The NRC has made these changes to meet Goal 6 of this rulemaking, as it relates to improving clarity in the language of the final rule.

The final rule adds several terms to refer to urine specimens that have characteristics that are inconsistent with those expected of normal human urine, as identified through validity testing. The terms include ''adulterated specimen,'' ''dilute specimen,'' ''substituted specimen,'' and ''invalid result.'' The final rule also adds the term ''oxidizing adulterant'' to refer to one class of substances that may be used to adulterate urine specimens. These new terms and definitions have been adapted from the HHS Guidelines.

With respect to the proposed rule, the final rule adds the term ''questionable validity'' to mean the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid. The NRC has added this term based on the consideration identified by a commenter that licensee testing facilities may not be able to determine whether a specimen is substituted, dilute, or meets some of the invalid criteria because they are not required to test for specific gravity of a specimen. This term replaces the term ''suspect specimens'' in the former rule. Therefore, the NRC has made this change to improve clarity in the language of the rule, consistent with Goal 6 of this rulemaking.

The final rule also adds several terms that are associated with new requirements for maintaining quality control of urine specimen validity and drug testing, such as the term ''quality control sample.'' The final rule also adds definitions of the terms ''calibrator,'' ''control,'' and ''standard'' to distinguish among the types of quality control samples that are associated with urine specimen testing in Subparts F [Licensee Testing Facilities] and G [Laboratories Certified by the Department of Health and Human Services] of the final rule.

The final rule changes certain terms that describe drug and alcohol tests to reflect the addition of urine specimen validity testing requirements. The changes include replacing the term ''initial or screening test'' with more specific terms to distinguish between drug testing and testing for urine specimen validity. The NRC has added the terms ''validity screening test,'' ''initial drug test,'' and ''initial validity test'' to refer to the first tests of a urine specimen that are performed to determine whether a urine specimen is free of drugs and drug metabolites and has the expected characteristics of normal urine, or whether further testing of the specimen is required. The final rule modifies the proposed definition of ''validity screening test'' to clarify that both non-instrumented tests, in which the endpoint result is obtained by visual evaluation, and instrumented (machine read) tests are acceptable methods to determine the need for initial validity testing of urine specimen. The NRC has made these changes to improve clarity in the language of the rule, consistent with Goal 6 of this rulemaking.

The final rule also modifies the definition of ''initial or screening test'' in the former rule to eliminate the requirement that the test must be performed using immunoassay techniques because the NRC addresses that requirement in other sections of the rule. The final rule replaces the general term ''confirmatory test'' in the former rule with the more specific terms, ''confirmatory drug or alcohol test'' and ''confirmatory validity test.'' In addition, the definitions of these terms in the final rule do not include requirements for the methods to be used in performing confirmatory tests because these requirements are addressed in other sections of the rule. Therefore, the NRC has removed the requirement that confirmatory drug testing be performed using gas chromatography/mass spectrometry (GC/MS) testing from the definition. The final rule also eliminates the reference to GC/MS testing of blood samples for confirmatory alcohol testing in the definition of ''confirmatory drug or alcohol test'' because the final rule does not allow donors the option to provide a blood sample for alcohol confirmatory testing, as discussed with respect to § 26.83(a).

The final rule also adds two terms that refer to testing for very low levels of drugs, drug metabolites, or adulterants in a urine specimen, ''limit of detection (LOD)'' and ''limit of quantitation (LOQ).'' The NRC has adapted the definitions of these terms from the HHS Guidelines.

In addition, the final rule modifies the definitions of two terms in the former and proposed rules to be consistent with the new drug and alcohol testing terminology that is used throughout the rule. The final rule amends the definition of ''cutoff level'' in the former rule to clarify that the term is also applicable to the interpretation of results from specimen validity testing. The final rule further modifies this definition to refer to test results as ''positive,'' ''of questionable validity,'' and ''adulterated, substituted, dilute, or invalid'' to account for validity tests results from a licensee testing facility. The final rule amends the definition of ''Medical Review Officer (MRO)'' to refer to a ''drug and validity'' test result, rather than a ''positive'' test result, to clarify that the MRO reviews validity test results in addition to drug test results.

The rule also adds six terms that are related to the requirements contained in Subpart C. The term ''potentially disqualifying FFD information'' refers to the types of information that licensees and other entities who are subject to the rule consider when deciding whether to grant or maintain an individual's authorization to have the types of access or perform the duties that are listed in § 26.4. The final rule also adds definitions for four terms that are used within the definition of ''potentially disqualifying FFD information,'' including ''substance abuse,'' ''legal action,'' ''employment action,'' and ''reviewing official.'' The NRC has also added the term ''best effort'' to refer to the actions that a licensee or other entity who is subject to the rule must take to obtain the information that is necessary to complete a suitable inquiry and employment history check, as discussed with respect to § 26.63(a).

The final rule, with respect to the proposed rule, also adds a definition of the term ''authorization'' in response to public comment. The final rule uses the term, ''authorization,'' to refer to an individual's status as having been determined by a licensee or other entity to be eligible to perform the duties or have the types of access listed in § 26.4(a) through (e), and at the licensee's or other entity's discretion, § 26.4(f) and (g) of the final rule. The agency selected this term to differentiate ''authorization'' under Part 26 from the terms, ''unescorted access authorization'' and ''unescorted access,'' that are used by nuclear power plant licensees to refer to individuals who are subject to both Part 26 and related access authorization requirements under 10 CFR 73.56 [Personnel access authorization requirements for nuclear power plants]. The NRC created a new term because some categories of individuals who are subject to Part 26 are not required to meet the additional requirements of 10 CFR 73.56. For example, the NRC has not promulgated access authorization requirements in § 73.56 for FFD program personnel. Therefore, the final rule uses the term ''authorization'' to refer to the determination that these categories of individuals may perform the duties or have the types of access specified in § 26.4 to distinguish the requirements in this part from the additional requirements that a licensee or other entity must meet in order to grant individual ''unescorted access authorization'' or ''unescorted access'' to nuclear power plant protected areas.

The final rule adds a definition of ''maintenance'' to clarify the scope of duties described as maintenance in § 26.4(a)(4) of the final rule. The definition also distinguishes duties performed by individuals covered by § 26.4(a)(4) from duties performed by individuals that are subject to different work hour limits, such as the duties described in § 26.4(a)(1) through (3). Specifically, the definition clarifies that § 26.205(a) requires that individuals identified in § 26.4(a)(4) (i.e., individuals who are maintaining or providing onsite direction for the maintenance of systems and components that ''a risk informed evaluation process has shown to be significant to public health and safety'') must be subject to the work hour requirements. These requirements apply to those individuals who perform the following maintenance activities within the licensee's owner-controlled area: modification, surveillance, post-maintenance testing, and corrective and preventive maintenance. This definition is similar to the language used in GL 83–14, ''Definition of 'Key Maintenance Personnel,' (Clarification of Generic Letter 82–12)'' and 10 CFR 50.65, ''Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.'' The definition of ''maintenance'' in § 26.5 of the final rule excludes the term ''calibration,'' found in GL 83–14, because the NRC considers ''calibration'' to be part of ''preventive maintenance'' and, therefore, within the definition of ''maintenance.''

The final rule also adds several terms that are necessary to implement the requirements of Subpart I. These terms include ''fatigue,'' ''acute fatigue,'' and ''cumulative fatigue,'' which refer to the degradation in an individual's cognitive (mental) and motor (physical) functioning resulting from inadequate rest within the past 24 hours or over successive days and weeks, respectively. The rule also uses the term ''alertness'' to refer to an individual's ability to remain awake and sustain attention, which is adversely affected by fatigue. The new term ''circadian variation in alertness and performance'' defines a factor that licensees would consider when conducting a fatigue assessment under § 26.211 [Fatigue assessments]. The final rule also adds the term ''increased threat condition'' to refer to circumstances in which the rule provides licensees with some flexibility in implementing the work hour controls of § 26.205. With respect to the proposed rule, the final rule modifies the term ''increased threat condition'' to clarify that any increase in the protective measure level is relative to the lowest protective measure applicable to the site during the previous 60 days.

The final rule, with respect to the proposed rule, adds a definition of ''shift cycle'' to mean a series of consecutive work shifts and days off that is planned by the licensee or other entity to repeat regularly, thereby constituting a continuous shift schedule. Similarly, the final rule adds ''8-hour shift schedule,'' ''10-hour shift schedule,'' and ''12-hour shift schedule'' to define these schedules in terms of allowable hours of a workday averaged over a shift cycle.

Also, the NRC has added the term ''unit outage'' to the final rule to clarify that the specific reactor unit has to be disconnected from the electrical grid to be declared in an outage. This term was added in response to stakeholder comment raised at a public meeting on whether, for purposes of implementing the work hour controls, a unit was considered to be in an outage if reactor power was reduced for repair or maintenance of a system or component, but the reactor was not shutdown. Consequently, the NRC defined unit outage as the reactor being disconnected from the electrical grid. This definition provides a clearly identifiable plant state for applying the work hour controls in § 26.205(d)(4) and (d)(5).

The term ''directing'' clarifies new requirements for MRO staff under § 26.183(d) and the scope of individuals who would be subject to work hour controls in § 26.205. The NRC has

revised this definition in response to public comment regarding the lack of clarity of the term ''directing'' as used in Subpart I in the proposed rule and the scope of personnel that should be subject to work hour controls. Specific comments included remarks regarding the scope of engineering functions that should or should not be subject to work hour controls. The revised definition in the final rule clarifies the NRC's expectations that a limited scope of personnel providing technical input would be subject to the requirements of § 26.205. The definition explicitly states the criteria that the term ''directing'' refers to an individual who is ''directly involved in the execution of the work activity'' or ''is ultimately responsible for the correct performance of that work activity'' as opposed to, for example, the planning, development or scheduling of the activity, and that the technical input does not receive ''subsequent technical review.'' The NRC believes that, in the context of Subpart I, the revised definition more clearly focuses on activities that have the potential to substantively and immediately affect safety. These changes are consistent with the changes that the NRC has made to the final rule in Subpart I and meet Goal 6 of this rulemaking as it relates to improving clarity in the language of the rule.

Similarly, with respect to the proposed rule, the NRC has added the term ''supervises or manages'' to the final rule. The definition of ''supervises or manages'' explicitly states the criteria that the term refers to an individual who is ''not directly involved in the execution of the work activity,'' but who either makes technical decisions without technical review, or is ''ultimately responsible for the correct performance of that work activity,'' as opposed to, for example, the planning, development or scheduling of the activity, and that the technical input does not receive ''subsequent technical review.'' This definition is intended to clearly focus on activities that have the potential to substantively and immediately affect safety. These changes are consistent with the changes that the NRC has made to the final rule in Subpart I and meet Goal 6 of this rulemaking as it relates to improving clarity in the language of the rule.

The final rule, with respect to the proposed rule, also adds several terms that are necessary to interpret and implement the requirements in Subpart K. The final rule includes definitions of ''constructing or construction activities,'' ''safety-related SSCs,'' and ''security-related SSCs.'' The NRC has added these definitions in response to public comments that recommended that the NRC reconsider the proposed requirements for licensees or other entities who will build new nuclear power plants. The NRC defined these terms to clarify the point in the construction process at which an FFD program for construction is required, the physical location where the FFD program for construction must be implemented, and to specify the individuals who are subject to an FFD program for construction in terms of the duties they will perform.

The former rule in § 26.2(c) imposed FFD requirements on construction permit holders ''with a plant under active construction'' but did not define that term. The proposed rule in § 26.3(e) would have required an FFD program for construction following NRC authorization to construct. However, the NRC recognizes that there may be a period of time that elapses between the authorization to construct and the commencement of specific construction activities that have the potential to affect public health and safety and the common defense and security when the nuclear power plant begins operations. Therefore, the NRC has added a definition of ''constructing and construction activities'' to clarify that an FFD program for construction is not required until a licensee or other entity begins ''fabricating, erecting, integrating, and testing safety- and security-related SSCs, and the installation of their foundations, including the placement of concrete.''

In addition, this definition specifies that the FFD program for construction applies only to construction activities that are performed at the location where the new plant will be constructed and operated. The NRC added this phrase to the definition of construction activities to clarify that any fabrication, integration, or testing of safety- or security-related SSCs that is not performed within or near the licensee's or other entity's owner-controlled area in which the new plant will be operated would not be subject to Subpart K. For example, fabricating, integrating, and testing safety- or security-related SSCs at a vendor's or manufacturer's facility that is located in another city or state or outside of the U.S. would not be subject to Subpart K, whereas producing the concrete to be used for the foundation of the reactor building in a facility located on the site where the nuclear power plant will be constructed and operated would be subject to Subpart K (although the construction of the cement mixing facility would not). The NRC anticipates that the focus of the Subpart K program on construction activities involving safety- and security-related SSCs at the location where the new plant will be constructed and operated will lead licensees and other entities to ensure that the program covers all those individuals who perform construction activities within the footprint of the new power reactor (e.g., the exterior boundary of the reactor building once it is completed) as well as the nearby areas where safety- and security-related SSCs will be installed and operated when the plant begins operations.

The former rule and the proposed rule also did not specify the individuals who would be subject to an FFD program for construction. The NRC recognizes that there will be other construction work performed at the location where a new plant will be constructed and operated that will not have the potential to affect public health and safety and the common defense and security when the nuclear power plant begins operations, such as constructing a building that will be used only for training or administration purposes. The NRC does not intend that individuals who are performing these other construction activities must be subject to the FFD program. Therefore, the final rule also includes definitions of safety- and security-related SSCs to clarify that only those individuals who are constructing (i.e., fabricating, erecting, integrating, testing, and installing foundations of) these specific SSCs must be subject to a Subpart K program. Thus, as one example of a safety-related SSC, the rule requires individuals who are constructing the containment structure that surrounds the reactor to be subject to an FFD program because the containment is relied on to mitigate the consequences of accidents that could result in potential offsite exposure. Similarly, individuals who are constructing security-related SSCs, such as the central and secondary alarm stations, physical barriers, communications systems, guard towers, surveillance and detection systems, or installing locks and illumination systems, that will be necessary to implement the physical security and safeguards contingency plans that are required under 10 CFR Part 73 also are subject to an FFD program for construction.

The development of the revised requirements contained in Subpart K (described in Sections V and VI of this document) compelled the NRC to define these terms in the final rule. Adding definitions of these terms satisfies Goal 6 of this rulemaking as it relates to improving clarity in the language of the rule.

The final rule also adds many terms related to other revisions to the former rule. Specifically, the final rule adds ''analytical run'' for use in establishing amended performance testing requirements for licensee testing facilities in § 26.137 [Quality assurance and quality control]. For consistency with the use of the term in the related regulations of other Federal agencies, the term ''donor'' replaces the former terms that are used to refer to an individual from whom a specimen is collected for drug or alcohol testing. The new term ''nominal'' refers to the leeway in the time periods within which certain requirements must be met, such as the requirement for annual FFD refresher training in § 26.29(c)(2). The term ''other entity'' refers to organizations who are subject to Part 26, but who are not licensed by the NRC, including, but not limited to, the organizations who hold the NRC certificates or permits listed in § 26.3. The terms ''formula quantity'' and ''strategic special nuclear material'' (SSNM) have been defined consistently with the definitions of the same terms in 10 CFR 70.4. The term ''subversion and subvert the testing process'' clarifies the language of provisions related to urine specimen validity testing, as discussed with respect to § 26.31(d)(3)(i), and sanctions in § 26.75(b) that are imposed on individuals who are subject to Part 26.

Section 26.5 of the final rule also retains and amends a number of other definitions formerly contained in § 26.3 and Section 1.2 in Appendix A to Part 26, as described in the following paragraphs.

The rule revises the former definition of ''aliquot'' to clarify that an aliquot is a representative sample of a urine specimen that may be used for testing. The amended definition is consistent with the same definition in the HHS Guidelines.

The final rule simplifies the former definition of ''blood alcohol concentration (BAC)'' by deleting references to the instruments that licensees and other entities are permitted to use for alcohol testing. The text of § 26.91 [Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use] specifies acceptable devices for alcohol testing under the final rule.

The final rule revises the definition of ''category IA material'' to conform with the former definition contained in 10 CFR 74.4.

The final rule expands the definition of ''chain of custody'' to indicate that the terms ''chain of custody'' and ''custody and control'' are synonymous.

The NRC has modified the definition of ''collection site'' in the final rule to include a reference to oral fluids as specimens that are acceptable for initial alcohol testing. The basis for permitting the use of oral fluids for initial alcohol testing is discussed in Section VI of this document with respect to § 26.83(a).

The final rule replaces the term ''collection site person'' with the term ''collector'' to simplify the terminology used to refer to individuals who collect specimens for testing and for consistency with the terminology used by other Federal agencies. In addition, the definition no longer includes the qualifications required for collectors because they are specified in § 26.85 [Collector qualifications and responsibilities].

The final rule adds the term ''contractor/vendor (C/V),'' combining the definitions of ''contractor'' and ''vendor'' in the former rule, because the final rule does not distinguish between the two types of entities.

The final rule updates the definition of ''HHS-certified laboratory'' to reference the most recent version of the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs.

In addition, the final rule simplifies the definition of ''licensee testing facility'' by eliminating the reference to collecting specimens for alcohol testing in the former definition, because alcohol testing typically occurs at a collection site rather than at the licensee testing facility. Also, with respect to the proposed rule, the NRC has clarified this definition in the final rule to be consistent with the inclusion of specimen validity testing at licensee testing facilities.

Finally, the final rule eliminates six terms that were defined in former § 26.3 and Section 1.2 in Appendix A to Part 26. Specifically, the rule eliminates ''followup testing,'' ''random test,'' ''suitable inquiry,'' ''reason to believe,'' and ''split specimen'' because the text of the rule defines them in the section where each term is used. The rule also eliminates the term ''permanent record book'' in former Section 1.2 in Appendix A to Part 26 because laboratories now use other mechanisms to maintain testing records. Therefore, this term is no longer used in the rule.

Section 26.7 Interpretations

Section 26.7 in the final rule retains former § 26.4 [Interpretations] but moves the qualifying phrase, ''other than a written interpretation by the General Counsel,'' to the end of the sentence to improve its clarity. The NRC has made this change in keeping with the Commission's commitment to using plain language in its regulations and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.8 Information Collection Requirements: OMB Approval

Section 26.8 in the final rule amends former § 26.8 [Information collection requirements: OMB approval] to reflect the modified sections of the final rule in which recordkeeping requirements are incorporated.

Section 26.9 Specific Exemptions

Section 26.9 in the final rule revises former § 26.6 [Exemptions] to include the citation of 10 CFR 50.12 and 70.17. The NRC has made this change in the final rule to ensure consistency between Part 26 and these related requirements.

Section 26.11 Communications

New § 26.11 in the final rule improves consistency with similar sections in other parts of 10 CFR and ensures that communications with the NRC are addressed and, therefore, processed properly.

Subpart B—Program Elements

Throughout Subpart B, the final rule makes minor clarifications to the proposed rule because of public comment, to make conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule also makes more substantive changes to the proposed rule in this subpart because of public comment or to improve clarity in the organization and language of the rule. The substantive changes in this subpart can be found in §§ 26.21; 26.27(b)(3), (c)(1), (c)(2)(ii), (c)(3), and (c)(3)(ii); 26.29(c)(2); 26.31(d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(v), (d)(3)(i), and (d)(3)(iii); 26.35(b); 26.37(a), (b)(5) and (d); 26.39(c) and (e); and 26.41(a). These changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed, without change.

Section 26.21 Fitness-for-Duty Program

The final rule modifies the proposed rule's text in this section to specify which entities and individuals are subject to the requirements of this subpart. This section requires that the licensees and other entities specified in § 26.3(a) through (c) must establish, implement, and maintain FFD programs that, at a minimum, comprise the program elements contained in this subpart. This new statement serves as

an introduction to the remaining text of the final rule and eliminates the need for the phrase ''[licensees and other entities] who are subject to this subpart'' (or a derivation of this phrase) from several provisions in this subpart. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has also added a sentence to this section to specify which individuals are subject to FFD programs. The sentence in the final rule includes cross-references to provisions in § 26.4 [FFD program applicability to categories of individuals], which eliminates the need for the phrase ''[individuals] who are subject to this part'' (or a derivation of this phrase) from several provisions in this subpart. This change is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The third sentence of the section of the final rule is based on former § 26.23(b). This provision retains permission for licensees and other entities to rely upon the FFD program or program elements of a C/V to meet the requirements of this part, if the FFD program or program element of a C/V meets the applicable requirements of this part. The other requirements contained in former § 26.23 [Contractors and vendors] are discussed with respect to § 26.23 [Performance objectives].

Section 26.23 Performance Objectives

Section 26.23 amends former § 26.10 [General performance objectives] as described in the following paragraphs.

The final rule divides the performance objectives contained in § 26.10(a) into two provisions (§ 26.23(a) and (b), respectively) to clarify that the performance objective of assuring that personnel are trustworthy and reliable is separate and distinct from the performance objective of assuring that personnel are fit for duty.

Section 26.23(a) of the final rule requires that FFD programs provide reasonable assurance that persons who are subject to this part are trustworthy and reliable as demonstrated by the avoidance of substance abuse and the adverse behaviors that accompany it. The NRC has placed an increased emphasis on the trustworthiness and reliability of individuals who have access to certain types of sensitive information, certain types of radiological materials, and protected areas in nuclear power plants since September 11, 2001. These are the same individuals who are subject to the final rule. Because these individuals have unimpeded access to sensitive information and safety equipment and systems, their trustworthiness and reliability are essential. This level of emphasis is necessary to reduce the risk of an insider threat, maintain public health and safety, and provide for the common defense and security in the post-September 11, 2001, threat environment. Substance abuse by these individuals presents an unacceptable risk to public health and safety and the common defense and security in several ways.

First, by increasing an individual's vulnerability to coercion, substance abuse increases the likelihood that such individuals may pose an insider threat. Under 10 CFR 73.1 [Purpose and scope], a passive insider is defined as an individual who obtains or attempts to obtain safeguards or other relevant information, such as a nuclear power plant's physical configuration and design, and who does not have a functional or operational need to know this information. Section 73.1 defines an active insider as a knowledgeable individual who, while within the protected area of a nuclear power plant in an unescorted status, takes direct action to facilitate entrance and exit, disable alarms and communications, and/or participates in a violent attack. An individual who uses illegal drugs may be coerced into cooperating, actively or passively, with a terrorist in an attempt to commit radiological sabotage if, for example, the terrorist were to threaten the individual with revealing his or her illegal drug use or was somehow able to withhold drugs from an individual who is addicted.

Second, an individual's judgment and self-control are impaired while an individual is abusing drugs or alcohol. When an individual is intoxicated from abusing any of the substances for which testing is conducted under Part 26, including alcohol, the individual is more likely to inadvertently reveal sensitive information that terrorists could use in a radiological sabotage attempt than when he or she is not intoxicated.

Third, the use of illegal drugs establishes that an individual is willing to disobey the law, thus indicating that the individual will disregard other rules and regulations. The use of illegal drugs raises questions about the individual's trustworthiness and reliability in terms of scrupulously following the regulations, procedures, and other requirements, such as safeguards requirements, that ensure the protection of public health and safety.

Many provisions of the former rule provided means to identify and reduce the risks posed by any individuals whose substance abuse casts doubt on their trustworthiness and reliability. In combination with other measures the NRC has taken since September 11, 2001, a number of the changes to the former rule provide further assurance that individuals who are subject to the rule are trustworthy and reliable. Changes to strengthen the effectiveness of the final rule in assuring individuals' trustworthiness and reliability include, but are not limited to, the following:

(1) Adding requirements for specimen validity testing to identify individuals who are willing to attempt to subvert the testing process, and may be willing to subvert other rules and regulations that are important for public health and safety and the common defense and security;

(2) Increasing the rigor of the evaluations that licensees and other entities must perform before granting authorization to an individual who has previously violated Part 26 requirements to ensure that the individual has ceased abusing drugs or alcohol; and

(3) Imposing more stringent sanctions on individuals who violate Part 26 requirements, including, but not limited to, permanently denying authorization to any individual who attempts to subvert the drug and alcohol testing process.

The NRC believes that implementation of these provisions of the final rule, in addition to related measures the agency has taken in the post-September 11, 2001, threat environment, provides an increased level of requirements appropriate for the new threat environment, as well as reasonable assurance that individuals who are subject to the rule are trustworthy and reliable.

Section 26.23(b) of the final rule retains the performance objective of providing reasonable assurance that personnel are fit for duty, which appeared in former § 26.10(a). The use of the term ''reasonable'' to describe the level of assurance required by the rule reflects the NRC's awareness that many different factors may affect an individual's fitness at any particular moment in time. Some of these factors may be difficult for the licensee or other entity to detect and many (such as a transitory illness) may not warrant management action or the imposition of sanctions because they do not pose a significant risk to public health and safety.

As mentioned above, the level of requirements associated with achieving reasonable assurance of trustworthiness and reliability is greater than that associated with achieving reasonable assurance that individuals are not

impaired. Another example of this relates to the sanctions that the final rule requires licensees and other entities to impose on individuals who demonstrate questionable trustworthiness and reliability compared to the management actions licensees are expected to take with individuals who may be impaired. For example, if an individual demonstrates dishonesty by attempting to bring a substitute urine specimen to the collection site with a clear intent to subvert the testing process or demonstrates a willingness to break the law by possessing illegal drugs on site, the final rule (under § 26.75(b) and 26.75(c), respectively) requires the licensee or other entity to terminate the individual's authorization. Terminating the individual's authorization is necessary to provide reasonable assurance that the individual could pose no further risk to public health and safety or the common defense and security. In contrast, the final rule does not require a licensee or other entity to terminate an individual's authorization if he or she is mentally or physically impaired while on duty from such transitory causes as illness or emotional stress resulting from a family problem.

For example, an individual who arrives at work with a severe migraine headache may suffer impairment on the job that would adversely affect the individual's ability to perform his or her duties safely and competently while the headache persists. The final (and former) rule (under § 26.77(b)(3) and former § 26.27(b)(1), respectively) require the licensee or other entity to take action to prevent the individual from performing the duties that require the individual to be subject to this part if the individual's fitness is questionable. These actions could include, for example, assigning the individual to other duties until medication brings the headache under control or sending the individual home until the headache resolves. Such actions 'meet the performance objective of providing reasonable assurance that the individual is fit when he or she resumes his or her normal duties. However, it would be unreasonable for a licensee's FFD policy to impose sanctions on the individual, such as terminating his or her authorization. Sanctions could have no deterrent effect on the recurrence of the individual's headache, which is one purpose of including requirements for minimum sanctions in Part 26. In addition, there would not be any continuing risk to public health and safety from permitting the individual to resume his or her duties after the headache is resolved.

Another difference between the performance objectives of providing ''reasonable'' assurance of trustworthiness and reliability and ''reasonable'' assurance that the individuals who are subject to the final rule are fit for duty lies in the severity of the enforcement actions that the NRC would be likely to take against an FFD program that failed to meet these performance objectives. The NRC's enforcement actions would be severe in the case of an FFD program that, for example, granted authorization to an individual who had previously had his or her authorization permanently denied under § 26.75(b) but would take less severe enforcement action in the case of an FFD program that failed to remove an individual who was experiencing impairment related to family stress from his or her duties under § 26.77(b)(3).

Section 26.23(c) of the final rule retains the performance objective in former § 26.10(b) to ''provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part.'' However, the final rule replaces the phrase ''perform activities within the scope of this part'' with the phrase ''perform the duties that require them to be subject to the FFD program.'' The final rule requires that certain individuals must be subject to an FFD program based on their duties. These duties include performing activities, such as measuring, guarding, or transporting Category IA material. They also include having access to certain locations, material, and sensitive information, such as nuclear power plant protected areas, Category IA material, procedures and records for safeguarding SSNM, and the drug test results of an individual before the MRO reviews those results. Therefore, the phrase ''perform the duties that require them to be subject to the FFD program'' is more accurate. Replacing the former phrase with the more accurate phrase is consistent with Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.23(d) of the final rule amends former § 26.10(c) to require that FFD programs must provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol. The final rule revises the former performance objective to ''have a goal of achieving a drug-free workplace and a workplace free of the effects of such substances'' for several reasons. First, the terms ''drug-free'' and ''free from the effects of such substances'' do not accurately capture the NRC's intent with respect to this performance objective. These terms could be misunderstood as requiring FFD programs to have the goal of preventing any drugs and their effects from being present in the workplace, which could include medications that individuals who are subject to the rule may take to treat health problems. Therefore, the final rule replaces ''drug-free'' and ''free of the effects of such substances'' with the more specific phrase ''free from the presence and effects of illegal drugs and alcohol'' to refer to the specific substances that are proscribed. This revision clarifies that the NRC does not intend for FFD programs to prohibit individuals from taking the medications they need to maintain their health or bringing those medications to the workplace. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule also replaces the phrase ''have a goal of'' in the former rule with the phrase ''provide reasonable assurance'' which more accurately captures the intent of this performance objective. The NRC has eliminated the phrase ''have a goal of'' because § 26.23(d) is a performance objective and, therefore, the phrase is unnecessary. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule without changing the intended meaning of the performance objective.

Section 26.23(e) of the final rule adds a provision to require licensees and other entities to provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety. This new performance objective, consistent with Goal 2 of this rulemaking to strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue, specifies the objective of the requirements concerning worker fatigue that the NRC has added to the final rule. Worker fatigue cannot be measured or controlled with precision. Also, licensees and other entities do not have direct control over all matters that may influence worker fatigue. Therefore, § 26.23(e) establishes a ''reasonable assurance'' criterion for the performance objective. Worker fatigue

can result from many causes (e.g., work hours, sleep disorders, demands outside the workplace). In addition, individuals differ in their responses to conditions that cause fatigue. As a consequence, work-hour limits alone do not address all causes of fatigue, nor do they prevent fatigue related to work hours for all workers. Contemporary methods for addressing worker fatigue (e.g., Rogers, 1996, 1997; Hartley, 1998; Carroll, 1999) are commonly referred to as ''fatigue management'' programs and use diverse methods (e.g., training, behavioral observation, fatigue countermeasures) in addition to work-hour controls to prevent, detect, and mitigate fatigue. Accordingly, § 26.23(e) establishes a performance objective of reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are ''managed'' commensurate with maintaining public health and safety. The performance objective permits licensees and other entities to apply risk-informed fatigue management controls for individuals consistent with the significance of their work activities to the protection of public health and safety.

Section 26.25 [Reserved]

The final rule has amended and moved the requirements from proposed § 26.25 [Individuals subject to the fitness-for-duty program] to § 26.4 of the final rule. This change is discussed in detail in this document with regard to § 26.4.

Section 26.27 Written Policy And Procedures

Section 26.27 of the final rule reorganizes and amends former § 26.20 [Written policy and procedures. The final rule divides into separate paragraphs the requirements related to the FFD policy and FFD program procedures that are intermixed within the former section. This organizational change makes the requirements related to the FFD policy and procedures easier to locate within this section, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(a) of the final rule amends the first paragraph of former § 26.20. The former provision required licensees to establish and implement written policies and procedures designed to meet the performance objectives and specific requirements of this part and to retain superseded copies of the policies and procedures. The final rule replaces the term ''licensee'' in the former rule with the phrase ''licensees and other entities'' because entities other than licensees are subject to this requirement, as discussed with respect to § 26.3 [Scope]. The final rule adds the term ''maintain'' to the former requirement to ''establish and implement'' written policies and procedures to reflect the fact that licensees and other entities who are subject to Part 26 must occasionally revise FFD program policies and procedures to keep them current when FFD program personnel or other aspects of the FFD program change. The final rule replaces ''specific'' with the term ''applicable'' in the final sentence because all the requirements in Part 26 do not apply to all the licensees and other entities who are subject to the rule, as discussed with respect to § 26.3. The final rule also eliminates ''designed to'' from this sentence because it is unnecessary. The NRC has moved the records retention requirements contained in the second sentence of the former provision to § 26.713(d) in Subpart N [Recordkeeping and Reporting Requirements] of the final rule. Subpart N groups together the recordkeeping and reporting requirements that are interspersed throughout the former rule. The NRC has made these changes to the organization and language of former § 26.20 to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b) of the final rule amends former § 26.20(a). The former provision established requirements for the written FFD policy, and the final rule expands the list of topics that the FFD policy must address as a result of discussions with stakeholders during the public meetings mentioned in Section I.D. Stakeholders noted that the list of topics in the former rule is incomplete because it does not include many topics about which individuals who are subject to the policy should be aware in order to be able to comply with the policy. Therefore, the final rule adds topics to the policy content requirements in former § 26.20(a) to ensure that FFD policies will be complete. The NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

Section 26.27(b) of the final rule also adds requirements for the written FFD policy to be clear, concise, and readily available to all individuals who are subject to the policy because neither the former nor final rules require licensees and other entities to provide site-specific FFD training to individuals. However, FFD policies may vary between licensees and other entities with respect to, for example, the sanctions that are applied for confirmed positive, adulterated, or substituted test results, the cutoff levels used in drug or alcohol testing, or the time periods within which an individual who has been selected for random testing must report to the collection site.

Under this final rule, the written FFD policy continues to be the primary means by which a licensee or other entity communicates local variations in FFD policy. In the past, however, a few individuals challenged determinations that they had violated a licensee's FFD policy on the basis that they were not aware of the specific provisions of the policy to which they were subject. Therefore, the final rule adds requirements that the FFD policy must be clear, concise, and readily available in order to promote individuals' awareness of the site-specific FFD policy to which they are subject. The NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

The final rule also adds examples of acceptable methods to make the written policy ''readily available'' to individuals who are subject to the FFD policy, including, but not limited to, posting the policy in various work areas throughout the licensee's or other entity's facilities, providing individuals with brochures, or allowing individuals to print the policy from a computer. The NRC has added these examples to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(1) amends the second sentence of former § 26.20(a). Former § 26.20(a) required that ''the policy must address the use of illegal drugs and abuse of legal drugs (e.g., alcohol, prescription and over-the-counter drugs).'' Section 26.27(b)(1) of the final rule expands this sentence to require the FFD policy to describe the consequences of onsite or offsite use, sale, or possession of illegal drugs in § 26.27(b)(i); the abuse of legal drugs and alcohol in § 26.27(b)(ii); and the misuse of prescription and over-the-counter drugs in § 26.27(b)(iii). The final rule replaces the phrase ''must address'' in the former sentence with the phrase ''must describe the consequences of.'' The updated phrase clarifies the information that the policy must convey to ensure that individuals who are subject to the policy are aware of the consequences of these actions, as specified in the licensee's or other entity's FFD policy. The NRC has made these changes to meet Goal 6 of this

rulemaking to improve clarity in the organization and language of the rule.

The final rule adds § 26.27(b)(2) that requires the FFD policy to state the time period specified by the licensee or other entity within which individuals must report to the collection site after being notified that they have been selected for random testing. The provision does not establish a time limit because there are a variety of circumstances among the different licensees and other entities who are subject to this rule that make it impractical to establish a universal time limit. However, adding the requirement for the licensee's or other entity's FFD policy to establish and convey a time limit is necessary because some programs have not done so. As a result, circumstances have arisen in which individuals who were selected for random testing intentionally delayed reporting to the collection site in order to take steps to subvert the testing process, such as obtaining an adulterant to bring to the collection site or drinking large amounts of liquid to be able to provide a dilute specimen. Furthermore, the longer that an individual who has abused illegal drugs or alcohol is able to delay providing specimens for testing, the more likely it is that the concentrations of an illegal drug or alcohol in the individual's urine, breath, or oral fluids will decrease because of metabolism. As a result, the concentrations may fall below the cutoff levels for those substances by the time the specimens are collected and the individual's substance abuse would not be detected. Therefore, the requirement to establish a time limit within which individuals must report for random testing after notification meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs. The final rule also requires the FFD policy to convey this time limit to ensure that individuals are aware of it, given that a failure to appear for testing within the prescribed time limit may lead to the imposition of sanctions under the FFD policy. The NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

Section 26.27(b)(3) adds a requirement that the FFD policy inform individuals of the consequences of refusing to be tested and attempting to subvert the testing process. With respect to the proposed rule, the final rule clarifies that the written policy statement must also describe the actions that constitute a refusal to provide a specimen for testing. This change, in response to a public comment, clarifies the intent of the provision, consistent with Goal 6 of the rulemaking to improve clarity in the language and organization of the rule. This provision ensures that persons who are subject to the rule are aware of § 26.75(b), which requires licensees and other entities to impose the sanction of permanent denial of authorization for these actions. Section 26.27(b)(3) protects the due process rights of individuals who are subject to drug and alcohol testing under this part by ensuring that they are informed, in advance, of the licensee's or other entity's policies to which they are subject. Therefore, adding this requirement to the final rule meets Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26.

Section 26.27(b)(4)(i) amends former § 26.20(a)(1). Former § 26.20(a)(1) required the FFD policy to prohibit the consumption of alcohol within an abstinence period of at least 5 hours preceding ''any scheduled working tour.'' The final rule replaces the phrase ''any scheduled working tour'' with the phrase ''the individual's arrival at the licensee's or other entity's facility'' as a result of stakeholder comments on the language in the former rule at the public meetings mentioned in Section I.D. The stakeholders commented that the former phrase lacked clarity and could be misinterpreted as meaning, ''any working tour scheduled by the licensee or other entity.'' If the phrase was so interpreted, individuals who are subject to the rule may believe that, if they work on a weekend or work overtime that is not part of their normally scheduled working tour, the rule would permit them to consume alcohol within the 5-hour period before they arrive at work, which would be incorrect. Therefore, the revised language of the final rule clarifies that the pre-work abstinence period applies to the 5 hours before an individual arrives at the licensee's or other entity's facility for any purpose, except if an individual is called in to perform an unscheduled working tour, as discussed with respect to § 26.27(c)(3). The NRC has made this final change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(4)(ii) retains former § 26.20(a)(2) without change.

The NRC has added § 26.27(b)(5) to the final rule to require that the FFD policy inform individuals that abstinence from alcohol during the 5 hours preceding any scheduled tour of duty may not be sufficient to ensure that an individual is fit for duty upon reporting to work. Some individuals who have complied with the 5-hour abstinence requirement could have BACs above the cutoff levels specified in § 26.103 [Determining a confirmed positive test result for alcohol] preceding a scheduled tour of duty, depending on the amount of alcohol and food that the individual consumed before the abstinence period began, body weight, and other factors. By ensuring that individuals who are subject to this part are aware that the required 5-hour abstinence period may be insufficient to ensure they have a BAC below the cutoff levels in this part when arriving at the licensee's or other entity's facility, this provision to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to alcohol testing under Part 26.

Section 26.27(b)(6) amends the last sentence of former § 26.20(a). That sentence required the FFD policy to address other factors that could affect individuals' abilities to perform their duties safely and competently, such as mental stress, fatigue, and illness. The final rule adds a requirement for the FFD policy also to address the use of prescription and over-the-counter medications that could cause impairment at work. For example, some licensees or other entities may require individuals to self-report to the FFD program their use of any prescription medications that are labeled with a warning indicating that use of the medication may cause impairment. The licensee's or other entity's FFD policy may require that an individual who is taking a medication that can cause impairment must be temporarily reassigned to duties that the individual can perform without posing a risk to the individual or public health and safety while he or she is taking the medication. Therefore, the final rule requires licensees and other entities to include such information in the FFD policy to ensure that individuals are aware of the actions they may be required to take when using these substances, consistent with Goal 7 of this rulemaking with respect to protecting the rights (including due process) of individuals who are subject to the policy. The addition of this requirement also increases the internal consistency of the rule because other portions of the final rule establish requirements related to using prescription and over-the-counter medications. For example, § 26.29(a)(6) requires FFD training to address use of prescription and over-the-counter medication. Also, § 26.185(j)(2) requires the MRO to determine whether a positive confirmatory drug test result that results from using a prescription or over-the-counter medication represents

substance abuse. Therefore, the requirement for the FFD policy to address the use of prescription and over-the-counter medications that could cause impairment at work also meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(7) amends former § 26.20(b). Former § 26.20(b) required the FFD policy to describe programs that are available to individuals desiring assistance in dealing with drug, alcohol, or other problems that may adversely affect their performance of their duties. Section 26.27(b)(7) of the final rule adds fatigue as one of the problems for which individuals may be seeking assistance because sleep disorders (e.g., sleep apnea, insomnia, restless leg syndrome) can substantially affect individuals' abilities to obtain sufficient quality sleep. Poor quality sleep causes fatigue that may degrade an individual's ability to safely and competently perform his or her duties. Sleep disorders affect a sizeable portion of the U.S. work force. According to polls conducted by NSF, about two-thirds of U.S. adults report experiencing one or more symptoms associated with insomnia, sleep apnea, or restless leg syndrome at least a few nights a week (National Sleep Foundation, 2003) and nearly one out of five (19 percent) report making occasional or frequent errors because of sleepiness (National Sleep Foundation, 2000). Section 26.27(b)(7) ensures that individuals are aware of the services that are available for diagnosing and treating sleep disorders that can adversely affect their job performance. The NRC has made this change to meet Goal 2 of this rulemaking to strengthen the effectiveness of FFD programs at nuclear power plants by reducing the potential for worker fatigue to adversely affect public health and safety and the common defense and security, through establishing clear and more readily enforceable requirements concerning the management of worker fatigue. In addition, the final rule replaces the phrase ''adversely affect the performance of activities within the scope of this part'' in the former provision with the phrase ''could adversely affect an individual's ability to safely and competently perform the duties that require an individual to be subject to this part'' for the reasons discussed with respect to § 26.23(c).

Section 26.27(b)(8) retains the requirement in former § 26.20(d) that the FFD policy must specify the consequences of violating the policy. The NRC has moved the former requirements that were related to the procedures that the licensee or other entity would implement if an individual violates the FFD policy to § 26.27(c) of the final rule, which addresses FFD program procedures, for organizational clarity.

Section 26.27(b)(9) adds a requirement that licensees' and other entities' FFD policies must describe the individual's responsibility to report legal actions, as defined in § 26.5 [Definitions]. The new requirement to report legal actions is discussed with respect to § 26.61 [Self-disclosure and employment history]. The final rule requires the FFD policy to address the reporting of legal actions to ensure that individuals are aware of this and are not at risk of sanctions for failing to report any legal actions. Thus, the NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to the policy.

Section 26.27(b)(10) adds a requirement for the FFD policy to describe the responsibilities of managers, supervisors, and escorts to report FFD concerns. The former rule implied that managers and supervisors have the responsibility to report FFD concerns in § 26.22(a)(5), which required managers and supervisors to be trained in procedures ''for initiating appropriate corrective action.'' Similarly, the last phrase of former § 26.22(b) required that escorts be trained in procedures ''for reporting problems to supervisory or security personnel'' and, therefore, also implied that escorts have a reporting responsibility. However, the former rule did not explicitly state that the FFD policy must convey this requirement. Therefore, the final rule adds § 26.27(b)(10) to enhance the internal consistency of the rule. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(b)(11) adds a requirement for the FFD policy to state that individuals who are subject to the rule must report FFD concerns, consistent with § 26.33 [Behavioral observation]. Section 26.33 requires individuals who are subject to the rule to perform behavioral observation and to report an FFD concern if they detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from fatigue or any cause that, if left unattended, may constitute a risk to the health and safety of the public. Section 26.29 [Training] requires individuals to be trained in behavioral observation. The agency has added these requirements to enhance the effectiveness of Part 26 by ensuring the early detection of individuals who are not fit to perform the duties that require them to be subject to this part. This is one of the performance objectives that FFD programs must meet, as discussed with respect to § 26.23(c). This provision also improves consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56 [Personnel access authorization requirements for nuclear power plants] as supplemented by orders to nuclear power plant licensees dated January 7, 2003, as discussed in Section IV.B of this document. The specific requirement in § 26.27(b)(11) for licensees' and other entities' FFD policies to state that individuals must report FFD concerns is necessary to ensure that individuals are aware of their responsibility to report concerns (and that sanctions may be imposed if they do not) to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to the policy.

Section 26.27(c) of the final rule combines the requirements related to procedures contained in former § 26.20(c) through (e), and adds other requirements, as described in the following paragraphs.

Section 26.27(c)(1) retains the requirements in former § 26.20(c). The NRC has replaced the phrase in the proposed rule ''privacy and due process rights of an individual who provides a specimen'' with the phrase ''privacy and other rights (including due process) of an individual who provides a specimen'' in the final rule. The NRC has made this change in response to a public comment that stated the proposed phrase may be interpreted to limit individuals' protected rights to due process. This phrase clarifies the requirement for ''protecting the employee'' contained in former § 26.20(c). For example, individuals' privacy rights under the final rule include, but are not limited to, requirements for the protection of personal information that is collected about the individual and individual privacy during specimen collections. Other examples of individuals' rights under the final rule include, but are not limited to, the right to an objective and impartial review of a determination that the individual has violated the FFD policy, the right to advance knowledge of rule provisions and FFD policy requirements that affect the individual, and the right to request testing of a split specimen or retesting an aliquot of a single specimen, if the individual questions a confirmed positive, adulterated, or substituted test result.

The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(2)(i) and (c)(2)(ii) divides former § 26.20(d) into separate paragraphs that address different topics. Section 26.27(c)(2)(i) retains the former requirement that licensees and other entities must have procedures that specify the immediate and followup actions that must be taken if an individual is determined to have been involved in the use, sale, or possession of illegal drugs. Like the former provision, § 26.27(c)(2)(ii) requires licensees' and other entities' procedures to specify the immediate and followup actions to be taken if an individual is determined to have consumed alcohol to excess before the mandatory prework abstinence period, or while on duty, as determined by a test that measures BAC. With respect to the proposed rule, the final rule also adds the phrase ''or consumed any alcohol during the mandatory prework abstinence period'' to clarify the prohibition against any alcohol consumption, not only excess consumption, during the pre-work abstinence period. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(2)(iii) and (c)(2)(iv) adds requirements that licensees and other entities must prepare written procedures for implementing the FFD program that describe immediate and followup actions for attempted subversion of the testing process. Section 26.27(c)(2)(iii) requires procedures to specify immediate and followup actions if an individual has attempted to subvert the testing process by adulterating, substituting, or diluting specimens (in vivo or in vitro), or by any other means. Section 26.27(c)(2)(iv) requires procedures to address the actions to be taken if an individual has refused to provide a specimen for testing. The final rule adds these provisions for consistency with § 26.75(b). Section 26.75(b) requires licensees and other entities to terminate an individual's authorization and, thereafter, permanently deny authorization to any individual who has committed or attempted any act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen for any test required under § 26.31(c). Adding the requirements for procedures to address these circumstances meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(2)(v) adds a requirement that the written procedures must describe immediate and followup actions for individuals who have had drug- or alcohol-related legal actions taken against them, as defined in § 26.5. This provision supports related provisions in § 26.69(d). Section 26.69(d), in general, requires licensees and other entities to take certain steps if an individual has had drug- or alcohol-related legal actions taken against them while they are maintaining authorization to perform the duties that require them to be subject to this part. Adding the requirement for procedures to address these circumstances ensures the internal consistency of the final rule and meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has reorganized § 26.27(c)(3) of the final rule, with respect to the proposed rule, to clarify which provisions apply to ''emergencies'' and which apply to ''unscheduled working tours.'' The NRC received a public comment that suggested the term ''emergency'' may be too limiting. However, the NRC believes the term ''emergency'' accurately reflects NRC's intent and has retained this term in the final rule. Section 26.27(c)(3) amends former § 26.20(e). The provision requires licensees and other entities to have procedures to describe the process that the licensee or other entity will use to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty.

The final rule retains and modifies the other requirements of former § 26.20(e), as described in the following paragraphs.

Section 26.27(c)(3)(i) retains former § 26.20(e)(1). The provision requires the individual who is called in to state whether the individual considers himself or herself fit for duty and whether he or she has consumed alcohol within the pre-duty abstinence period stated in the FFD policy. The final rule adds the requirement to state whether he or she considers himself or herself to be fit for duty, in addition to stating whether he or she has consumed alcohol because the NRC recognizes that conditions other than the consumption of alcohol may cause an individual to be unable to safely and competently perform duties, including, but not limited to, fatigue (as discussed with respect to Subpart I [Managing Fatigue]). The NRC received a comment suggesting that individuals who are called in should only be required to report if they are not fit for duty or have consumed alcohol during the pre-duty abstinence period. The NRC believes that this alternative would be less protective of public health and safety, as an affirmative obligation to provide a statement may dissuade individuals who would be tempted to remain silent. Requiring individuals to report other conditions that may cause them to be impaired when called in under § 26.27(c)(3)(i), strengthens the effectiveness of FFD programs by providing the licensee or other entity with more complete information about the individual's condition to determine whether there is a need to establish controls and conditions under which the individual may safely perform work, as required under § 26.27(c)(3)(iii). Therefore, the NRC has adopted the proposed provision as final. The NRC has made these changes to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.27(c)(3)(ii) specifies the procedures to follow if the individual has consumed alcohol in the pre-duty abstinence period and is called in for an unscheduled working tour, including an unscheduled working tour to respond to an emergency. Section 26.27(c)(3)(ii)(A) retains former § 26.20(e)(2). The provision requires that an individual who reports that he or she has used alcohol and is called in must be subject to a determination of fitness by breath analysis. The NRC has added a new § 26.27(c)(3)(ii)(B) to the final rule to permit the licensee or other entity to assign the individual to duties that require him or her to be subject to this part, if the results of the determination of fitness indicate that the individual is fit to safely and competently perform his or her duties. The NRC has also added a new § 26.27(c)(3)(ii)(C) to the final rule to prohibit the licensee or other entity from assigning the individual to duties that require him or her to be subject to this part, if the individual is not required to respond to an emergency and the results of the determination of fitness indicate that the individual may be impaired. The NRC has also added § 26.27(c)(3)(ii)(D) that retains a portion of former § 26.20(e)(3). The provision requires the procedures to state that consumption of alcohol during the 5-hour abstinence period required in paragraph (b)(4)(i) of this section may not by itself preclude a licensee or other entity from using individuals who are needed to respond to an emergency. This provision also retains and modifies a portion of former § 26.20(c)(3). It states that if the determination of fitness indicates that an individual who has been called in for an unscheduled working tour to

respond to an emergency may be impaired, the procedure must require the establishment of controls and conditions under which the individual who has been called in can perform work if necessary.

The NRC has added § 26.27(c)(3)(ii)(E) to the final rule to clarify that licensees and other entities may not impose sanctions if an individual is called in for an unscheduled working tour for having consumed alcohol during the preduty abstinence period specified in the FFD policy. This change ensures that, if an individual who is called in unexpectedly has a confirmed positive test result for alcohol, he or she would not be subject to the sanctions that are otherwise required under this part for a confirmed positive alcohol test result. The NRC believes that sanctions for the consumption of alcohol in these circumstances would be inappropriate because the individual would have been unaware that he or she would be called in to work. The revision is also consistent with the original intent of the rule. Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.27(c)(4) adds a requirement that FFD procedures must describe the process to be followed when another individual's behavior raises an FFD concern and the process for reporting the concern. As discussed with respect to § 26.27(b)(11), this provision is consistent with § 26.33, which establishes a requirement that all individuals must perform behavioral observation and report any FFD concerns. This provision is also consistent with § 26.29, which requires individuals to be trained to perform behavioral observation. The NRC has added this requirement to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 4 to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.27(d) of the final rule retains the requirements of former § 26.20(f) without changes.

Section 26.29 Training

Section 26.29 of the final rule combines and amends former § 26.21 [Policy communications and awareness training] and § 26.22 [Training of supervisors and escorts]. This section clarifies that all individuals subject to this subpart must receive the same scope of training, to include, for example, behavioral observation, whereas former § 26.22 required that only supervisors and escorts must receive behavioral observation training. Increasing the number of individuals who are trained in behavioral observation enhances the effectiveness of FFD programs by increasing the likelihood of detecting potential impairment, consistent with Goal 3 of this rulemaking.

Section 26.29(a) of the final rule combines the training topics listed in former §§ 26.21(a)(1) through (a)(5), 26.22(a)(1) through (a)(5), and 26.22(b). The agency has rewritten the required training topics in terms of knowledge and abilities (KAs) to be consistent with terminology used by licensees and other entities in other required training programs. This change meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.29(a)(1) combines former § 26.21(a)(1) with the latter portion of former § 26.21(a)(5). Consistent with the former training requirements, the provision requires licensees and other entities to ensure that individuals who are subject to this subpart have knowledge of the FFD policy and procedures that apply to them, the methods used to implement the policy and procedures, and the consequences of violating the policy and procedures.

Section 26.29(a)(2) retains the requirement in former § 26.22(a)(1) that licensees and other entities must ensure that individuals understand their roles and responsibilities under the FFD program, such as avoiding substance abuse and reporting for testing within the time limit specified in FFD program procedures.

Section 26.29(a)(3) amends the terminology used in former § 26.22(a)(2). Former § 26.22(a)(2) required FFD training to address the roles and responsibilities of others, such as the personnel, medical, and EAP staffs. The final rule replaces the references to the ''personnel'' function and ''medical'' staff in former § 26.22(a)(2) with ''human resources'' and ''FFD'' staff, respectively. The final rule also moves the reference to the MRO into this section from former § 26.21(a)(3). These updates to the terminology in this section are consistent with other terms used throughout the final rule to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.29(a)(4) and (a)(5) amends former § 26.21(a)(4) and (a)(2), respectively, by changing some of the language used in the former provisions. Former § 26.21(a)(4) required FFD training to inform individuals who are subject to the rule of any EAPs that are available to them. The final rule eliminates the reference to EAPs ''provided by the licensee'' in the former provision and amends it as ''EAP services available to the individual'' because other entities are also subject to this requirement under the final rule. Section 26.29(a)(5) amends former § 26.21(a)(2) by replacing the phrase ''abuse of drugs and misuse of alcohol'' with ''abuse of illegal and legal drugs and alcohol'' for greater accuracy in describing the required knowledge. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.29(a)(6) retains the portion of former § 26.21(a)(3) that required licensees to ensure that individuals understand the effects of prescription and over-the-counter drugs and dietary factors on job performance. The final rule adds a requirement for FFD training to address the effects of alcohol, illness, mental stress, and fatigue on job performance, in order to ensure that individuals understand the bases for the licensee's or other entity's FFD policy regarding these conditions. The NRC has moved the requirement in the last sentence of former § 26.20(a) to § 26.27(b)(6) of the final rule because that section addresses FFD policy requirements. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.29(a)(7) retains the portion of former § 26.21(a)(3) that required licensees and other entities to ensure that individuals who are subject to the rule understand the effects of prescription and over-the-counter drugs and dietary factors on drug and alcohol test results. Examples of medications, supplements, and dietary factors that can affect drug and alcohol test results may include, but are not limited to, ingesting foods containing poppy seeds, drinking coca tea, using some liquid or inhalant cold and cough preparations containing alcohol or codeine, and taking supplements containing hemp oil.

Section 26.29(a)(8) and (a)(9) of the final rule retains the requirements in former § 26.22(a)(3) and (a)(4), respectively, without changes.

Section 26.29(a)(10) amends former § 26.22(a)(5). The provision retains the former requirement for FFD training to address the licensee's or other entity's process for initiating appropriate corrective action if an individual has an FFD concern about another person, including referral to the EAP. The final rule adds a requirement for FFD training

to ensure that individuals understand their responsibility to report FFD concerns to the person(s) who are designated to receive such reports in FFD program procedures. This change is consistent with § 26.33, which requires individuals to perform behavioral observation and report any FFD concerns, as discussed with respect to § 26.27(b)(11). The change is also consistent with § 26.27(c)(4), which requires procedures for implementing the requirement. The NRC has added this group of interrelated requirements to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 4 to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.29(b) of the final rule adds a requirement that individuals must demonstrate attainment of the KAs specified in § 26.29(a) by passing a comprehensive examination. The NRC has added this requirement because in several instances since Part 26 was first promulgated, individuals were able to overturn determinations that they had violated a licensee's FFD policy on the basis that they had not understood the information they received during FFD training and could not be expected to comply with the requirements of the policy. Therefore, the final rule requires individuals to demonstrate their attainment of the KAs listed in § 26.29(a) to ensure that the FFD training has been effective. The final rule requires remedial training for those who fail to achieve a passing score of 80 percent on the examination. Section 26.29(b) also requires the examination to include at least one question for each KA. These requirements are modeled on other required training programs that have been successful in ensuring that examinations are valid and individuals have achieved an adequate understanding of the subject matter. Establishing a method to ensure that individuals understand the requirements with which they must comply meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The provision also permits the use of various media for administering the comprehensive examination, in order to achieve the efficiencies associated with computer-based training and testing, for example, and other new training delivery technologies that may become available. Permitting the use of various media to administer the examination meets the portion of Goal 3 of this rulemaking to improve the efficiency of FFD programs. The permission also meets Goal 5 to improve Part 26 by eliminating or modifying unnecessary requirements through providing flexibility in the methods that licensees and other entities may use to administer the required examination.

Section 26.29(c) of the final rule combines and amends the portions of former §§ 26.21(b) and 26.22(c) that required FFD training for individuals who are subject to this section before they are permitted to perform duties that require them to be subject to this part.

Section 26.29(c)(1) requires that all personnel who are subject to this section must complete FFD training before the licensee or other entity grants initial authorization to the individual, as defined in § 26.55 [Initial authorization]. The final rule also requires that an individual's training must be current before the licensee or other entity grants an authorization update or reinstatement to the individual, as defined in § 26.57 [Authorization update] and § 26.59 [Authorization reinstatement], respectively. The provision also eliminates the requirement in former § 26.22(c) to upgrade training for newly assigned supervisors within 3 months of a supervisory assignment because all personnel will receive the same scope of training and be required to complete the training before a licensee or other entity grants authorization to any individual. These changes are consistent with the requirements related to granting and maintaining authorization that are established in Subpart C [Granting and Maintaining Authorization] of the final rule, as discussed in this document with respect to that subpart. The changes also meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.29(c)(2) retains and combines the requirements for annual refresher training in former §§ 26.21(b) and 26.22(c). Former § 26.21(b) addressed individuals who are subject to this part and former § 26.22(c) addressed supervisors and escorts. The final rule combines the former requirements because all personnel receive the same scope of training under the final rule. The final rule specifies that individuals must complete the refresher training every 12 months, or more frequently when the need is indicated. With respect to the proposed rule, the final rule gives some examples of situations that indicate a need to conduct the refresher training more frequently than every 12 months, but this list is not inclusive of all situations that may indicate this need. Adding these examples clarifies the NRC's intent and meets Goal 6 of the rulemaking to clarify the language of the rule. The final provision permits individuals who pass a comprehensive annual examination that demonstrates their continued understanding of the FFD program requirements to be excused from the refresher training that the provision otherwise requires. The examination is necessary to meet the examination requirements specified in § 26.29(b) [Comprehensive examination]. Individuals who do not pass must undergo remedial training. Permitting individuals to pass a comprehensive examination rather than take refresher training each year ensures that they are retaining their FFD KAs while reducing some costs associated with meeting the annual refresher training requirement. Therefore, this change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.29(c)(3) permits licensees and other entities to use various media, in addition to traditional classroom instruction, for presenting initial and refresher training for the same reasons discussed with respect to the portion of § 26.29(b) that permits licensees and other entities to use various media to administer the comprehensive examination. The requirements for a licensee or other entity to monitor the completion of training and provide access to an instructor or subject matter expert ensures that individuals who are trained using different media achieve the same understanding as persons who are trained in a classroom setting with an instructor present. This flexibility may reduce the costs associated with presenting initial and refresher training only in a classroom setting. Therefore, this change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

To meet the annual refresher training requirement for individuals, § 26.29(d) of the final rule permits licensees and other entities to accept the training of individuals who have been subject to another training program that meets the requirements of this section. Licensees and other entities are also permitted to accept a passing result from a comprehensive examination that was administered by another training program that meets the requirements of this section in lieu of refresher training, if the examination meets the requirements of § 26.29(b). This requirement meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31 Drug and Alcohol Testing

Section 26.31 of the final rule renames former § 26.24 [Chemical and alcohol testing]. The final rule, in general, replaces the former term ''chemical testing'' with ''drug testing'' because the testing for chemicals that is required in the rule is performed only in the context of urine drug testing. Therefore, the term ''drug testing'' more accurately conveys the nature of the testing that is performed. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(a) [General] of the final rule retains but updates the language in former § 26.24(a) to be consistent with the new terminology used throughout the rule as discussed in § 26.5. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.31(b) [Assuring the honesty and integrity of FFD program personnel] of the final rule amends former Section 2.3 in Appendix A to Part 26. Other than making minor clarifications to the rule text as explained below, the NRC has adopted the requirements of paragraph (b) of this section as proposed, without change.

Section 26.31(b)(1) amends the first paragraph of former Section 2.3 in Appendix A to Part 26. This paragraph required licensees to carefully select and monitor persons responsible for administering the testing program to ensure that they meet the highest standards of honesty and integrity. The final rule replaces the former list of individuals who are subject to this requirement with a cross-reference to § 26.4(g) of the final rule, which specifies in detail the FFD program personnel who must be subject to the FFD program. This cross-reference avoids repeating the list of personnel in this provision.

The provision also adds a reference to factors, other than a personal relationship with an individual who is subject to testing, that have the potential to cause an individual to be subject to influence attempts or may adversely affect the honesty and integrity of FFD program personnel. In addition to a personal relationship with an individual who is subject to testing, factors that could cause an individual to be compromised may include, but are not limited to, a substance abuse problem or financial problems. Therefore, the final rule adds a reference to these additional factors to more accurately characterize the scope of potential concerns that licensees and other entities must consider when selecting and monitoring the honesty and integrity of FFD program personnel. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.31(b)(1)(i) amends former Section 2.3(2) in Appendix A to Part 26 in response to implementation questions regarding the former requirements. The provision clarifies that the background investigations, credit and criminal history checks, and psychological evaluations that are required for persons who are granted unescorted access to protected areas in nuclear power plants are acceptable when determining the honesty and integrity of FFD program personnel. The final rule retains the term ''appropriate'' in the former rule for two reasons. First, it indicates that FFD program personnel who are employed by entities who are subject to the rule but are not nuclear power plants, may meet the requirements through investigations, checks, and evaluations that provide the information needed to determine the honesty and integrity of FFD program personnel, but the investigations, checks, and evaluations may differ from those required under nuclear power plant access authorization programs. In addition, the final rule retains the term ''appropriate'' because it has particular relevance to the requirement for licensees and other entities to conduct criminal history checks for FFD program personnel. In some cases, licensees and other entities cannot legally obtain the same type of criminal history information about FFD program personnel as they are able to obtain for other individuals who are subject to Part 26. Therefore, the term ''appropriate'' is used to indicate that local criminal history checks for FFD program personnel who do not have unescorted access to nuclear power plant protected areas are acceptable. The NRC has made these changes to meet the portion of Goal 6 of this rulemaking that pertains to improving clarity in the language of the rule.

The NRC has relaxed the requirement in former Section 2.3(2) in Appendix A to Part 26 for appropriate background checks and psychological evaluations to be conducted at least once every 3 years to require that credit and criminal history checks and updated psychological assessments be conducted nominally every 5 years. The final rule relaxes the former requirement for several reasons. First, the NRC is not aware of any instances in which licensees and other entities have identified new information about FFD program personnel from updating the background checks and psychological assessments that had not already been identified through other avenues, including self-reports by FFD program personnel, drug and alcohol testing, and behavioral observation. However, the NRC continues to believe that the required updates provide an independent method to verify the ongoing honesty and integrity of FFD program personnel that is necessary because of the critical importance of FFD program personnel in assuring program effectiveness. Therefore, the final rule retains the former requirement for updated background checks and psychological assessments, but reduces the required frequency of these updates from every 3 years to every 5 years under the final rule. The NRC has made this change to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. In addition, the frequency for these updates increases the consistency of Part 26 with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003, which is Goal 4 of this rulemaking.

Section 26.31(b)(1)(ii) amends and clarifies former Section 2.3(1) in Appendix A to Part 26 in response to the many implementation questions that have arisen after the regulation was published. The former rule prohibited individuals who have a personal relationship with the individual being tested (i.e., a donor), such as the donor's ''supervisors, coworkers, and relatives,'' from performing any ''collection, assessment, or evaluation procedures'' involving the individual being tested. The NRC included the restriction on ''supervisors, coworkers, and relatives'' in the former rule to provide examples of the ''personal relationships'' referenced in the introductory paragraph of former Section 2.3 in Appendix A to Part 26. Some licensees have misinterpreted the restriction on coworkers in the former rule as meaning that no one who is an employee of the same corporation may be involved in collection, assessment, or evaluation procedures. However, in a large corporation, many individuals employed by the same corporation will not have personal relationships with FFD program personnel, specifically, or with other individuals who are subject to testing, in general. Therefore, in § 26.31(b)(1)(ii), the phrase ''in the same work group'' clarifies that the example regarding coworkers pertains to individuals who report to the same manager. For example, FFD program

personnel report to the FFD program manager and would be considered ''coworkers in the same work group'' to whom the restriction applies. In addition, the section adds a reference to determinations of fitness (discussed with respect to § 26.189 [Determination of fitness]) to provide a clarifying example of the assessment and evaluation procedures that FFD program personnel are prohibited from performing if the FFD program staff member has a personal relationship with the subject individual. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(b)(1)(iii) relaxes the prohibition on individuals who have ''personal relationships'' with the donor from performing specimen collection procedures in former Section 2.3(1) in Appendix A to Part 26. The NRC acknowledges that the former restriction imposed an unnecessary burden when the objective of ensuring the integrity of specimen collections in these circumstances could be achieved by other means. Therefore, in § 26.31(b)(1)(iii), individuals who have a personal relationship with a donor are permitted to collect specimens, if another individual who does not have a personal relationship with the donor and is not a supervisor, a coworker in the same work group, or a relative of the donor monitors the collection and preparation of the specimens for shipping. The section also provides examples of the types of individuals who may monitor the integrity of specimen collection procedures in these circumstances, including but not limited to, security force or quality assurance personnel. By permitting monitored collections in these circumstances while continuing to assure the integrity of specimen collections from FFD program personnel, this provision meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. The final rule retains the prohibition for individuals who have personal relationships with the donor from performing assessment and evaluation procedures because monitoring of these activities by qualified personnel is not feasible.

If a directly observed collection is required, § 26.31(b)(1)(iv) of the final rule adds a prohibition for an individual who has a personal relationship with the donor from acting as a urine collector or observer. This prohibition is necessary to minimize embarrassment to the donor (and the collector) during a directly observed collection. The NRC has added this provision to meet Goal 7 of this rulemaking, relating to protecting the privacy rights of individuals who are subject to Part 26.

Section 26.31(b)(1)(v) amends former Section 2.3(3) in Appendix A to Part 26 to require that MROs who are on site at a licensee's or other entity's facility must be subject to behavioral observation. For the purposes of § 26.31(b)(1)(v), a ''facility'' includes, but is not limited to, a licensee's or other entity's corporate offices and any medical facilities that the licensee or other entity operates. The NRC has added this requirement because MROs are ''persons responsible for administering the testing program,'' but some FFD programs have not included MROs in the behavioral observation element of their programs. However, the final rule limits the behavioral observation of MROs to those times when they are on site at a licensee's or other entity's facility in order to permit licensees and other entities to continue relying on the services of MROs who normally work independently, often alone, in offices at a geographical distance from the licensee's or other entity's facilities so that behavioral observation is impractical. Limiting the requirement for behavioral observation of MROs to those instances in which the MRO is working on site at a licensee's or other entity's facility is adequate to ensure the continuing honesty and integrity of these MROs because MROs who work off site would not interact on a daily basis with other individuals who are subject to the FFD program. Therefore, off site MROs would be less likely to be subject to potential influence attempts than MROs who normally work on site because they are generally inaccessible. The final rule continues to require all MROs to be subject to the other FFD program elements that are required in this subpart. These elements include drug and alcohol testing and regular psychological assessments and background investigations, which permit licensees and other entities to monitor the honesty and integrity of off site MROs. The NRC has added this relaxation to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

A new § 26.31(b)(2) provides another relaxation from the former rule related to collecting specimens from FFD program personnel. The provision permits FFD program personnel to submit specimens for testing at collection sites that meet the requirements of 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944; August 9, 2001). As discussed with respect to § 26.31(b)(1), some FFD program personnel, such as contract MROs and EAP staff members, normally work at locations that are so distant from a licensee's collection site(s) as to make it impractical for them to be randomly tested at a licensee's or other entity's collection site. Permitting these FFD program personnel to be tested at local collection sites that follow similar procedures is adequate to meet the goal of ensuring their continuing honesty and integrity. Therefore, the NRC has added this provision to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.31(c) [Conditions for testing] replaces former § 26.24(a)(1) through (a)(4). The provision lists the situations in which testing is required in separate paragraphs, such as ''pre-access,'' ''for cause,'' and ''post-event'' testing to clarify that each situation for which testing is required stands on its own. The former provision in § 26.24(a)(3), in particular, has led to confusion and misinterpretation of the requirements, to be corrected as noted below. Subparts E [Collecting Specimens for Testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services] address the specific requirements for conducting the testing. The final rule reorganizes and amends former § 26.24(a)(1) through (a)(4) to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(c)(1) [Pre-access] amends former § 26.24(a)(1). Former § 26.24(a)(1) required pre-access testing within 60 days before the initial granting of unescorted access to protected areas or assignment to duties within the scope of this part. Section 26.31(c) of the final rule introduces the concepts of ''initial authorization,'' ''authorization update,'' and ''authorization reinstatement,'' which refer to categories of requirements that licensees and other entities must meet in order to assign an individual to duties that require the individual to be subject to Part 26. Section 26.65 [Pre-access drug and alcohol testing] in Subpart C of the final rule specifies detailed requirements for conducting pre-access testing.

Section 26.31(c)(2) [For cause] and (c)(3) [Post event] clarifies and amends former § 26.24(a)(3), as follows:

Section 26.31(c)(2) continues to require for-cause testing in response to any observed behavior or physical

condition indicating possible substance abuse. The final rule also retains the former requirement for testing if the licensee or other entity receives credible information that an individual is engaging in substance abuse. Section 26.3 defines the term ''substance abuse.''

Section 26.31(c)(3) [Post event] amends the portion of former § 26.24(a)(3) that required drug and alcohol testing when an event involving a failure in individual performance leads to significant consequences. The final rule amends the former provision because it has been subject to misinterpretation and numerous questions from licensees.

The phrase ''if there is reasonable suspicion that the worker's behavior contributed to the event'' in former § 26.24(a)(3) has been subject to misinterpretation. The location of this phrase at the end of the list of conditions under which post-event testing must be performed has led some licensees to conclude that this phrase applies only to events involving actual or potential substantial degradations of the level of safety of the plant. Other licensees have misinterpreted the term ''reasonable suspicion'' as meaning ''reasonable suspicion of substance abuse'' or some other ''illegal'' or ''disreputable'' activity. Neither of these interpretations is consistent with the intent of this provision. Therefore, to clarify the intent of the provision, the final rule eliminates the phrase ''if there is reasonable suspicion that the worker's behavior contributed to the event'' from the end of the list of significant events that require post-event testing and, instead, requires post-event testing as soon as practical after significant events (as listed in § 26.31(c)(3)(i) through (c)(3)(iii)) involving a human error that may have caused or contributed to the event. The final rule uses the term ''human error'' rather than the former term ''worker's behavior'' to emphasize that post-event testing is required for acts that unintentionally deviated from what was planned or expected in a given task environment (see NUREG/CR–6751, ''The Human Performance Evaluation Process: A Resource for Reviewing the Identification and Resolution of Human Performance Problems'') as well as failures to act (i.e., errors of omission). Therefore, testing is required regardless of whether there was ''reasonable suspicion'' that the individual was abusing drugs or alcohol for the consequences listed in the section.

In addition, the NRC has added the second sentence of § 26.31(c)(3) to clearly delineate the scope of individuals who must be subject to post-event testing. Some licensees have misinterpreted the former provision as requiring the testing of all individuals who are involved in a significant event, including individuals whose behavior played no causal or contributing role in the event. For example, these licensees' FFD programs would require testing an individual who was exposed to radiation in excess of regulatory limits, even if other individuals' actions (or failures to act) were responsible for the event and the individual who suffered the exposure was a bystander. Therefore, the second sentence of the provision clarifies the original intent of this section by stating that only the individual(s) who committed the error(s) is subject to post-event testing.

Section 26.31(c)(3)(i) provides a threshold for the types of workplace personal injuries and illnesses for which post-event testing is required in response to implementation questions related to former § 26.24(a)(3). Some licensees have misinterpreted the former provision as requiring post-event testing for any personal injury, no matter how minor. This section clarifies the type of personal injuries and illnesses for which post-event testing would be required by establishing a threshold that is based on the general criteria contained in 29 CFR 1904.7, ''General Recording Criteria,'' of the regulations of the Occupational Safety and Health Administration (OSHA) for recording occupational injuries and illnesses. As defined in the OSHA standard and the final rule, these include any injuries and illnesses which result in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant injury or illness as diagnosed by a physician or other licensed health care professional. In the case of a significant injury or illness diagnosed by a physician or health care professional, a serious injury or illness does not need to result in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, or loss of consciousness. The final rule adds this clarification to reduce the number of unnecessary post-event tests performed for minor injuries and illnesses and meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31(c)(3)(i) also includes the qualifying phrase, ''within 4 hours after the event,'' with reference to the recordable personal injuries and illnesses that would trigger post-event testing. The NRC acknowledges that in some cases it is difficult to detect illnesses and injuries that meet the threshold for post-event testing at the time they occur. For example, if an individual has been injured on site but does not report the injury to the licensee or other entity and waits for several days to seek treatment from his or her private physician, the licensee or other entity may not learn of the injury. The extent of an injury may be unclear at the time it occurs and may appear to fall below the threshold for post-event testing until several days have passed. In these examples, if the licensee or other entity learns after several days that the injury would have met the threshold for post-event testing, it would be too late for post-event testing to be of any value in determining whether the individual's use of drugs or alcohol may have contributed to the event. If alcohol or drug use had contributed to the event, testing several days later would be unlikely to detect it because of the effects of metabolism. Further, it would be difficult to prove that any positive test results reflected the individual's condition at the time the event occurred rather than subsequent drug or alcohol use. Therefore, the final rule limits post-event testing to situations in which the licensee or other entity can determine that an injury or illness meets the threshold within four hours after the event has occurred, and can conduct the testing within a time frame that will provide useful information about the individual's condition at the time of the event. However, the section should not be misinterpreted as requiring post-event testing to be completed within four hours after the event. Section 26.31(c)(3) defines the time period after the event within which testing must be completed as ''as soon as practical.'' The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31(c)(3)(ii) retains the relevant language in the corresponding portion of former § 26.24(a)(3) without change.

Section 26.31(c)(3)(iii) retains the relevant language in the corresponding portion of former § 26.24(a)(3). However, as discussed with respect to § 26.31(c), the final rule eliminates the former qualifying phrase ''if there is reasonable suspicion that the worker's behavior contributed to the event.'' The NRC has eliminated this phrase because it is preferable to determine the need for post-event testing using an objective standard based on the severity of the underlying event. The experience of the DOT with post-accident testing, for example, is that it is more effective to separate completely ''for cause''

concepts (such as ''reasonable suspicion'' of substance abuse) from post-event testing. Under the final rule's approach, if one of the events occurs that is defined in the regulations as requiring post-event testing, then that testing should be carried out irrespective of the presence or absence of any ''reasonable suspicion'' of substance abuse.

Section 26.31(c)(4) [Followup] retains the intent of former § 26.24(a)(4) but amends its language. The final rule eliminates the former phrase ''to verify an individual's continued abstention from the use of substances covered under this part'' because it could be misinterpreted as limiting the substances for which followup testing is permitted to only those listed in § 26.31(d)(1) [Substances tested]. The final rule revises this phrase as ''to verify continued abstinence from substance abuse'' to clarify that FFD programs are permitted to conduct followup testing for any substances an individual may have abused, subject to certain additional requirements discussed with respect to § 26.31(d)(1)(i). Section 26.69 [Authorization with potentially disqualifying fitness-for-duty information] establishes detailed requirements for conducting followup testing, where they apply to licensees' and other entities' processes for granting and maintaining authorization. The final rule makes these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(c)(5) [Random] simplifies former § 26.24(a)(2) to define random testing as one of the conditions under which testing is required. The NRC has moved the detailed requirements for implementing random testing that were contained in former § 26.24(a)(2) to § 26.31(d) [General requirements for drug and alcohol testing] of the final rule. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.31(d) to the final rule to better organize requirements related to the general administration of drug and alcohol testing. The final rule presents more detailed requirements for conducting drug and alcohol testing in Subparts E, F, and G. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(d)(1) [Substances tested] retains the list of drugs for which testing must be conducted in former Section 2.1(a) in Appendix A to Part 26, but clarifies that for some drugs the testing is conducted to detect drug metabolites. The NRC has moved the provisions detailing the circumstances in which testing for these substances must be performed (i.e., pre-access, post-event, random) to § 26.31(c) for organizational clarity. In addition, the section adds adulterants to the list of substances for which testing must be conducted, consistent with the addition of specimen validity testing requirements to the final rule, as discussed with respect to § 26.31(d)(3)(i). Section 26.31(d)(1)(i) retains the permission in the second sentence of former § 26.24(c) for licensees and other entities to consult with local law enforcement agencies or other sources of information to identify drugs that may be abused by individuals in the geographical locale of the FFD program.

Section 26.31(d)(1)(i)(A) retains the permission in former § 26.24(c) for licensees and other entities to add to the panel of drugs for which testing is required in § 26.31(d)(1). Additional drugs may include, but are not limited to, ''designer drugs,'' such as ecstasy or ketamine, and illegal drugs that are popular in some geographical areas, such as lysergic acid diethylamide-25 (LSD). The provision also requires that any additional drugs must be listed on Schedules I–V of section 202 of the Controlled Substances Act [21 U.S.C. 812], which is consistent with the definition of ''illegal drugs'' in former § 26.3.

Section 26.31(d)(1)(i)(B) retains the last sentence in former § 26.24(c). The provision requires licensees and other entities to establish appropriate cutoff levels for any additional substances for which testing will be conducted.

Section 26.31(d)(1)(i)(C) retains the requirement in former Section 2.1(c) in Appendix A to Part 26. The provision specifies that licensees and other entities must establish rigorous testing procedures for any additional drugs.

Section 26.31(d)(1)(i)(D) further clarifies the requirement in § 26.31(d)(1)(i)(C) for ''rigorous testing procedures.'' The provision replaces the portion of former Section 1.1(2) in Appendix A to Part 26 that required licensees to obtain written approval from the NRC to test for additional drugs. The purpose of the former requirement was to provide an opportunity for the NRC to verify that the assays and cutoff levels licensees use in testing for additional drugs are scientifically sound and legally defensible. However, the former requirement also imposed a reporting burden. The final provision eliminates this reporting requirement and replaces it with requirements for an independent forensic toxicologist who has no relationships that could be construed as potential conflicts of interest to conduct the review that the NRC currently performs. The final rule requires the independent forensic toxicologist to certify, in advance and in writing, that the assay to be used in testing for any additional drugs or drug metabolites, and the cutoff levels to be applied, are scientifically sound and legally defensible. This section also specifies the required qualifications for the forensic toxicologist.

Certification of the assay and cutoff levels are not required in two circumstances: (1) If the HHS Guidelines are revised to permit use of the assay and the cutoff levels in Federal workplace drug testing programs and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for drug or drug metabolites; and (2) if the licensee and other entity received written approval of the NRC to test for the additional drug or drug metabolites before the implementation date of the final rule, which is 365 days after the date the final rule is published in the **Federal Register.** Certification by a toxicologist is unnecessary in these two circumstances because it would be redundant. By eliminating or modifying unnecessary requirements, while continuing to ensure that any drug testing conducted under Part 26 is scientifically sound and legally defensible, this provision meets Goal 5 of this rulemaking.

Section 26.31(d)(1)(ii) amends former Section 2.1(b) in Appendix A to Part 26. The provision permits licensees and other entities, when conducting for-cause, post-event, and followup testing, to test for any drugs listed on Schedules I–V of the Controlled Substances Act that the licensee or other entity suspects the individual may have abused, as follows:

The section adds a reference to post-event testing for consistency with the intent of former Section 2.1(b) in Appendix A to Part 26, which permitted testing for any illegal drugs during a for-cause test. The former rule included post-event testing within the definition of for-cause testing. The final rule uses a distinct term ''post-event'' testing to refer to the testing that is required following certain events as discussed with respect to § 26.31(d)(3). Therefore, it is necessary to add a reference to post-event testing to this section to retain the full intent of the former provision.

The section also adds a reference to followup testing, which permits the

licensee or other entity to test for an additional drug if an individual who is subject to followup testing is suspected of having abused it. For example, if an SAE, in the course of performing a determination of fitness under § 26.189 found that an individual was abusing barbiturates, this provision would permit followup testing to verify that the individual is abstaining from such abuse. The NRC has made this change to strengthen the followup testing element of FFD programs by ensuring that followup testing would detect continued drug abuse. Therefore, this provision is consistent with Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The section retains the limitation in former Section 2.1(b) in Appendix A to Part 26 that permitted testing only for illegal drugs that the individual is suspected of having abused and extends that limitation to followup testing. The final rule extends this limitation to followup testing to protect donors' rights to privacy, which is the same reason that the limitation was established in the former rule with respect to for-cause testing. Licensees and other entities are prohibited from conducting a wide spectrum of tests for any drugs without suspicion that the individual had abused them because such tests could reveal personal medical information about the individual that is irrelevant to the performance objectives of this part, as discussed with respect to § 26.23. Thus, extending the former limitation on for-cause testing to followup testing meets Goal 7 of this rulemaking to protect the privacy rights and other rights (including due process) of individuals who are subject to Part 26.

The final rule replaces the term ''illegal drugs'' in former Section 2.1(b) in Appendix A to Part 26 with a specific reference to the drugs that are listed on Schedules I–V of the Controlled Substances Act. These schedules list drugs with abuse potential and include many drugs with legitimate medical uses that are not ''illegal'' when used with a valid prescription for medical purposes. Therefore, replacing the term ''illegal drugs'' with the reference to Schedules I–V of the Controlled Substances Act (CSA) more accurately characterizes the specific drugs for which testing is permitted. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.31(d)(1)(ii) also applies the new requirements in § 26.31(d)(1)(i)(D) related to testing for drugs that are not included in the FFD program's panel of drugs to for-cause, post-event, and followup testing. The section requires that a forensic toxicologist certify the assays and cutoff levels to be used in testing for the additional drugs. The provision provides consistency with § 26.31(d)(1)(i)(D) and ensures that the testing is scientifically sound and legally defensible. The NRC has made this change to protect donors' rights as it relates to minimizing the possibility of false positive test results. The provision also strengthens the effectiveness of FFD programs by ensuring that tests for additional drugs that are conducted for cause, post-event, or as part of a followup program will accurately detect drugs that an individual may have abused. Therefore, the NRC has made this change to meet Goal 7 of this rulemaking to protect the rights (including due process) of individuals who are subject to Part 26 and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added the last sentence of § 26.31(d)(1)(ii) to prohibit inappropriate practices that some FFD programs have implemented. The NRC is aware that some FFD programs have directed their HHS-certified laboratories to test specimens that are collected for for-cause, post-event, or followup testing at the assay's LOD without first subjecting the specimens to initial testing. In addition, if a drug or drug metabolite is detected at the LOD, the MROs in these programs have confirmed the test result as an FFD policy violation even if the quantitative test result falls below the FFD program's established confirmatory cutoff level. Although these practices may increase the likelihood of detecting drug abuse, they are inconsistent with one of the bases for establishing cutoff levels for drug testing. This basis is to minimize the likelihood of false positives that could result in the imposition of sanctions on an individual who has not abused drugs. It also subjects individuals who are undergoing for-cause, post-event, or followup testing to unequal treatment when compared to individuals who are subject to random and pre-access testing, in which the established cutoff levels must be applied. Therefore, the final rule specifically prohibits these practices, but adds, with respect to the proposed rule, an exception for a situation in which the specimen is dilute and the licensee or other entity has requested the HHS-certified laboratory to evaluate the specimen under §§ 26.163(a)(2) and 26.185(g)(3). The NRC has made these changes to meet Goal 7 of this rulemaking as it relates to protecting the rights of individuals (including due process) who are subject to Part 26, by requiring that individuals who are subject to for-cause, post-event, and followup testing must be subject to the same testing procedures and cutoff levels as others who are tested under this part.

With respect to the proposed rule, the NRC has added § 26.31(d)(1)(iii) to the final rule to require the licensee or other entity to document the additional drug(s) for which testing will be performed in written policies and procedures. A public comment suggested that licensees and other entities should not screen for drugs in addition to those listed in paragraph (d)(1) of this section without identifying them in advance. The NRC agrees that informing individuals of the substances for which testing will routinely occur and the cutoff levels to be applied may deter abuse of those substances. Information about the drugs for which testing will occur, and their potential effects on job performance, is also an important part of the FFD training that individuals must receive under § 26.29, to assist individuals in meeting their responsibilities under the rule. This added provision is also consistent with § 26.31(d)(3)(iii)(A) that requires licensees and other entities to document more stringent cutoff levels for drug testing than those specified in § 26.163 in written policies and procedures. However, the NRC does not agree that a licensee should be prohibited from testing for drugs in addition to those listed in the rule without identifying them in advance. Although deterring substance abuse is an important goal of the rule, detecting substance abuse is equally important. Therefore, both the former and final rules permit licensees to add drugs to the panel of substances for which they routinely test, as well as to conduct tests to detect any drugs listed on Schedules I–IV of the CSA in followup, post-event, and for-cause testing that the individual is suspected of abusing. The NRC has added this requirement to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.31(d)(2) [Random testing] reorganizes and amends the requirements for conducting random testing. These requirements appeared in former § 26.24(a)(2), as described in the following paragraphs.

Section 26.31(d)(2)(i) adds a requirement for licensees and other entities to administer random testing in a manner that provides reasonable assurance that individuals are unable to

predict the time periods during which specimens will be collected. The NRC has added this provision because the NRC is aware of instances when individuals who believed they would have a positive test result if tested have been able to determine the days on which collections were being conducted. This determination then gave them the opportunity to leave work under the guise of illness in order to avoid the possibility of being tested. The ability to detect that specimens are being or will be collected for random testing also provides an opportunity for individuals to be prepared to subvert the testing by procuring an adulterant or urine substitute and keeping it available on their persons during the periods that specimens are collected. However, the NRC also recognizes that it is impossible to ensure that individuals are unable to detect the periods when specimens are being collected. At a minimum, coworkers will be suspicious that collections are occurring if they observe an individual leaving the work site and returning within a short time, even if the supervisor and individual do not discuss the reason for the individual's short absence. Therefore, the section requires licensees and other entities to conduct random testing in a manner that would provide ''reasonable assurance'' that individuals are unable to predict when specimens will be collected, rather than requiring them to ''ensure'' that the period of time during which specimens will be collected cannot be detected. However, licensees and other entities are required to minimize the likelihood that individuals who are subject to testing know that they are more likely to be called for testing at certain times than others.

Within this context, § 26.31(d)(2)(i)(A) adds a requirement that licensees and other entities take reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period, or create the appearance that specimens are being collected during a portion of each day on at least 4 days in each calendar week at each site. With respect to the proposed rule, the final rule clarifies that in the latter instance, the portions of each day and the days of the week must vary in a manner that cannot be predicted by donors. The NRC, after publishing the proposed rule, recognized the need for additional clarity in this provision to illustrate the NRC's intent. Therefore, the NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 23.31(d)(2)(i)(A) requires licensees and other entities to take reasonable steps to minimize the cues that persons may use to detect that specimens will be collected at a certain time. These cues may include, but are not limited to, the presence of a mobile collection facility on site and the presence of collectors at the site only on days that collections occur, or having the lights on in a designated collection site and occupying it only when the collection site is in use. A reasonable step to minimize cues associated with activities inside a collection site could be covering any outside windows so that a passerby cannot detect whether the collection site is occupied. Other steps to meet the requirement could include, but would not be limited to, stationing a mobile collection facility on site for some part of the day on 4 days each week or assigning individuals to staff the designated collection site during periods that specimens are not being collected during some portion of each day on at least 4 days in each calendar week. Maintaining the appearance that the collection site is active on more than half of the days in each week makes it more difficult for individuals to plan to subvert the testing process by leaving work when they believe specimens are being collected. By reducing the opportunities for individuals to subvert the testing process by having advanced warning that specimens are being collected, the requirements in § 26.31(d)(2)(i) and paragraph (A) of this section meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.31(d)(2)(i)(B) amends the third sentence of former § 26.24(a)(2). This sentence required that specimens must be collected ''at various times during the day.'' The final rule expands the former requirement to require licensees and other entities to collect specimens on an unpredictable schedule, including weekends, backshifts, and holidays, and at various times during a shift. The purpose of the former and final provisions is to ensure that individuals cannot predict the times they will be tested, as well as prevent them from perceiving that there are ''safe'' periods during which they will not be tested, which may lead them to believe they could engage in substance abuse without fear of detection. Varying the time periods during which specimens are collected on an unpredictable schedule also increases the rule's effectiveness in deterring substance abuse, which meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.31(d)(2)(ii) retains the third sentence of former § 26.24(a)(2). Section 26.31(d)(2)(ii) states that random testing must be administered on a nominal weekly frequency. The former requirement to collect specimens for random testing at ''various times during the day'' is retained in § 26.31(d)(2)(i)(B).

Section 26.31(d)(2)(iii) requires individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after they have been notified that they have been selected for testing within the time period established in the FFD policy. The necessity for the FFD policy to establish a time limit within which individuals must report for testing is discussed with respect to § 26.27(b)(2). Section 26.31(d)(2)(iii) further clarifies this requirement by emphasizing the individual's responsibility to report as soon as reasonably practicable after notification. For example, in order to cover all of the possible situations when it may not be possible for an individual to immediately report for testing after notification (which could include the time required to travel to a collection site or to change clothes and be monitored for contamination after working under a radiation work permit), the FFD policy may permit individuals up to two hours to report for testing after notification. However, if no legitimate work, travel, or other demands would prevent an individual from immediately reporting for testing, the provision requires the individual to report as soon as he or she is notified. This provision strengthens FFD programs by further reducing opportunities for individuals to subvert the testing process and, therefore, meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section (d)(2)(iv) retains the portion of the first sentence of former § 26.24(a)(2) that required licensees to ensure that individuals subject to testing have an equal probability of being selected and tested. The final rule splits proposed § 26.31(d)(2)(iv) into two paragraphs after the first sentence of the proposed paragraph, and renumbers the subsequent paragraphs to accommodate this change. This reorganization is an effort to clarify the requirements of this section, consistent with Goal 6 of this rulemaking to improve clarity in organization and language of the rule.

As a result of this renumbering, § 26.31(d)(2)(v) of the final rule amends the first sentence of former § 26.24(a)(2) to clarify that individuals who are off site when selected for testing and not reasonably available for testing when selected, must be tested at the earliest

reasonable and practical opportunity. However, the final rule, with respect to the proposed rule, adds a clarification that individuals who are on site and not reasonably available for testing also must be tested at the earliest reasonable and practical opportunity. The NRC has made this change in response to a public comment, which suggested that the second sentence of proposed § 26.31(d)(2)(iv) could be interpreted as requiring individuals who are on site but not reasonably available for testing to be tested immediately. The commenter gave the example of an individual who is suited up for work in a radiologically controlled area from which he or she could not exit to be tested in a reasonable period of time. The NRC notes that in these cases, individuals who are on site but not reasonably be available for testing are required to report to the collection site as soon as reasonably practical after notification (emphasis on ''notification''), under § 26.31(d)(2)(iii). In the given example, the supervisor would only notify the individual about testing after he or she is out of containment and has changed back to street clothes. If this were to occur at the end of the shift when collectors have left the site, this individual would not be notified that he or she must report for testing until the next time both the donor and the collectors are available to collect specimens for testing. Because there would be no known reason that this individual will test positive at the time of collection, any possible delays in testing should not compromise the performance objectives of the FFD program. However, the FFD program is responsible for preventing potential abuses brought on by such delays, which could include a supervisor protecting known substance abusers through improper notifications or delaying testing until completion of a critical job. Therefore, based on this analysis, the NRC has clarified this provision to reflect the public comment and clarify the NRC's intent, consistent with Goal 6 of this rulemaking to improve clarity in the language of the rule.

The requirements of § 26.31(d)(2)(v) prohibit licensees and other entities from returning the names of the individuals who are offsite when selected for testing or who are on site and not reasonably available for testing when selected to the random testing pool without conducting a test, as has been the practice of some licensees. Returning these individuals' names to the random testing pool without conducting a test ensures that they are immediately eligible for another unannounced test, as required in § 26.31(d)(2)(vi), but does not ensure that all individuals who are subject to this part have an equal probability of being tested. Therefore, the requirement that individuals who are off site when selected for testing or who are on site and not reasonably available for testing when selected must be tested at the earliest reasonable and practical opportunity meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The section includes the phrase ''at the earliest reasonable and practical opportunity when both the donor and collectors are available to collect specimens for testing'' to clarify that licensees and other entities are not required to call an individual back to the site if he or she is off site when selected for testing. In addition, the provision does not require licensees and other entities to make special arrangements to ensure that a collector is available to collect the specimens as soon as the individual returns to the site. The NRC is aware that some licensees have called in individuals and collectors in the past under these circumstances. However, these practices may permit individuals to predict that they will be subject to testing when they return to the site. This prediction would provide them with an opportunity to take actions to subvert the testing process, as discussed with respect to § 26.31(d)(2)(i). Therefore, the provision requires licensees and other entities to collect specimens from an individual who is off site when selected for testing or on site and not reasonably available for testing, in a manner that also ensures that the individual does not have advance notification that he or she has been selected for testing. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.31(d)(2)(vi) of the final rule, renumbered from (d)(2)(v) in the proposed rule, retains the second sentence of former § 26.24(a)(2). This provision requires that an individual who has completed a test is immediately eligible for another random test.

Section 26.31(d)(2)(vii) of the final rule, renumbered from (d)(2)(vi) in the proposed rule, amends the last sentence of former § 26.24(a)(2). The NRC has made this change in response to licensee implementation questions with respect to the meaning of the term ''workforce'' in the former rule. These questions related to whether ''workforce'' means all individuals who are employed by the licensee, including individuals who are not subject to Part 26, all individuals at a site, or all individuals who are subject to the licensee's FFD program. This provision clarifies that the number of random tests that must be performed in a year must equal 50 percent of the population of individuals who are subject to random testing under the FFD program. If a common FFD program covers several sites, the ''population'' would include all individuals who are subject to the common FFD program. The population also includes individuals who have applied for authorization and who are subject to random testing under § 26.67 [Random drug and alcohol testing of individuals who have applied for authorization]. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.31(d)(3) [Drug testing] to the final rule to group requirements in one section that are related to the general administration of drug testing. The NRC has made this change because requirements that address this topic were dispersed throughout the former rule. Grouping them together in a section makes them easier to locate within the final rule. This reorganization meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(d)(3)(i) combines and modifies some of the requirements in former Section 1.1(3) in Appendix A to Part 26, former § 26.24(f), the first sentence of former Section 2.8(e)(1) in Appendix A, and former Section 2.8(a) and (b) in Appendix A to Part 26. These former provisions required licensees and other entities to use only HHS-certified laboratories to perform drug testing, except if initial tests were performed at a licensee testing facility. However, the final rule has clarified the first sentence of this section, with respect to the proposed rule, to include validity tests, validity screening tests, and initial validity tests. The NRC has retained other detailed requirements in these sections, but they are presented in the appropriate sections in Subparts E, F, and G of the final rule. The agency has made these changes to meet Goal 6 of this rulemaking to improve the organizational clarity of the rule.

In addition, § 26.31(d)(3)(i) requires that specimens sent to the HHS-certified laboratory by the licensee or other entity must be subject to initial validity and drug testing by the laboratory. However, the final rule clarifies the language of the proposed rule to require that any specimens that yield ''positive initial drug test results or are determined by initial validity testing to be of

questionable validity'' must be subject to confirmatory testing by the laboratory. The final rule deletes the term ''non-negative'' from the proposed rule and adds the term ''questionable validity'' for the reasons discussed with respect to § 26.5. The NRC has made these changes to meet Goal 6 of this rulemaking to improve the organizational clarity of the rule.

Specimen validity testing refers to testing conducted by a laboratory to identify attempts to tamper with a specimen. Attempts to tamper with a specimen may include:

(1) Adulteration, which means putting a substance into a specimen that is designed to mask or destroy the drug or drug metabolite that the specimen may contain or to adversely affect the assay reagent;

(2) Dilution, which means adding a liquid that, in contrast to an adulterant, would not be detected by validity testing, to the urine specimen to decrease the concentration of a drug or metabolite below the cutoff concentration; and

(3) Substitution, which means replacing a valid urine specimen with a drug-free specimen.

When HHS published its Notice of Final Revisions to the HHS Guidelines (66 FR 43876; August 21, 2001) to establish requirements for specimen validity testing performed by HHS-certified laboratories, HHS reported that the number of adulterated and substituted urine specimens has been increasing among the specimens tested under the Federal agency workplace drug testing program and the DOT regulations (49 CFR Part 40). Program experience gained after Part 26 was first promulgated has also indicated an increasing number of adulterated and substituted urine specimens submitted to HHS-certified laboratories from Part 26 testing programs.

Although former Part 26 contained a number of requirements related to specimen validity (e.g., the fifth sentence of former Sections 2.1(e), 2.4(f)(2), 2.4(g)(14) through (g)(16), and 2.7(d) in Appendix A to Part 26), the methods available to tamper with specimens have become more sophisticated after the rule was first published and more sophisticated methods of detecting tampering are necessary. Therefore, the final rule incorporates new requirements for HHS-certified laboratories to conduct specimen validity tests that are consistent with similar provisions contained in the most recent revision to the HHS Guidelines (69FR 19643; April 13, 2004). The NRC has added these new requirements for specimen validity testing to strengthen FFD programs by improving current laboratory procedures to detect specimens that are diluted, adulterated, or substituted. This change is consistent with Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. Detecting specimen tampering is necessary to identify individuals who may attempt to hide drug abuse. Attempts to tamper with a specimen provide clear evidence that the individual is not trustworthy and reliable. Also, these individuals' drug use may pose a risk to public health and safety and the common defense and security, as discussed with respect to § 26.23.

Section 26.31(d)(3)(ii) amends the first sentence of former § 26.24(d)(1). This sentence permits licensees and other entities to conduct initial testing of urine specimens at a licensee testing facility, provided that the licensee testing facility staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented. The final rule adds permission for licensees and other entities to perform initial validity testing at a licensee testing facility for the reasons discussed with respect to § 26.31(d)(3)(i). Subpart F establishes detailed requirements related to specimen validity testing at licensee testing facilities.

Section 26.31(d)(3)(iii) is based upon the portions of former Section 2.7(e)(1) and (f)(2) in Appendix A to Part 26. These former sections established the cutoff levels for initial and confirmatory drug testing, respectively, which licensees must apply under the former rule. However, the final rule requires FFD programs to apply the updated cutoff levels specified in § 26.163(a)(1) for initial drug testing and § 26.163(b)(1) for confirmatory drug testing. The final rule clarifies the language of the proposed rule by adding that either the licensee testing facility or HHS-certified lab conducts the initial drug testing and the HHS-certified laboratory conducts the confirmatory testing. Consistent with the first sentence of former § 26.24(b), the second sentence of this provision permits FFD programs to implement more stringent cutoff levels than specified in the rule, but establishes additional requirements related to lower cutoff levels, as is discussed with respect to paragraphs (d)(3)(iii)(A) through (C). The NRC has relocated the permission in the first sentence of former § 26.24(b) to implement a broader panel of drugs to § 26.31(d)(1), as discussed with respect to that section. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.31(d)(3)(iii)(A) retains the third and fourth sentences of former § 26.24(b) regarding management actions and sanctions for confirmed positive drug test results based on any lower cutoff levels established by the FFD program. The final rule adds a requirement that the FFD program's written policy and procedures must document the FFD program's lower cutoff levels in the written policy and procedures to ensure that individuals who are subject to testing are aware of the cutoff levels that would be applied to their drug test results in order to protect their rights. The NRC has made this change to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.31(d)(3)(iii)(B) requires the uniform application of the FFD program's cutoff levels for drugs and drug metabolites, including any more stringent cutoff levels in all tests conducted under this part and equally to all individuals who are subject to testing, except as permitted under § § 26.31(d)(1)(ii), 26.163(a)(2) for dilute specimens, and § 26.165(c)(2) for retesting specimens. As discussed with respect to § 26.31(d)(1)(ii), some FFD programs have adopted the practice of testing specimens at the assay's LOD for for-cause, post-event, and followup tests, which results in some individuals receiving unequal treatment under the rule. Therefore, the NRC has added the section to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC has added § 26.31(d)(3)(iii)(C) to the final rule to specify requirements for establishing more stringent cutoff levels. Before implementing the more stringent cutoff levels, licensees and other entities are required to obtain certification from a forensic toxicologist that the more stringent cutoff levels are technically sound and legally defensible, with two exceptions. Certification by a forensic toxicologist is not required if: (1) If the HHS Guidelines are revised to lower the cutoff levels for the drug or drug metabolites in Federal workplace drug testing programs and the licensee or other entity implements the cutoff levels published in the HHS guidelines; or (2) if the licensee or other entity received written approval of the NRC to test for lower cutoff levels before the implementation date of this rule, which is 365 days after the date the final rule

is published in the **Federal Register**. Certification by a toxicologist is unnecessary in these two circumstances because it would be redundant. The NRC has made this change to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements, while continuing to protect donors' right to accurate and reliable drug testing.

Section 26.31(d)(4) [Alcohol testing] updates former § 26.24(g) that contained general requirements for conducting alcohol testing. The update reflects other changes that have been made in the final rule. The NRC has amended the former cross-reference to Section 2.7(o)(3) in Appendix A to Part 26 to refer to § 26.91(a) in Subpart E, which contains detailed requirements for conducting alcohol testing. The NRC has added the reference to oral fluids as acceptable specimens for initial alcohol testing to this section. The basis for adding oral fluids as acceptable specimens for initial alcohol testing is discussed with respect to § 26.83 [Specimens to be collected]. The NRC has changed the BAC at which a confirmatory test is required to 0.02 percent (from 0.04 percent) in the provision for consistency with the revised alcohol cutoff levels in § 26.99 [Determining the need for a confirmatory test for alcohol] and § 26.103 [Determining a confirmed positive test result for alcohol]. The basis for the revised alcohol cutoff levels is discussed with respect to those sections of the final rule. The agency has deleted reference to blood testing for alcohol because the final rule no longer permits donors to request blood testing for alcohol, as discussed with respect to § 26.83(a) of the final rule.

The NRC has added § 26.31(d)(5) [Medical conditions] to the final rule to address circumstances when it may be impossible or inadvisable to test an individual using the procedures specified in this part. Circumstances have arisen under Part 26, as well as the programs of other Federal agencies, when an individual's medical condition has made it inadvisable to implement testing procedures under the relevant requirements. Therefore, § 26.31(d)(5)(i) permits alternative specimen collection and evaluation procedures for rare instances when it would be difficult or hazardous to the donor to collect breath, oral fluids, or urine specimens, including, but not limited to, required post-event testing when an individual has been seriously injured. Only the MRO is permitted to authorize an alternative evaluation procedure that may include, but is not limited to blood testing for alcohol. Section 26.31(d)(5)(ii) clarifies that necessary medical treatment may not be delayed in order to conduct drug and alcohol testing. These sections are consistent with the requirements of other Federal agencies and meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.31(d)(6) [Limitations of testing] retains and amends former Section 2.1(d) in Appendix A to Part 26. This former section stated that specimens collected under Part 26 may only be designated or approved for testing as described in this part and may not be used for any other analysis or test without the permission of the tested individual. The final rule adds examples of the types of analyses and tests that are prohibited without the donor's written permission. Although the NRC is not aware of any instances when such unauthorized testing has occurred in FFD programs under this part, the technology for performing these analyses and tests has become increasingly available since the regulation was first promulgated. The NRC has added these examples to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.33 Behavioral Observation

The NRC has added § 26.33 to the final rule to emphasize that behavioral observation is a required element of FFD programs. The first sentence of § 26.33 requires behavioral observation of individuals subject to this subpart. The second sentence retains former § 26.22(a)(3), (a)(4), and (b), which stated that the individuals who perform behavioral observation must be trained. The third sentence of the section requires that individuals must report FFD concerns arising from behavioral observation to the appropriate personnel designated in the FFD program procedures. The NRC has added these requirements to the final rule to strengthen the behavioral observation element of FFD programs by increasing the likelihood that the licensees and other entities detect and appropriately address impairment and other adverse behaviors. These changes are consistent with Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.35 Employee Assistance Programs

Section 26.35 amends former § 26.25 [Employee assistance programs].

Section 26.35(a) retains the former provision without change and specifies that licensees and other entities shall maintain EAPs that offer confidential assessment, short-term counseling, referral services, and treatment monitoring to individuals who have problems that could adversely affect the individuals' abilities to safely and competently perform their duties. The provision also requires that the EAP be designed to achieve early intervention and provide for confidential assistance.

The NRC has added § 26.35(b) to the final rule to clarify that licensees and other entities are not required to provide EAP services to C/V employees, including those who are working at a licensee's or other entity's facility. With respect to the proposed rule, the final rule clarifies that licensees and other entities are not required to provide EAP services to C/V employees whose work location is a licensee's or other entity's facility. This provision is consistent with the interpretation of the former rule in item 13.1.4 of NUREG–1354. The final rule continues to require that C/V employees who are subject to Part 26 must have access to an EAP, and that licensees and other entities who rely upon the FFD program of a C/V continue to be required to ensure that the EAP of a C/V meets the requirements of this part.

The provision also states that licensees and other entities need not provide EAP services to individuals who have applied for but have not yet been granted authorization under Subpart C. Licensees and other entities are not required to provide an EAP to applicants for authorization because these individuals would not yet be performing duties that could affect public health and safety or the common defense and security. The NRC has added this clarification because applicants are subject to other requirements under the final rule as discussed with respect to § 26.4(h).

Section 26.35(c) amends the last sentence of former § 26.25. The provision emphasizes that the identity and privacy of an individual who seeks EAP services must be protected and clarifies the conditions under which EAP personnel may or must violate an individual's confidentiality. The final rule permits EAP personnel to communicate information about an individual by name to the licensee or other entity under only two conditions: (1) If the individual waives the right to privacy, or (2) EAP personnel determine that the individual's condition or actions pose or have posed an immediate threat to himself or herself or others. By clarifying the NRC's intent

with respect to EAP confidentiality, the provision meets Goal 6 of this rulemaking to improve clarity in the language of the rule because the former provision has been misinterpreted.

The last sentence of former § 26.25 required confidentiality for individuals who seek EAP services, except if EAP professionals determine that the individual's condition ''constitutes a hazard to himself or herself or others.'' Some licensees have over-interpreted this phrase and routinely require EAP staff to report individuals who self-refer for any reason, which is not the intent of this provision. The NRC is also aware that some individuals who are subject to the rule have misinterpreted this phrase as meaning that no self-referral to the EAP would remain confidential and that EAP staff always report self-referrals to licensee management. This perception appears to be widely shared, including by individuals who are subject to FFD programs that have not misinterpreted the former rule and who correctly permit EAP staff to make the determination of whether to report an individual's condition to licensee management.

A key purpose of requiring EAPs under Part 26 is to encourage individuals and their family members to self-refer for any type of problem that could potentially impair job performance, so that early intervention may be offered to prevent the problem from adversely affecting the individuals' job performance. Upon assessment, it is not uncommon for EAP staff to find that a developing substance abuse problem is contributing to a financial or family problem for which an individual has sought assistance. As a result, the EAP provides an important means to detect and achieve early resolution of developing substance abuse and other problems, which if left untreated could have the potential to adversely affect an individual's ability to safely and competently perform his or her duties. The knowledge or perception among individuals who are subject to the rule that self-referrals to the EAP will be reported to management and will routinely result in the loss of authorization represents a significant barrier to the effectiveness of the EAP element of FFD programs. Therefore, the section amends the last sentence of former § 26.25 to clarify that an individual's use of the licensee's or other entity's EAP must remain confidential, except in very limited circumstances.

The NRC has added § 26.35(c)(1) to the final rule to prohibit licensees and other entities from requiring the EAP to routinely report the names of individuals who self-refer to the EAP and the nature of assistance the individuals sought. The provision is necessary to eliminate some licensees' practices of requiring these reports, protect individuals' privacy, and strengthen the EAP element of FFD programs by eliminating a former barrier to self-referrals in some FFD programs. The term ''routinely'' is used to indicate that the final rule permits EAP personnel to report individuals' names and the nature of their problems if the individuals have waived the right to privacy in writing or EAP personnel determine that an individual's condition or actions pose or have posed an immediate risk to public health and safety or the common defense and security. The provision does not prohibit EAPs from reporting program utilization statistics or aggregated data that characterize the types of problems for which the program has provided services because this type of information does not compromise individuals' privacy.

The NRC has added § 26.35(c)(2) to the final rule to provide further clarity in the language of the rule with respect to the conditions under which EAP personnel are excepted from the confidentiality requirement in § 26.35(c) and required to report a concern about an individual to the licensee or other entity. The NRC is confident that EAP personnel have the qualifications and training necessary to continue to make the professional judgments required under the regulations in these circumstances. However, the final rule includes more detail with respect to the conditions and actions that an EAP professional is required to report to ensure that licensees, other entities, and individuals who are subject to the rule better understand the intent of the former and final provisions. The final rule requires EAP personnel to report a concern about a specific individual to licensee or other entity management only when they have substantive reasons to believe that an individual's condition or actions pose or have posed an immediate hazard to themselves or others. The phrase ''substantive reasons to believe'' is used to clarify that casual and/or contextually appropriate comments made by an individual during a counseling session are not a sufficient basis for reporting to the licensee or other entity. For example, an individual's statement that he or she is concerned about becoming an alcoholic would not constitute a substantive reason to believe that the individual's condition poses an immediate hazard. In contrast, this stated concern, in addition to evidence that the individual's personal relationships, financial condition, and/or health are suffering from his or her alcohol consumption, and any indications that the individual has been impaired while in a work status, would constitute substantive reasons to believe that the individual's condition poses an immediate hazard and must be reported.

The NRC has added § 26.35(c)(2)(i) through (iii) to the final rule to provide several examples of conditions and actions that require EAP personnel to provide a report about an individual who has self-referred to licensee or other entity management. Section 26.35(c)(2)(i) requires reporting if the EAP staff has substantive reasons to believe that an individual may harm himself or herself or others, including, but not limited to, plans threatening suicide, radiological sabotage, or physical violence against others. Section 26.35(c)(2)(ii) requires reporting if the EAP staff has substantive reasons to believe that an individual has been impaired from drugs or alcohol while in a work status and is likely to be impaired in the future, as discussed with respect to § 26.35(c)(2). Section 26.35(c)(2)(iii) requires reporting if the EAP staff has substantive reasons to believe that an individual has committed any of the acts that would require a report to the NRC under § 26.719(b)(1) through (b)(3), including but not limited to, the use, sale, distribution, possession, or presence of illegal drugs, or the consumption or presence of alcohol within a protected area or while performing duties that require the individual to be subject to this part. The examples included in these sections are illustrative, and do not represent an exhaustive list of the conditions and actions that EAP staff may encounter that would be reported to licensee or other entity management under the final rule.

For additional clarity, the NRC has added § 26.35(c)(3) to the final rule to cross-reference the provisions in the final rule that specify the actions that licensees and other entities would take after receiving a report from EAP personnel that an individual's condition or actions pose or have posed an immediate hazard to himself or herself or others. As discussed with respect to (§§ 26.69(d) and 26.77(b) of the final rule, those provisions require the licensee or other entity to take immediate action to prevent the individual from performing any duties that require the individual to be subject to this part, ensure that a determination of fitness is performed by a professional who has specific qualifications and

training to address the nature of the individual's problem, and either terminate the individual's authorization or ensure that the condition is resolved before permitting him or her to return to performing duties under this part.

These changes to former § 26.25 are consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, as well as Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.37 Protection of Information

Section 26.37 amends former § 26.29 that contained requirements for protecting the personal information that must be collected under Part 26. In general, this section of the final rule groups requirements related to the protection of personal information that were dispersed throughout the former rule to aid in locating these requirements in the final rule. The NRC has moved the records retention requirement in former § 26.29(a) to Subpart N of the final rule. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.37(a) combines and retains the first sentence of former § 26.29(a) and the second sentence of former Section 3.1 in Appendix A to Part 26. The final rule modifies the language of the proposed rule to require licensees and other entities to establish, use, and maintain a system of files and procedures that protects the individuals' privacy. The NRC, after publishing the proposed rule, recognized the need for more clarity in the language of this provision to illustrate the NRC's intent. Therefore, this change meets Goal 6 of the rulemaking to improve clarity in the language of the rule.

Section 26.37(b) amends former § 26.29(b) and divides it into several sections for clarity. The first sentence of the section amends the first sentence of former § 26.29(b) that prohibited licensees and other entities from disclosing personal information collected under this part to any individuals other than those listed in the sentence. The final rule continues to permit disclosure of the personal information to the listed individuals and adds permission for the licensee or entity to disclose the personal information to others if the licensee or other entity has obtained a signed release for such a disclosure from the individual. The NRC has added the permission to release the personal information to individuals who are not listed in the section with the written consent of the subject individual because some licensees have misinterpreted the former requirement as prohibiting them from releasing the personal information under any circumstances, except to the parties listed in this section. In some instances, such failures to release information have inappropriately inhibited an individual's ability to obtain information that was necessary for a review or appeal of the licensee's determination that the individual had violated the FFD policy. Therefore, the NRC has added the explicit permission for licensees and other entities to release personal information when an individual consents to the release, in writing, to meet Goal 7 of this rulemaking to protect the privacy rights and other rights (including due process) of individuals who are subject to Part 26.

Section 26.37(b)(1) through (b)(8) lists the individuals to whom licensees and other entities are permitted to release personal information about an individual. Section 26.37(b)(3), (b)(4), and (b)(8) retains unchanged the permission for the release of information to NRC representatives, appropriate law enforcement officials under court order, and other persons as required by court order. Section 26.37(b)(1), (b)(2), (b)(5), (b)(6), and (b)(7) amends the related requirements contained in former § 26.29(b) to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The specific changes to former § 26.29(b) include the following:

Section 26.37(b)(1) retains the permission for the release of information to the subject individual and his or her designated representative. The provision adds requirements for the individual to designate his or her representative in writing and specify the FFD matters to be disclosed. The NRC has made these changes in response to implementation questions from licensees. Licensees have sought guidance from the NRC related to the way an individual must ''designate'' a representative.

Section 26.37(b)(2) retains the permission for the release of information to the licensee's or other entity's MROs. The final rule also permits the release of information to MRO staff members for consistency with § 26.183(d), which permits MRO staff to serve some MRO functions under the direction of the MRO. MRO staff require access to the personal information in order to perform their duties. The role of MRO staff in FFD programs is discussed with respect to § 26.183(d) of the final rule.

Section 26.37(b)(5) amends the former reference to licensee representatives who have a need to have access to the information in performing assigned duties. The former rule referred only to individuals who are performing audits of FFD programs. As a result, some licensees have misinterpreted the former rule as limiting the release of personal information only to such individuals. This was not the intent of the provision. Rather, the NRC intended that licensees and other entities were permitted to release information to their representatives who must have access to the personal information in order to perform assigned duties.

With respect to the proposed rule, the final rule modifies proposed § 26.37(b)(5) to clarify the NRC's intent that the only licensee or other entity representatives who may have access to the personal information collected under this part are persons who have a need for that information to implement the requirements of the rule. The NRC made this change to provide greater assurance that personal information, such as medical records that an individual has submitted to the MRO to document prescription medication for a ''shy bladder'' situation, is not released to persons who do not have assigned duties under the FFD program that specifically require access to that information. Reviewing officials, MROs, SAEs, and other FFD program personnel, as well as auditors, require access to some personal information about individuals in order to perform their assigned duties to implement the FFD program. Human resources personnel may need to know that an individual has violated the FFD policy, if the licensee or other entity terminates an individual's employment in response to an FFD policy violation, but do not need access to the personal information collected about the individual under the FFD program to carry out the process of terminating the individual's employment. The NRC has determined that this additional clarification is necessary to provide further protection of the privacy of persons who are subject to the rule.

Section 26.37(b)(6) and (b)(7) amends the portion of former § 26.29(b) that referred to ''persons deciding matters on review or appeal.'' The NRC has amended the provision in response to implementation questions from licensees, including whether the rule covers persons deciding matters in judicial proceedings or only the internal appeals process specified in former § 26.28 [Appeals], as well as whether

information could be released in a judicial proceeding that the subject individual did not initiate. The final rule clarifies that the permission includes individuals who are presiding in a judicial or administrative proceeding, but only if the subject individual in § 26.37(b)(6) initiates the proceeding. Section 26.37(b)(7) covers ''persons deciding matters under review in § 26.39'' [Review process for fitness-for-duty policy violations], as discussed with respect to that section. The NRC has made these changes to meet Goal 6 of this rulemaking relating to improving clarity in the organization and language of the rule.

The NRC has added § 26.37(c) to the final rule to require the disclosure of relevant information to licensees and other entities, including C/Vs, and their authorized representatives who have a legitimate need for the information and a signed release from an individual who is seeking authorization under this part. This provision clarifies former § 26.29(b) because some licensees have misinterpreted the former provision as prohibiting the release of information to C/Vs who have licensee-approved FFD programs and conduct suitable inquiries on behalf of licensees and other entities. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.37(d) through (f) retains several requirements related to the protection of information in the former rule but moves them into this section for organizational clarity. Section 26.37(d) combines requirements in former § 26.29(b) and Section 3.2 in Appendix A to Part 26 as they relate to an individual's access to records that are necessary for a review of an FFD policy violation. However, the final rule modifies the language of the proposed rule by specifying that it is the FFD program that is required to promptly provide all requested records. The NRC has made this change to meet Goal 6 of the rulemaking to improve clarity in the language of the rule. The final rule also adds ''collection site'' and ''SAE'' to the list of entities who must provide records to an individual or his or her designated representative. The final rule also expands the proposed language to specify the types of records that must be provided. The examples given for the types of records that must be provided to the individual are illustrative, but are not comprehensive of all the types of records that must be provided upon request. The agency has made these changes in response to public comment, to clarify the rule language, to ensure that individuals and representatives can verify the accuracy of FFD records, and to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals subject to Part 26. Section 26.37(e) and (f) retains former Section 3.1 in Appendix A to Part 26 and the last sentence of former § 26.29(b), respectively.

Section 26.39 Review Process for Fitness-for-Duty Policy Violations

Section 26.39 amends former § 26.28 and separates it into several sections. The change from the former section heading eliminates the implication that the internal management review is a legal proceeding. The agency has added several requirements to clarify and strengthen individuals' rights during the review, consistent with Goal 7 of this rulemaking, as described in the following paragraphs.

Former § 26.28 required that individuals who are subject to the rule have an opportunity for a management review of a determination that the individual has violated the licensee's or other entity's FFD policy. Section 26.39(a) retains the requirement that the review must be impartial and adds a requirement that the review must be objective. The NRC has added the requirement for an objective review because some licensees have permitted the same individuals who were involved in the initial determination that an individual violated the FFD policy to provide the review that was required under former § 26.28. The impartiality of individuals who are reviewing their own decisions is questionable and calls into question the effectiveness of the review process. Therefore, the requirement for the review to be both impartial and objective emphasizes the NRC's intent that the review process be effective.

In keeping with revisions to several other sections that are intended to counter subversion of the testing process, § 26.39(a) extends this opportunity to request a review to all FFD violations, including, but not limited to, violations based upon confirmed positive, adulterated, or substituted, or invalid test results. The section also clarifies that applicants for authorization must be given the opportunity for a review. Experience with implementing this section of Part 26 has indicated that some licensees did not provide a review process to individuals who tested positive on pre-access tests. However, the factors that could produce false positive test results among licensee and C/V employees (e.g., administrative or testing errors) are equally likely to occur during pre-access testing of applicants for authorization. If applicants are not provided with a review process, it is possible that some of them would be effectively barred from the industry based on test results erroneously determined to be a violation of the licensee's or other entity's FFD policy. Providing applicants with the opportunity to request a review also enhances program credibility.

Section 26.39(b) specifies that FFD procedures must describe the contents and purpose of the notice that licensees and other entities would be required to provide to an individual who has violated an FFD policy. The provision also requires that the procedures must state that the individual may submit additional relevant information as part of the review process. This clarification is necessary because experience with implementing former § 26.28 has indicated that individuals do not understand the purpose of the review process and their associated rights in some cases.

Section 26.39(c) specifies that the procedure must ensure that the individual who conducts the review is not associated with the administration of the FFD program. The final rule modifies the proposed rule by requiring that only one representative of the licensee's or other entity's management shall conduct the review. The final rule allows only one individual to conduct the review in response to a public comment that stated that the review process required by this section should be consistent with that required by 10 CFR 73.56(e) (personnel access authorization) because this would simplify licensee procedures and would improve the consistency between FFD requirements and access authorization requirements. In specifying that the reviewer may not be anyone associated with the administration of the FFD program, including anyone who made the initial determination that the individual violated the FFD policy, the final rule strengthens the impartiality and objectivity of the review process in order to further enhance individuals' rights. The NRC has made these changes to meet Goal 3 of the rulemaking to increase the effectiveness and efficiency of FFD programs, and Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.39(d) adds a requirement that any records associated with the FFD policy violation must be deleted or corrected, as appropriate, if the policy violation decision is overturned. This requirement is necessary because the final rule permits licensees and other entities to share and rely on information

gathered by other Part 26 programs to a greater extent than is currently possible. Therefore, incorrect records related to an FFD policy violation could significantly inhibit an individual from further employment under a Part 26 program if this information is transmitted to other licensees and entities who are considering whether to grant authorization to an individual. The requirement to delete or correct any records associated with an FFD policy violation that has been overturned will protect individuals from such potential adverse consequences.

Section 26.39(e) of the final rule amends the last sentence of former § 26.28. This sentence stated that licensees and other entities are not required to provide a review procedure to C/V employees and applicants when the C/V is administering its own drug and alcohol testing. The final rule amends the former paragraph in response to implementation questions from licensees who have asked whether the former provision excuses them from providing a review process for C/V employees at any time, including situations when the FFD policy violation was determined as a result of testing conducted by the licensee. The final rule revises this sentence to clarify that the licensee or other entity need not provide a review process if the C/V's drug and alcohol testing program identified the FFD violation to be reviewed. If the licensee's drug and alcohol testing determined the FFD violation, the licensee is required to provide the impartial and objective review. The final rule modifies the proposed rule to state that the licensee need not provide a review procedure to a C/V subcontractor when the FFD policy violation was determined under a C/V's program. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41 Audits and Corrective Action

Section 26.41 of the final rule renames and amends former § 26.80 [Audits]. The NRC has added the phrase ''and corrective action'' to the section heading to emphasize the NRC's intent that licensees and other entities must ensure that corrective actions are taken in response to any adverse findings resulting from an audit. In addition, the final rule reorganizes the audit requirements in former § 26.80, and moves several audit and inspection requirements into this section that were addressed in Appendix A to Part 26. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41(a) [General] of the final rule amends the last sentence in former § 26.80(a). This sentence stated that licensees retain responsibility for the effectiveness of C/V programs and the implementation of appropriate corrective action. The final rule revises this requirement to include HHS-certified laboratories, as well as any C/V FFD program elements and FFD programs that the licensee or other entity relies upon, consistent with the intent of the former requirement. The final rule has added a phrase to the proposed rule that requires licensees to be responsible for the continuing effectiveness of any FFD program services a subcontractor provides to the C/V. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.41(b) [FFD program] of the final rule amends the required audit frequency in former § 26.80(a). (Other provisions of § 26.41 address the other requirements contained in former § 26.80(a), as discussed with respect to the sections of the final rule that address those topics.) The final rule decreases the former 12-month FFD program audit frequency to a nominal 24-month frequency, which grants a petition for rulemaking (PRM–26–1) submitted by Virginia Power on December 30, 1993. Experience with implementing Part 26 has shown that annual audits of the entire FFD program are unnecessary to ensure continued program effectiveness and, therefore, place an unnecessary burden on those entities who are subject to the rule. The NRC decreased the audit frequency to 24 months to relieve this burden and to be consistent with the NRC's schedule for inspecting FFD programs. The change is consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Although the final rule decreases the required audit frequency, licensees and other entities are required to monitor program performance indicators and operating experience, consistent with a performance-based approach, and audit FFD program elements more frequently than every 24 months as needed. In determining the need for more frequent audits, the final rule requires licensees and other entities to consider FFD performance, including but not limited to, the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, and previous audit findings. The provision is intended to promote performance-based rather than compliance-based audit activities and clarify that programs must be audited following a significant change in personnel, procedures, or equipment as soon as reasonably practicable. The NRC recognizes that FFD programs evolve and new issues and problems continue to arise. Turnover of FFD program personnel and contracted services personnel, such as specimen collectors, exacerbates this concern. Licensee audits have identified problems that were associated in some way with personnel changes, such as new personnel not understanding their duties or procedures, the implications of actions that they took or did not take, or changes in processes. The purpose of these focused audits is to ensure that changes in personnel, procedures, or equipment do not adversely affect the operation of the particular program element or function in question. Accordingly, the audit requirement ensures that any programmatic problems that may result from significant changes in personnel, procedures, or equipment are detected and corrected on a timely basis. By requiring more frequent audits of FFD program performance that may require closer monitoring than a nominal 24-month frequency would provide, these changes meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.41(c) [C/Vs and HHS-certified laboratories] of the final rule amends the audit and inspection requirements that are contained in the second sentence of former § 26.80(a) and the third sentence of Section 2.7(m) in Appendix A to Part 26, as follows:

Section 26.41(c)(1) further amends the requirement in former § 26.80(a) for annual audits of C/V FFD programs and program elements and HHS-certified laboratories. The former annual audit frequency is retained only for those portions of C/V FFD programs whose personnel work off site and are not under the daily supervision of FFD program personnel. The activities of C/V personnel who work on site and are under the daily supervision of FFD program personnel are audited under § 26.41(b). Retention of the annual audit requirement for C/Vs whose personnel work off site meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FD programs. The provision is necessary to ensure that the services provided continue to be effective because other means of monitoring their effectiveness, such as daily oversight, are unavailable. The section also retains the annual audit requirement for HHS-certified laboratories. The NRC has retained this audit frequency because of the key role

the laboratories play in the overall effectiveness of Part 26 programs. Retention of these annual audit requirements in the section denies the petition for rulemaking (PRM–26–1) submitted by Virginia Power on December 30, 1993.

Section 26.41(c)(2) relaxes some requirements related to annual audits and inspections of the HHS-certified laboratories that licensees and other entities rely upon for drug testing services. The final rule permits licensees and other entities who are subject to the rule to rely upon the inspections of HHS laboratories that are performed for HHS-certification reviews and no longer requires licensees and other entities to audit the effectiveness of services that HHS inspectors review. The former rule contained a number of requirements that are inconsistent with the requirements for drug testing under other Federally mandated programs. For example, the former rule permitted donors to request confirmatory alcohol testing of a blood specimen at an HHS-certified laboratory, which other Federal agencies do not permit. Also, some of the cutoff levels established in the former rule are higher, in the case of testing for marijuana metabolite, or lower, in the case of testing for opiates, than those of other Federal agencies. These programmatic discrepancies have made licensee audits of HHS-certified laboratories necessary to ensure the effectiveness of the unique drug and alcohol testing services required for Part 26 programs because HHS inspections do not address these services. The final rule eliminates the majority of these discrepancies. Therefore, the annual audits of HHS-certified laboratories by licensees that have been necessary under the former rule would be redundant under the final rule, except in certain conditions described below. The NRC has made these changes to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.41(c)(2) continues to require licensees and other entities to conduct annual audits of any services provided to the licensee or other entity that the annual HHS-certification review did not address. The NRC has retained this annual audit requirement because § 26.31(d) retains the permission in the former rule for licensees and other entities to establish lower cutoff levels and test for drugs in addition to those for which testing is required under this part. If a licensee or other entity chooses to implement more stringent cutoff levels or a broader panel of drugs than required under the final rule, the licensee or other entity is required to ensure that annual audits of the HHS-certified services related to those cutoff levels and drug tests are performed.

The NRC has added the last sentence of § 26.41(c)(2) to clarify the scope of the former audit requirements. The final rule does not require licensees and other entities to audit organizations that do not routinely provide FFD services to the licensee or other entity, such as local hospitals or a substance abuse treatment facility. It is unnecessary to audit these organizations because the FFD program would use their services infrequently, there would be a reasonable expectation of quality, and weaknesses in these services could be identified through other means. For example, § 26.187 [Substance abuse expert] requires the SAE to monitor the substance abuse treatment of individuals who require it and the SAE would have the qualifications and information necessary to assess the quality of the treatment services an individual receives. The SAE has the authority to seek other services on behalf of the FFD program if he or she identifies weaknesses in a treatment program. Therefore, the NRC has made these changes to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.41(d) [Contracts] of the final rule incorporates and amends the requirements of former Section 2.7(m) in Appendix A to Part 26 and others that addressed contractual relationships to permit licensees and other entities access to the HHS-certified laboratories for the purposes of conducting the audits and inspections required under the rule. The portions of former Section 2.7(m) in Appendix A to Part 26 that related to NRC inspections of HHS-certified laboratories have been moved to § 26.821 [Inspections] in Subpart O [Inspections, violations, and penalties] of the final rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41(d)(1) amends the second sentence of former Section 2.7(m) in Appendix A to Part 26. The former section required licensee contracts with HHS-certified laboratories for drug testing and alcohol confirmatory testing, as well as contracts for collection site services, to permit the licensee to conduct unannounced inspections. The final rule retains the former requirement with respect to HHS-certified laboratories and expands it to require that contracts with any C/V (which would include collection services providers) must permit the licensee or other entity to conduct audits at any time, including unannounced times, and to review all information and documentation that is reasonably relevant to the audits. The provision extends the former requirement to any C/V with whom the licensee or other entity contracts for FFD program services to enhance the effectiveness of the licensees' and other entities' audits should unannounced audits appear to be necessary. For example, a licensee or other entity may receive allegations that an offsite C/V is falsifying records or that a contract MRO or SAE is using drugs. The licensee or other entity may determine that an unannounced audit would provide the most effective means to investigate these allegations. This provision ensures that the licensee's or other entity's contract with the C/V permits the unannounced audit as well as access to any information necessary to conduct the audit. Therefore, the NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC had added § 26.41(d)(2) to ensure that licensees' and other entities' contracts with C/Vs and HHS-certified laboratories permit the licensee or other entity to obtain copies of and take away any documents that auditors may need to assure that the C/V, its subcontractors, or the HHS-certified laboratory are performing their functions properly and that staff and procedures meet applicable requirements. This provision responds to several incidents when parties under contract to licensees did not permit Part 26 auditors to remove documents from a premises of a C/V that were necessary to document audit findings, develop corrective actions, and ensure the effectiveness of the corrective actions. Therefore, the new requirement meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs. The provision permits HHS-certified laboratories to reasonably limit the use and dissemination of the documentation that auditors copy and take off site. This change meets Goal 7 of this rulemaking to protect the privacy of individuals who are subject to Part 26 and protects the trade secrets of HHS-certified laboratories who are subject to auditing under the final rule.

Section 26.41(d)(3) amends the third sentence of former Section 2.7(m) in Appendix A to Part 26. This sentence required licensees and other entities to carry out inspections and evaluations of the procedural aspects of an HHS-certified laboratory drug testing operations before awarding a contract to the laboratory. The final rule adds a cross-reference to § 26.41(g). Section

26.41(g) permits licensees and other entities to forego the otherwise required pre-award evaluation under certain specific circumstances, as discussed with respect to that section.

Section 26.41(e) [Conduct of audits] of the final rule retains the requirements in former § 26.80(b).

Section 26.41(f) [Audit results] of the final rule retains the portion of former § 26.80(c) that required licensees and other entities to document audit findings and recommendations, report them to senior management, and document corrective actions taken in response to any identified adverse conditions. The final rule adds two requirements. The second sentence of § 26.41(f) specifies the required content of audit reports, including identification of any conditions that are adverse to the proper performance of the FFD program, the cause of the condition(s), and recommended corrective actions. The third sentence of the section requires licensees and other entities to review the audit findings and take corrective actions, including reauditing of indicated deficient areas, to preclude, within reason, repetition of the condition. The final rule adds these two sentences for consistency with Criterion XVI in Appendix B to 10 CFR Part 50 [Domestic licensing of production and utilization facilities] to indicate that the corrective action programs of licensees and other entities must include FFD audit reports. Some licensees have handled FFD audit reports outside of their normal corrective action programs that address other conditions adverse to quality. As a result, some corrective actions for FFD program weaknesses have not been timely or effective. Therefore, the final rule adds these requirements to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has deleted the last sentence of former § 26.80(c) that referred to the requirements for auditing HHS-certified laboratories in Appendix A to Part 26 because it is redundant with § 26.41(c). The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.41(g) [Sharing of audits] of the final rule responds to licensees' implementation questions related to the third and fourth sentences in former § 26.80(a) that permitted licensees and other entities to accept audits of C/Vs that other FFD programs conduct. The section clarifies the former permission to accept and rely on others' audits in response to implementation questions that the NRC has received from licensees with respect to the sharing of audits, as documented in Section 17 of NUREG–1354, and items 11.4 and 11.5 of NUREG–1385, ''Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions.''

Section 26.41(g) amends the former provision to incorporate specific permission for licensees and other entities to jointly conduct audits as well as rely on one another's audits. The NRC has also added a reference to HHS-certified laboratories to indicate the applicability of these permissions to licensees' and other entities' audits of HHS-certified laboratories. These changes are consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.41(g)(1) and (g)(2) to the final rule to require licensees and other entities to identify any areas that were not covered by a shared or accepted audit and ensure that any unique services used by the licensee or other entity that were not covered by the shared audit are audited. For example, an FFD program may use lower cutoff levels for drug testing than the FFD program(s) that conducted a shared audit with the result that the shared audit did not address the HHS-certified laboratories' procedures for testing at the first FFD program's lower cutoff levels. In this case, the first FFD program is not permitted to rely on the shared audit with respect to the lower cutoff levels and is required to ensure that the HHS-certified laboratories' procedures for testing at the lower cutoff levels are audited separately (or in conjunction with other FFD programs that use the same cutoff levels). These provisions are consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, the NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41(g)(3) retains the portion of the third sentence of former § 26.80(a) that stated that licensees and other entities need not re-audit the same C/V for the same period of time. This provision extends this permission to audits of HHS-certified laboratories, which is consistent with the guidance issued by the NRC in the documents referenced above and current licensee practices. Therefore, the NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.41(g)(4) retains the fourth sentence of former § 26.80(a). This provision requires licensees and other entities to retain copies of the shared audit reports.

The NRC has added § 26.41(g)(5) to the final rule. The provision permits licensees and other entities to immediately obtain drug testing services from another HHS-certified laboratory, subject to certain conditions, if the laboratory used by the licensee or other entity loses its certification. Within 3 months of obtaining services from the replacement laboratory, the section requires the licensee or other entity to ensure that an audit is conducted of any aspects of the laboratory's services that the licensee or other entity use that have not been audited within the past 12 months by another licensee or entity who is subject to this subpart. This provision enhances the effectiveness of FFD programs by ensuring that drug testing will not be interrupted or delayed if an HHS-certified laboratory loses its certification as some licensees have experienced. The reliability of drug testing services provided by the replacement laboratory is ensured by the auditing and inspection activities of other licensees and entities who have been using the services of the replacement laboratory, as well as the audit conducted by the licensee or other entity of any services that have not been audited by other licensees or entities who are subject to this part. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Subpart C—Granting and Maintaining Authorization

Throughout Subpart C, the final rule makes minor clarifications to the proposed rule based on public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

One clarification that the final rule makes in numerous sections in this subpart is to state that licensees or other entities subject to this subpart shall ''ensure'' that a requirement under this subpart has been met. This language differs from that of the proposed rule, which stated that the licensee or other entity shall explicitly perform the activity (i.e., obtain, review, conduct, complete) to meet the requirement. For example, in § 26.55(a)(1), the proposed rule stated that the licensee or other entity shall ''obtain and review a self-disclosure.'' The final rule states that the licensee or other entity shall ''ensure that a self-disclosure has been obtained

and reviewed.'' This modified language clarifies the NRC's intent that licensees or other entities may rely on other entities to assist in performing the activities necessary to meet the requirements of this subpart. For example, many licensees rely on contractors to conduct the suitable inquiry required under § 26.63. However, the final rule retains the language of the proposed rule in § 26.69(b) for the reasons discussed with respect to that paragraph. In another change from the proposed rule text, the NRC has eliminated the term ''non-negative'' and replaced it with the phrase ''positive, adulterated, or substituted'' for the reasons discussed with respect to § 26.5 [Definitions].

The final rule also makes more substantive changes to the proposed rule in this subpart because of public comment or to improve clarity in the organization and language of the rule. The substantive changes in this subpart can be found in § § 26.51; 26.53(d) through (i); 26.57(b); 26.61(c) and (d); 26.63(c), (c)(3), (d) and (f); 26.65(c), (c)(2), (d)(1)(i), (d)(2)(ii), (e) and (f); and 26.69(c), (c)(1) and (e)(1). These changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed, without change.

Section 26.51 Applicability

The final rule amends § 26.51 of the proposed rule to describe the applicability of the subpart. The NRC has changed the heading of this section from ''Purpose'' to ''Applicability'' because the NRC has revised the content of the section to specify the licensees, entities, and categories of individuals to whom the requirements Subpart C apply by using cross-references to the relevant paragraphs in § § 26.3 [Scope] and 26.4 [FFD program applicability to categories of individuals]. The NRC made this change in response to public comments requesting this clarification in the rule text and to meet Goal 6 of this rulemaking.

Section 26.53 General Provisions

The NRC has added § 26.53 to the final rule to provide an overview of the requirements and process for determining when individuals may be granted and maintain authorization. With respect to the proposed rule, paragraph (e) has been added to this section to specify the requirements for relying on the FFD program of a C/V when granting or maintaining authorization. Paragraph (f) specifies that licensees and other entities may not rely on FFD programs under Subpart K [FFD programs for Construction] of this rule to meet the requirements of this subpart. The reasons for adding these paragraphs are discussed with respect to the specific paragraphs.

Section 26.53(a) of the final rule introduces four new terms to Part 26: ''Initial authorization,'' ''authorization update,'' ''authorization reinstatement,'' and ''authorization with potentially disqualifying FFD information.'' The final rule uses these terms to describe categories of requirements for granting authorization. These categories are based on whether an applicant has previously held authorization under Part 26 and the length of time that has elapsed after the individual's last period of authorization ended, and are described in § 26.55 [Initial authorization], § 26.57 [Authorization update], § 26.59 [Authorization reinstatement], and § 26.69 [Authorization with potentially disqualifying fitness-for-duty information]. Section 26.53(a) directs licensees or other entities to use the criteria for granting authorization to individuals found in § § 26.55, 26.57, 26.59, or 26.69, depending on which of these sections applies to the individual seeking authorization. The former rule in § 26.27 [Management actions and sanctions to be imposed] discussed actions that the licensee must take before initially granting access or assigning specified duties to an individual, but did not use the concepts of ''initial authorization,'' ''authorization update,'' ''authorization reinstatement,'' or ''authorization with potentially disqualifying FFD information.'' The final rule uses these concepts to focus the requirements for authorization more precisely on whether the individual has an established record (i.e. authorization history) in the industry. The NRC also uses these concepts to specify the amount of original information-gathering activities licensees or other entities are required to perform, according to whether previous FFD programs have collected information about the individual. In addition, the NRC uses similar concepts in access authorization requirements found in 10 CFR 73.56 [Personnel access authorization requirements for nuclear power plants] and access authorization orders issued by the agency to nuclear power plant licensees. The NRC has incorporated these concepts into Part 26 to increase the consistency between the related regulations in accordance with Goal 4 of this rulemaking.

Section 26.53(b) of the final rule defines the meaning of the term ''interruption'' which is used in § 26.57 and § 26.59 to refer to the interval of time between periods during which an individual holds authorization under Part 26. Licensees and other entities shall calculate an interruption in authorization as the total number of days falling between the day the individual's last period of authorization ended and the day the licensee or other entity grants authorization to the individual. Section 26.53(b) also specifies that if potentially disqualifying FFD information is disclosed or discovered about an individual, licensees and other entities must implement the applicable requirements in § 26.69 in order to grant or maintain an individual's authorization, rather than relying on the requirements in § § 26.55, 26.57, or 26.59.

Section 26.53(c) of the final rule references the FFD training requirements in § 26.29 [Training] and the fatigue training requirements in § 26.203(c) [Training and examinations] to clarify that all individuals who are subject to Subpart C must meet the applicable requirements for initial or refresher FFD training, as appropriate, before the licensee or other entity may grant authorization to the individuals. This provision references the training requirements for organizational clarity because they apply to the authorization process. As discussed in the preamble to the proposed rule, stakeholders requested that the regulation present requirements in the order in which they would apply to licensees' and other entities' FFD processes. The NRC has added this paragraph to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.53(d) of the final rule permits licensees and other entities to rely on other licensees' or entities' FFD programs and program elements to meet the requirements of this subpart for granting and maintaining authorization. Section 26.53(d) expands upon a section of the former rule that similarly permitted licensees and other entities to accept and rely on other FFD programs and program elements. Specifically, former § 26.24(a)(1) permitted licensees to accept results from drug and alcohol tests that were administered under another Part 26 program within the past 60 days. Consistent with the principle of permitting licensees to accept and rely on other Part 26 programs in their authorization decisions, guidance contained in NUREG–1385, ''Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions,'' also indicates that licensees may ''accept'' an authorization granted by a previous licensee for individuals

who transfer between licensees with only a short break in authorization.

The final rule substantially increases the specificity of the requirements that licensees or other entities must meet for granting authorization and establishes detailed minimum standards that all programs must meet. The agency designed these detailed minimum standards to address recent changes in industry practices that have resulted in a more transient workforce. Because the FFD programs of licensees and other entities will be substantially more consistent than in the past under these detailed standards, permitting licensees and other entities to rely on other FFD programs to meet the rule's requirements is reasonable and appropriate. Section 26.53(d) eliminates unnecessary redundancies in the steps required to grant authorization to an individual who is transferring from one FFD program to another, consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. With respect to the proposed rule, the final rule specifies that the receiving FFD program shall ensure that the program elements to which the individual is subject under the transferring FFD program remain current. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

In response to public comment, the final rule adds paragraph (e) to § 26.53 to clarify the relationship between licensees' and other entities' FFD programs and those of C/Vs. Section 26.53(e) retains the permission in former § 26.23 [Contractors and vendors] for licensees to rely upon C/Vs' FFD programs that have been formally reviewed and approved by the licensee. The paragraph also permits the licensees and other entities in § 26.3(a) through (c) to rely on a C/V's FFD program elements that meet the requirements of Part 26. For example, some C/Vs ensure that their employees receive initial and refresher FFD training so that, when the employee is assigned to work on a contract that requires him or her to have unescorted access to a nuclear power plant protected area, it is unnecessary for the licensee to provide FFD training to the C/V's employee in order to grant unescorted access to this individual. The final rule adds this permission to rely on a C/V's FFD program elements to codify a long-standing industry practice that has been endorsed by the NRC and to provide clarity in the language of the rule.

Section 26.53(e)(1) permits a C/V to grant, maintain, deny, or unfavorably terminate an individual's authorization under the C/V's FFD program. As defined in § 26.5, granting authorization in this case means that a C/V has determined that the individual has met the requirements in this subpart and is eligible to have the types of access and perform the duties specified in § 26.4. Maintaining authorization under a C/V's FFD program means that the individual continues to meet the requirements of this subpart and be eligible to perform the duties specified in § 26.4. However, the second sentence of § 26.53(e)(1) retains the intent of the provisions in former § 26.23 that placed responsibility on licensees for ensuring that individuals who are ''performing activities within the scope of this part'' meet the requirements in Part 26. However, the final rule updates the terminology used to convey this intent and adds cross-references to other sections of the rule for clarity and consistency with other rule changes.

Section 26.53(e)(2) further clarifies the relationship between authorization under a C/V's FFD program and authorization under the FFD programs of licensees and other entities in § 26.3(a) through (c). This provision addresses circumstances when a C/V's FFD program determines that an individual does not meet the requirements of this subpart to be granted or maintain authorization and denies or unfavorably terminates the individual's authorization under the C/V's program. The rule requires that if the C/V's FFD program denies or unfavorably terminates the authorization of an individual who is performing the duties for a licensee that are listed in the specified sections of § 26.4, the C/V must inform the affected licensee or other entity of the denial or unfavorable termination. In this case, the licensee or other entity shall, on the day the licensee receives the information from the C/V, deny or unfavorably terminate the individual's authorization or implement the applicable process in § 26.69 to maintain the individual's authorization. For example, if a C/V's employee is convicted of selling illegal drugs and reports the conviction to the C/V, the C/V would unfavorably terminate this individual's authorization under the C/V's FFD program. If the individual was also assigned to a contract that required him or her to have unescorted access to the protected area of a nuclear power plant at the time he or she was convicted, this provision requires the C/V to inform the FFD program of the licensee or other entity of the conviction. The licensee would then either terminate the individual's unescorted access on the day that the licensee or other entity receives the information from the C/V or, in unlikely circumstances, may implement the process established in § 26.69(d) for determining whether an individual may maintain authorization after potentially disqualifying FFD information is disclosed or discovered. This provision codifies a long-standing industry practice that has been endorsed by the NRC and adds clarity in the rule language. The NRC has also added this requirement in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

The final rule has added § 26.53(e)(3) to the final rule to explicitly permit the licensees and other entities in § 26.3(a) through (c) to rely on a C/V's FFD program and program elements, or a combination of program elements from the licensee's or other entity's FFD program and the C/V's FFD program, to satisfy the requirements of Subpart C for maintaining an individual's authorization. This paragraph repeats the language in § 26.53(d), which permits licensees and other entities to rely on one another's FFD programs and program elements, but applies it to C/V FFD programs and program elements for additional clarity in the language of the rule. The final rule also clarifies that the receiving licensee's or other entity's FFD program shall ensure that the program elements to which the individual is subject under the C/V's FFD program remain current. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

The NRC has also added § 26.53(f) to the final rule to prohibit licensees and

other entities from relying on an FFD program that has been implemented under Subpart K of this part when granting authorization to an individual. This prohibition is necessary because Subpart K permits the licensees and other entities specified in § 26.3(c) greater flexibility in establishing and implementing an FFD program than is permitted in Subpart C. For example, Subpart K does not require the licensees and other entities in § 26.3(c) to conduct a suitable inquiry of individuals who are permitted to perform the duties described in § 26.4(f). Therefore, in order to grant authorization to such an individual to have the types of access or perform the duties in § 26.4(a) or (b), for example, a licensee in § 26.3(a) would be required to ensure that a suitable inquiry has been completed under § 26.63. However, this new provision would permit a licensee or other entity to rely on the program elements of a Subpart K FFD program if the program elements meet the applicable requirements of Subpart C. For example, if a Subpart K program included suitable inquiry requirements and implemented them under § 26.63, a licensee or other entity could rely on those suitable inquiry results when granting authorization under Subpart C. This section satisfies Goal 3 of this rulemaking by improving the effectiveness and efficiency of FFD programs.

The NRC has added 26.53(g) to the final rule to require licensees and other entities to identify any FFD violation to any licensee who has relied or intends to rely on the FFD program element that is determined to be in violation of this part. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

In the final rule, the NRC has added a new provision in § 26.53(h) to prohibit licensees and other entities from initiating any actions under Subpart C, such as beginning to gather information about the individual's authorization history from other licensees or entities, without the knowledge and consent of the individual who is applying for authorization. The new provision in the final rule also informs individuals that they may withdraw consent at any time, and specifies the actions that licensees and other entities must take if an individual withdraws his or her consent. The NRC has added this provision to provide additional protection of individuals' privacy by ensuring that licensees and other entities do not gather personal information about an individual without his or her permission. The requirements to inform the individual that he or she may withdraw consent and for licensees and other entities to inform the individual of what information will be documented and shared with other licensees or entities following a withdrawal of consent are necessary to protect individuals' other rights under the rule, including due process. Therefore, this provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals subject to Part 26. This provision meets Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

The NRC has added § 26.53(i) to the final rule to require licensees and other entities specified in § 26.3(a) and, as applicable, (c) and (d), to inform individuals applying for authorizations of the actions related to providing and sharing personal information that are sufficient cause for denial or unfavorable termination of authorization. The actions that are sufficient cause for denial or unfavorable termination of authorization include refusal to provide written consent, as specified in § 26.53(i)(1), and refusal to provide or the falsification of any personal information required under this subpart, including the failure to report any previous denial or unfavorable termination of authorization, as specified in § 26.53(i)(2). These provisions were moved from § 26.63(d) and § 26.61(d) of the proposed rule, respectively. The NRC has added § 26.53(i)(3) and (i)(4) to specify that a refusal to provide written consent for the sharing of personal information with other licensees or other entities, as required in § 26.53(h), and a failure to report any legal actions, respectively, are also sufficient cause for denial or unfavorable termination of authorization. Also, the NRC has made these changes to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.55 Initial Authorization

The NRC has added § 26.55 to the final rule, which defines the category of ''initial authorization'' requirements as applying both to individuals who have not previously held authorization under Part 26 and those whose authorization has been interrupted for a period of 3 years or more and ended favorably.

Two considerations support the mandate for individuals whose last period of authorization ended 3 or more years previously to satisfy the same requirements as individuals who have never previously held authorization. In general, the longer the period of time since the individual's last period of authorization ended, the greater the possibility that the individual has developed an active substance abuse problem or undergone significant changes in lifestyle or character that would diminish his or her trustworthiness, reliability, and ability to perform work safely and competently. Therefore, it is reasonable to require a full and extensive screening identical to that given an individual who has not held authorization, and has not been subject to drug and alcohol testing and behavioral observation, for 3 years or more. For similar reasons, access authorization requirements also require that individuals who have not held authorization for 3 years or more must be subject to the same screening as individuals who have not previously held authorization. Therefore, mandating that individuals whose last period of authorization ended 3 or more years previously must satisfy the same requirements as individuals who have never held authorization increases the consistency of Part 26 with the related access authorization requirements, consistent with Goal 4 of this rulemaking.

Section 26.55(a)(1) requires the licensee or other entity, before granting initial authorization to an individual, to ensure that a self-disclosure has been obtained and reviewed in accordance with the applicable requirements of § 26.61 [Self-disclosure and employment history]. As discussed with respect to § 26.61, the self-disclosure and employment history requirements mandate that the individual report violations, if any, involving drugs or alcohol and the individual's current and past employment history. The requirement is similar to that in § 26.27(a)(1) of the former rule that a

written statement must be obtained from the individual addressing the topics that are specified in former § 26.27(a)(1). The discussion of § 26.61 in this document compares the topics required to be addressed in the written statement under the former rule with the topics that are addressed in the self-disclosure under this final rule. As discussed with respect to § 26.61(b)(3), an applicant for initial authorization must address in the self-disclosure the shorter period of either the past 5 years or the interval of time that has elapsed since the individual's eighteenth birthday.

Section 26.55(a)(2) requires the licensee or other entity to ensure that a suitable inquiry has been completed under the applicable requirements of § 26.63 [Suitable inquiry] before granting initial authorization to an individual. The requirement is similar to that in § 26.27(a)(2) of the former rule that a suitable inquiry must be completed addressing the topics that are specified in § 26.27(a)(2). The discussion of § 26.63 in this document compares the topics that the suitable inquiry must address under the former rule with the topics that it addresses under the final rule. Section 26.63(f)(1) specifies that the suitable inquiry for an initial authorization must address the shorter period of either the past 3 years or the interval of time that has elapsed since the individual's eighteenth birthday.

Section 26.55(a)(3) requires the licensee or other entity to ensure that the individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65 [Pre-access drug and alcohol testing] before granting initial authorization to an individual. Former § 26.24(a)(1) required testing within the 60 days before initially granting unescorted access to protected areas or assignment to activities within the scope of Part 26. The discussion of § 26.65 in this document compares the pre-access drug and alcohol testing requirements for initial authorization in this rule to the requirements in the former rule. Section 26.65 requires the licensee or other entity to ensure that the individual had negative drug and alcohol test results from testing that had been completed within the past 30 days before granting authorization to the individual.

Section 26.55(a)(4) requires the licensee or other entity also to ensure that the individual has been subject to random drug and alcohol testing under the applicable requirements of § 26.67 [Random drug and alcohol testing of individuals who have applied for authorization]. Former § 26.64(a)(2) required unannounced drug and alcohol tests imposed in a statistically random and unpredictable manner. The discussion of § 26.67 in this document compares the random drug and alcohol testing requirements for initial authorization in this rule to the requirements in the former rule.

Section 26.55(b) of the final rule mandates that the licensee or other entity must meet the requirements in § 26.69 to grant authorization to the individual, if potentially disqualifying FFD information is disclosed or discovered about the individual who is applying for authorization that another licensee or other entity has not previously evaluated.

Section 26.57 Authorization Update

The NRC has added § 26.57 to the final rule, which defines the category of ''authorization update'' requirements for granting authorization to individuals whose authorization has been interrupted for more than 365 days but less than 3 years and whose last period of authorization was terminated favorably.

As noted in the discussion of Subpart C in Section IV.C, the requirements for granting an authorization update are less stringent than the requirements for granting initial authorization. The requirements are less stringent because (1) the individual who is applying for an authorization update will have a more recent history of successful performance within the industry, and (2) the licensee or other entity will have access to information about the individual from the licensee or other entity who last granted authorization to him or her because of the increased information-sharing requirements of the final rule. However, the requirements in the final rule for an authorization update focus on gathering and evaluating information from the interruption period because the licensee or other entity will not have information about the individual's activities during the period of the interruption. For example, in the case of an individual whose last period of authorization ended 2 years ago, the licensee or other entity will focus on gathering information about the individual's activities within the 2-year interruption period. If an individual's last period of authorization ended 13 months ago, the licensee or other entity will focus on gathering information about the individual's activities within those 13 months.

Section 26.57(a) of the final rule, like § 26.55(a), requires the licensee or other entity before granting authorization to ensure that:

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under the applicable requirements of § 26.63;

(3) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual has been subject to random drug and alcohol testing under the applicable requirements of § 26.67.

However, § 26.61(b)(3)(iii) and (c)(3) limits the period of time to be addressed in the self-disclosure and employment history to the interruption period. If an individual's last period of authorization ended 2 years ago, the self-disclosure and employment history would cover only the past 2 years. Similarly, § 26.63(f)(2) provides that the suitable inquiry for an authorization update must cover the interruption period. The final rule requires the self-disclosure, employment history, and suitable inquiry to address only the interruption period because the licensee or other entity may obtain information from earlier periods in the individual's history from the licensee or other entity who had last granted authorization to the individual.

The NRC has added § 26.57(b) to specify that if potentially disqualifying FFD information is disclosed or discovered about the individual who is applying for authorization, the licensee or other entity may not grant authorization to the individual, except under § 26.69.

Section 26.59 Authorization Reinstatement

The NRC has added § 26.59 to the final rule, which establishes two categories of authorization reinstatement requirements for individuals whose authorization has been interrupted for a short period and whose last period of authorization was terminated favorably.

One category of authorization reinstatement requirements applies to individuals whose authorization has been interrupted for more than 30 days but no more than 365 days in § 26.59(a), and the other to individuals whose authorization has been interrupted for 30 or fewer days in § 26.59(c). The steps for reinstating an individual's authorization after an interruption of 365 or fewer days are less stringent than those required for initial authorization or an authorization update because these individuals will have a recent, positive record within the industry and pose little risk to public health and

safety or the common defense and security.

The requirements that are related to an individual whose authorization has been interrupted for more than 30 days but no more than 365 days are more extensive than the requirements for granting authorization to an individual whose authorization has been interrupted for 30 or fewer days. The requirements for the 31–365-day category are consistent with those contained in the access authorization orders issued by the NRC to nuclear power plant licensees dated January 7, 2003. However, the requirements for individuals whose authorization has been interrupted for 30 or fewer days are more stringent than those contained in those orders. Under the access authorization orders, licensees are required to obtain and review a self-disclosure and employment history from the applicant before reinstating the individual's authorization. Under this amendment, licensees and other entities are also required to subject the individual to the possibility of selection for pre-access testing under § 26.65(e) [Authorization reinstatement after an interruption of 30 or fewer days]. The NRC has determined that this additional requirement is necessary to meet the final rule's performance objective of providing reasonable assurance that individuals are trustworthy and reliable by extending the deterrent effect of pre-access testing to individuals who have had an interruption in authorization of 30 or fewer days in length.

For individuals whose authorization has been interrupted for 31–365 days, § 26.59(a)(1) requires the licensee or other entity to ensure that a self-disclosure and employment history has been obtained and reviewed in order to reinstate authorization. Consistent with the requirements for authorization updates in § 26.57, the final rule in § 26.61(b)(3)(iii) and (c)(3) limits the period of time to be addressed in the self-disclosure and employment history to the period of the interruption in authorization. A self-disclosure and employment history for earlier periods of time is unnecessary because the granting licensee or other entity will have access to information about the individual from the licensee or other entity who recently terminated the individual's authorization.

Section 26.59(a)(2) permits the licensee or other entity to reinstate an individual's authorization without first ensuring that a suitable inquiry has been completed, in contrast to the requirements for an initial authorization and an authorization update. The final rule permits this because these individuals will have a recent, positive record within the industry and pose little risk to public health and safety or the common defense and security. As is required for an authorization update, this provision limits the period of time to be addressed by the suitable inquiry to the interruption period in § 26.63(f)(3). However, this provision requires licensees and other entities to ensure that the suitable inquiry is completed within 5 business days after reinstating the individual's authorization. If the suitable inquiry is not completed within the 5-day period, the licensee or other entity can maintain the individual's authorization for up to 10 business days following the day authorization was reinstated, but only if the licensee or other entity is unaware of any potentially disqualifying information about the individual. If the suitable inquiry is not completed within 10 business days, the rule requires the licensee or other entity to administratively withdraw the individual's authorization until the suitable inquiry is completed.

Section 26.59(a)(3) requires the licensee or other entity to ensure that the individual whose authorization has been interrupted for 31–365 days has been subject to pre-access drug and alcohol testing, and § 26.59(a)(4) requires the licensee or other entity to ensure that the individual whose authorization has been interrupted for 31–365 days is subject to random testing. Section 26.65(d) [Authorization reinstatement after an interruption of more than 30 days] establishes pre-access drug and alcohol testing requirements for authorization reinstatements. Section 26.67 specifies the requirements for the random testing of individuals who are applying for an authorization reinstatement.

The NRC has added § 26.59(b) to the final rule to ensure that any administrative withdrawal of authorization required under § 26.59(a)(2) is not reported or recorded as an unfavorable termination of authorization until the suitable inquiry is completed and it indicates that authorization should not be granted. This provision ensures that a temporary administrative withdrawal of authorization caused by a licensee's or other entity's delay in completing the suitable inquiry is not treated as an unfavorable termination caused by an FFD violation. The final rule specifies that the individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information. With respect to the proposed rule, the final rule clarifies that the individual is required to disclose the administrative action if the individual's authorization was subsequently denied or terminated unfavorably. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. Section 26.59(b) is necessary to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 by ensuring that they are not subject to any adverse consequences for the licensee's or other entity's delay in completing the suitable inquiry.

Section 26.59(c) of the final rule establishes authorization requirements for individuals whose authorization has been interrupted for 30 or fewer days. Section 26.59(c)(1) requires the licensee or other entity to ensure that a self-disclosure has been obtained and reviewed with certain exceptions that are specified in § 26.61. The licensee or other entity is permitted to forego conducting a suitable inquiry for individuals whose authorization has been interrupted for such a short period. Section 26.59(c)(2) permits licensees and other entities also to forego pre-access drug and alcohol testing of individuals whose authorization has been interrupted for 5 or fewer days. However, pre-access testing may be required under § 26.65(e) for individuals whose authorization has been interrupted for 6 to 30 days. Sections 26.61 and 26.65 specify the exceptions to the self-disclosure and pre-access testing requirements in this provision, respectively.

Section 26.61 Self-Disclosure and Employment History

The NRC has added § 26.61 to the final rule to replace former § 26.27(a)(1) for the reasons discussed in Section IV.C. The final rule replaces the term ''written statement'' in the former rule with the phrase ''self-disclosure and employment history'' to more accurately characterize the requirement. The NRC has made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

The NRC has added § 26.61(a) to the final rule to require licensees and other entities to ensure that a written self-disclosure and employment history has

been obtained from every applicant before granting authorization to the individual, except in two circumstances, as follows.

Section 26.61(a)(1) permits the licensee or other entity to forego obtaining a self-disclosure and employment history if all three of the following conditions are met:

(1) The individual previously held authorization under Part 26;

(2) The individual's last period of authorization was terminated favorably; and

(3) The individual has been subject to a behavioral observation and arrest-reporting program that meets the requirements of this part throughout the time the individual's authorization was interrupted.

The information to be obtained from the self-disclosure and employment history is unnecessary in these circumstances because it will already be available to the granting licensee or other entity from the FFD program that had been implementing the behavioral observation and arrest-reporting program during the interruption in the individual's authorization. A requirement for licensees and other entities to conduct another suitable inquiry is redundant and imposes an unnecessary burden.

Section 26.61(a)(2) permits licensees and other entities to forego obtaining an employment history from applicants for an authorization reinstatement whose authorization has been interrupted for 30 or fewer days. The employment history information is unnecessary in this case because the final rule does not require licensees or other entities to conduct a suitable inquiry for individuals who have had such a short break in authorization.

The NRC has added § 26.61(b) to the final rule to specify the required content of the written self-disclosure. Affirmative responses to any of the questions in § 26.61(b)(1) are considered potentially disqualifying FFD information, as defined in § 26.5. The final rule expands the scope of the questions to be asked from those required in former § 26.27(a)(1) in order to provide greater assurance that individuals will disclose information indicating an active substance abuse problem or an increased risk of recidivism into an active substance abuse problem after treatment. Former § 26.27(a)(2) required information about whether the applicant ''tested positive for drugs or use of alcohol that resulted in on-duty impairment.'' Section 26.61(b)(1) requires information about whether the applicant used, sold, or possessed illegal drugs, subverted or attempted to subvert a drug or alcohol testing program, or refused to take a drug or alcohol test. Both former § 26.27(a)(2) and § 26.61(b)(1) require information on whether the applicant has been subject to a plan for substance abuse treatment (except for a self-referral). Both require information about previous denials or terminations of authorization.

The NRC has added § 26.61(b)(2) to the final rule to require the applicant to disclose the circumstances surrounding any potentially disqualifying FFD information and the resolution of the matter. For example, § 26.61(b)(1) requires an applicant to report an arrest on drug-related charges, while § 26.61(b)(2) requires the applicant to report the outcome of the arrest (e.g., charges, a conviction, a finding of not guilty, the dropping of the charges).

Section 26.61(b)(3) defines the time period that the self-disclosure must address. The final rule establishes a time limit on the number of years in the past for which an individual is required to report and account for potentially disqualifying FFD information. One purpose of the self-disclosure is to identify indicators of an active substance abuse problem or an increased risk of recidivism into an active substance abuse problem after treatment. The relevant research literature indicates that post-treatment recidivism (i.e., relapse) rates decrease after 3 years of no further substance abuse, and a larger decrease occurs in the recidivism rate after 5 years. If the applicant discloses no indicators of a substance abuse problem within the past 5 years (or since the applicant's eighteenth birthday, in the case of an applicant who is less than 23 years of age), an applicant for initial authorization (see § 26.55) is not required to disclose earlier events related to substance abuse. For applicants who held authorization within the past 3 years, the self-disclosure addresses only the time interval after the individual's last period of authorization ended. However, the licensee or other entity shall obtain further information about the applicant over the past 5 years by reviewing the information made available by licensees or other entities who granted authorization to the applicant in the past. This includes information developed as part of previous suitable inquiries (see § 26.63) as well as information from the period(s) during which the individual was subject to other FFD programs.

Section 26.61(c) in the final rule modifies this provision as proposed. The proposed rule specified that applicants must provide information about current and past employers, which the licensee or other entity then uses for the suitable inquiry if a suitable inquiry is required under § 26.63. However, the final rule requires the individual to provide a list of employers to include the employer by whom he or she claims to have been employed on the day before he or she completes the employment history. The agency has also made this change in § 26.63(c). The NRC has made this change in response to a public comment, which stated that a licensee or other entity has the ability to ensure that a suitable inquiry has been conducted only of those employers that are listed in the self-disclosure or employment history. The NRC believes that this revision provides more specificity in cases when an individual's current employer changes after he or she submits the self-disclosure. This change is consistent with Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC has moved the provision in proposed § 26.61(d) to § 26.53(i)(2) of the final rule to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.63 Suitable Inquiry

The NRC has added § 26.63 to the final rule. This section amends former § 26.27(a)(2) and the requirements related to conducting a suitable inquiry that are contained within the definition of the term ''suitable inquiry'' in former § 26.3. The former rule defined a suitable inquiry as a ''best-effort verification of employment history for the past 5 years, but in no case less than 3 years, obtained through contacts with previous employers to determine if a person was, in the past, tested positive for illegal drugs, subject to a plan for treating substance abuse, removed from, or made ineligible for activities within the scope of 10 CFR Part 26, or denied unescorted access at any other nuclear power plant or other employment in accordance with a fitness-for-duty policy.'' In general, the NRC intends that the changes to the former requirements better focus the suitable inquiry on indicators of an active substance problem and/or an increased risk of recidivism into an active substance abuse problem following treatment, as discussed in Section IV.C; increase the consistency in implementing suitable inquiries among FFD programs by providing more detailed requirements, also as discussed in Section IV.C; and improve Part 26 by eliminating or modifying unnecessary

requirements, which is Goal 5 of this rulemaking.

For all authorization categories, the suitable inquiry required by the final rule is more thorough than previous industry practices to increase the likelihood that any potentially disqualifying FFD information is identified and provide reasonable assurance that individuals are trustworthy and reliable, as demonstrated by avoiding substance abuse. For individuals who have established a recent, favorable work history under Part 26, as demonstrated by having held authorization that was terminated favorably within the past 3 years, the NRC has reduced the period of time addressed in the suitable inquiry from the past 5 years in every case, to the past 3 years or fewer, depending on how recently the applicant held authorization. If potentially disqualifying FFD information within the past 5 years is identified regarding an applicant and a previous licensee or other entity has not addressed and favorably resolved it, the suitable inquiry requirements are more extensive, as described in § 26.69.

The NRC has added § 26.63(a) to the final rule to require licensees and other entities to ensure that a suitable inquiry has been conducted to verify the information provided by the applicant in the self-disclosure and employment history obtained under § 26.61 and to determine if additional potentially disqualifying FFD information is available regarding the applicant. The provision also establishes the circumstances in which a licensee or other entity is permitted to forego the suitable inquiry in order to grant authorization to individuals. A licensee or other entity is permitted to forego the suitable inquiry if the individual previously held authorization under Part 26, his or her last period of authorization was terminated favorably, and the individual was subject to a behavioral observation and arrest-reporting program that meets the requirements of this part throughout the period during which the individual's authorization was interrupted. The information to be obtained from a suitable inquiry is unnecessary in these circumstances because it will already be available to the granting licensee or other entity from the Part 26 program that implemented the behavioral observation and arrest-reporting program during the interruption in authorization.

The final rule adds § 26.63(b) to the final rule to permit licensees and other entities to rely on suitable inquiry information that was gathered by previous licensees and other entities who are subject to this subpart. This provision reduces the number of redundant suitable inquiries that licensees and other entities must conduct when the suitable inquiries would address the same employers and same time periods. The provision also permits licensees and other entities to accept the results of determinations of fitness that were performed under a previous Part 26 program, rather than requiring each new licensee and other entity to reevaluate the same information that was reviewed and resolved under the same requirements in another Part 26 program. The NRC has made this change to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

With respect to the proposed rule, the final rule adds a cross-reference to § 26.189 [Determination of fitness] in § 26.63(b) to specify that licensees and other entities may only rely on determinations of fitness that were conducted under § 26.189. This change is necessary because the licensees and other entities specified in § 26.3(c) have greater latitude in conducting fitness evaluations under Subpart K than is permitted under § 26.189. However, as discussed with respect to § 26.53(f), a licensee or other entity who is subject to this subpart is permitted to rely on a determination of fitness conducted under a Subpart K program if the determination of fitness met the requirements in § 26.189.

The NRC has added § 26.63(c) to the final rule, which specifies requirements for conducting suitable inquiries. Licensees and other entities shall ensure that a ''best effort'' is demonstrated to complete the suitable inquiry. The ''best effort'' criterion recognizes licensees' and other entities' status as commercial entities with no legal authority to require the release of the information from other private employers and educational institutions. Because of privacy and potential litigation concerns, some private employers and educational institutions may be unable or unwilling to release qualitative information about a former employee or student. For example, a former employer may verify the dates that the company employed an individual, but may be unwilling to reveal that the individual had been in treatment for drug or alcohol abuse while employed with the company. Therefore, the ''best effort'' criterion requires licensees and other entities to ensure that suitable inquiry information is sought from the primary source (e.g., a company, private employer, or educational institution that the applicant has listed on his or her employment history), but recognizes that it may not be forthcoming. The ''best effort'' criterion in the paragraph is consistent with the ''best-efforts basis'' in former § 26.27(a)(2). However, the final rule provides more detailed requirements in response to questions that the NRC has received from licensees about implementing a suitable inquiry on a ''best effort'' basis after Part 26 was first promulgated. Also, the final rule modifies the proposed rule to more clearly specify which employers must be questioned as discussed with respect to § 26.61(c).

The NRC has added § 26.63(c)(1) to the final rule, which specifies the type of information that the licensee or other entity must seek from employers regarding the applicant for authorization. This provision requires the licensee or other entity to ascertain the reason that the individual's employment was terminated, his or her eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization. The requirement to obtain this information is consistent with long-standing industry practices related to granting access authorization and related requirements in the access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.63(c)(2) specifies the type of information that licensees and other entities must seek when an applicant's claimed periods of employment include military service. The NRC has added this requirement for consistency with related requirements in the access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

The NRC has added § 26.63(c)(3) to the final rule to address circumstances in which a primary source of information refuses to provide the necessary suitable inquiry information or indicates an inability or unwillingness to provide it within 3 days of the request. Licensees and other entities are required to document that the request for information was directed to the primary source and the nature of the response (i.e., a refusal, inability, or unwillingness). If a licensee or other entity encounters the circumstances addressed in § 26.63(c)(3), the provision requires the licensee or other entity to seek suitable inquiry information from an alternate source to the extent of the alternate source's ability to provide the information. An alternate source may include, but is not limited to, a co-

worker or supervisor at the same company who had personal knowledge of the applicant, if such an individual could be located. However, the final rule prohibits the licensee or other entity from using the alternate source of suitable inquiry information to meet any other access authorization requirements for a character reference. The provision permits licensees and other entities to grant authorization, if warranted, when a response has been obtained from an alternate source without waiting more than 3 days after the request for information was directed to a primary source. With respect to the proposed rule, the final rule clarifies that the licensee shall evaluate and document the response if it is received. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. These alternative methods of meeting the suitable inquiry requirement are necessary because some employers are unwilling or unable to provide suitable inquiry information.

The NRC has added § 26.63(d) to the final rule, which requires licensees and other entities to share suitable inquiry information that they have collected when contacted by another licensee or entity who has a release signed by the applicant for authorization that permits the sharing of that information. This provision restates the permission to release suitable inquiry information in former § 26.29(b) as a requirement that licensees and other entities must share the information necessary to conduct the suitable inquiry. With respect to the proposed rule, the final rule clarifies this provision as a result of a public comment that disagreed with the use of the word ''presentation'' in the proposed provision. The NRC concurred with the comment and believes that current practices in the industry allow for verification of a signed release without the licensee presenting the actual document. Therefore, the NRC has made this change to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule. Also, the final rule expands the list of the types of information that licensees and other entities must make available and on which the denial or unfavorable determination of authorization was based. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity to reflect the NRC's intent beyond what the proposed rule contained.

Section 26.63(d) clarifies that the information must also be released to C/Vs who have licensee-approved FFD programs when the C/V has obtained the required signed release from the applicant. This clarification is necessary because some licensees have misinterpreted former § 26.29(b) as prohibiting the release of suitable inquiry information to C/Vs who have licensee-approved FFD programs. The provision also imposes the requirement on licensees and other entities who may be implementing an FFD program under Subpart K of this part. The NRC has made this change for consistency with the new requirements in Subpart K of this rule and to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has moved the portion of proposed § 26.63(d) that specified that a failure of an individual to authorize the release of information for the suitable inquiry is sufficient cause for a denial of authorization to § 26.53(i)(1) of the final rule. The NRC has made this change to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.63(e) to the final rule to permit licensees and other entities to use electronic means to obtain the suitable inquiry information. This permission is consistent with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003. The paragraph also adds cross-references to the applicable records retention requirements in § 26.711 [General provisions] and § 26.713 [Recordkeeping requirements for licensees and other entities] in Subpart N [Recordkeeping and Reporting Requirements] to the final rule to ensure that licensees and other entities are aware of the applicability of these requirements to the suitable inquiry information obtained electronically. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.63(f) to the final rule, which specifies the period(s) of time that the suitable inquiry must address for applicants for initial authorization, authorization update, and authorization reinstatement. The final rule specifies that the suitable inquiry requirements in this provision apply only to those individuals about whom no potentially disqualifying FFD information is known at the time the suitable inquiry is initiated. The NRC added this provision to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.63(f) specifies the following additional requirements for conducting the suitable inquiry for these authorization categories. Section 26.63(f)(1) [Initial authorization] requires licensees and other entities to conduct a suitable inquiry to address the 3-year period preceding the date the individual applies for authorization. The NRC has reduced the period of time that the suitable inquiry must address for applicants for initial authorization who do not disclose any potentially disqualifying FFD information. The NRC has reduced the period of time to be addressed in the suitable inquiry from 5 years in the former regulation to 3 years to better focus the suitable inquiry on identifying indicators of an active substance abuse problem or an increased risk of recidivism following treatment. If an applicant for initial authorization discloses no potentially disqualifying FFD information from the past 5 years and none is identified through the suitable inquiry or other means, it is unlikely that the applicant has an active substance abuse problem. Therefore, seeking a full 5 years of information about the individual would be unlikely to provide useful data and imposes an unnecessary burden. Industry experience has shown that employers are often reluctant to disclose adverse information to other private employers about former employees. Also, the longer it has been since an individual was employed, the less likely it is that a former employer will disclose useful information. Therefore, rather than retaining the requirement for a 5-year suitable inquiry in all cases, the final rule increases the thoroughness of the suitable inquiry over the past 3 years.

Section 26.63(f)(1) requires the licensee or other entity to ensure that the suitable inquiry has been conducted with every employer by whom the applicant claims to have been employed within the past year. This requirement leads to a more rigorous suitable inquiry than was common industry practice before the issuance of the January 7, 2003, access authorization orders, which imposed additional compensatory measures related to access authorization. The purpose of contacting every employer is to ensure that the licensee or other entity sought information related to any active substance abuse problem. For the earlier years of the suitable inquiry period, the

provision requires the licensee or other entity to ensure that the suitable inquiry has been conducted with every employer by whom the applicant claims to have been employed the longest within each calendar month. Contacting these employers increases the likelihood that the employers would have knowledge of the applicant and may provide more useful information than contacting employers who employed the applicant only briefly.

The NRC has added § 26.63(f)(2) [Authorization update] to the final rule, which specifies the period of time that the suitable inquiry must address for applicants for an authorization update (i.e., those who held authorization within the past 3 years and whose last period of authorization was terminated favorably, but who have not held authorization within the past year). The paragraph requires the licensee or other entity to ensure that the suitable inquiry has been conducted in the same manner as described in § 26.63(f)(1). However, for an authorization update, the suitable inquiry addresses only the period during which the individual's authorization was interrupted, rather than the full 3 years that is required for initial authorization. A 3-year period for the suitable inquiry is unnecessary for these individuals because the licensee or other entity will have access to the information about the individual that was gathered by the licensee or other entity under whose program the individual had been granted and successfully maintained authorization within the past 3 years.

Section 26.63(f)(3) [Authorization reinstatement after an interruption of more than 30 days] specifies the period of time that the suitable inquiry must address for applicants who held authorization within the past year and whose last period of authorization was terminated favorably, but who have not held authorization within the past 30 days. The final rule requires licensees and other entities to ensure that the suitable inquiry has been conducted with the employer by whom the applicant claims to have been employed the longest in each calendar month of the interruption. This provision does not require licensees and other entities to ensure that every employer by whom the individual claimed to have been employed during the interruption is contacted for the reasons discussed with respect to § 26.59(a)(2). Because these individuals have had only a short break in authorization, a sampling of employers from the interruption period is sufficient to determine if any indications exist that the individual has developed a previously undetected substance abuse or other problem that would adversely affect his or her fitness to have authorization reinstated.

The time periods and approach to conducting the suitable inquiry established in § 26.63(f)(1) through (f)(3) are consistent with those established in the access authorization orders issued to nuclear power plant licensees dated January 7, 2003.

Section 26.65 Pre-Access Drug and Alcohol Testing

Section 26.65 of the final rule amends former § 26.24(a)(1). The former provision required drug and alcohol ''testing within 60 days prior to the initial granting of unescorted access to protected areas or assignment to activities within the scope of this part.'' The final rule amends the former pre-access drug and alcohol testing requirement for individuals who are seeking authorization under Part 26 to strengthen the effectiveness of FFD programs.

The NRC has added § 26.65(a) [Purpose] to the final rule to describe the purpose of the section and identify the individuals to whom the requirements in the section apply. The pre-access testing requirements in this section cover applicants for authorization who have never held authorization under Part 26 or have held authorization under Part 26 and whose most recent period of authorization was terminated favorably, and about whom no potentially disqualifying FFD information has been discovered or disclosed that was not reviewed and favorably resolved by another licensee or entity who is subject to Subpart C. Requirements for granting authorization to individuals whose previous periods of authorization were terminated unfavorably or denied, or about whom new potentially disqualifying FFD information has been discovered or disclosed, are contained in § 26.69.

The NRC has added § 26.65(b) [Accepting tests conducted within the past 30 days] to the final rule to permit licensees and other entities to forego pre-access testing of an individual who has negative results from drug and alcohol tests that were performed under the requirements of Part 26 within the 30-day period before the licensee or other entity grants authorization to the individual, including tests that were conducted before the individual applied for authorization from the licensee or other entity. For example, if an individual was subject to random testing under another Part 26 program and was selected for testing under the other program before applying for authorization from the granting licensee or other entity, the final rule permits the granting licensee or other entity to accept negative test results from the random test in lieu of performing a pre-access test, if the random test was conducted within 30 days before the day authorization is granted to the individual. A requirement for the licensee or other entity to conduct pre-access testing in these circumstances is redundant and unnecessary.

The NRC has added § 26.65(c) [Initial authorization and authorization update] to the final rule, which establishes pre-access testing requirements for individuals who are applying for initial authorization and an authorization update. The final rule, with respect to the proposed rule, has added a specification that before granting initial authorization, any pre-access drug and alcohol tests must be conducted within the 30-day period preceding the day the licensee or other entity grants authorization to the individual. Under former § 26.24(a)(1), licensees and other entities were permitted to complete pre-access testing within the 60-day period before authorization is granted. The inclusion in the final rule of a shorter time period within which pre-access testing must be conducted, if required, increases the likelihood of detecting an active substance abuse problem among applicants for unescorted access to nuclear power plants and others who are subject to Part 26 by increasing the number of pre-access tests that are performed. In addition, the decreased time period for pre-access testing increases the likelihood that recent drug use, particularly marijuana, is detected before the concentration of metabolites in an individual's body could decrease below the cutoff levels prescribed in the final rule. Also, the final rule's provision for a decreased time period within which pre-access testing must be performed provides greater assurance that individuals subject to this part are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, as discussed with respect to § 26.23(a).

The final rule requires negative results from pre-access testing before the licensee or other entity grants authorization to the individual, except in the two circumstances described in § 26.65(c)(1) and (c)(2). Pre-access testing in these two circumstances is unnecessary because there is sufficient opportunity to detect substance abuse without the testing. In § 26.65(c)(1), licensees and other entities are permitted to forego pre-access testing if the applicant had been subject to drug and alcohol testing (including random testing), behavioral observation, and

arrest-reporting requirements under a Part 26 FFD program throughout the period the individual's authorization was interrupted.

In proposed § 26.65(c)(2), licensees and other entities were permitted to forego pre-access testing of an applicant who had negative results from Part 26 drug and alcohol tests that were performed within the past 30 days and who was subject to behavioral observation and arrest-reporting requirements during the time interval between the day the specimens were collected and the day the licensee or other entity grants authorization to the individual. However, the NRC received a public comment regarding this provision, which stated that licensees should be able to rely on drug and alcohol tests that were conducted before the individual applied for authorization if the individual has been subject to a behavioral observation and arrest-reporting program, and random drug and alcohol testing, during the time period following the drug and alcohol tests. The NRC agrees that pre-access testing within 30 days before authorization is granted is unnecessary in these circumstances and has removed reference to § 26.65(b) in this provision. This amendment clarifies that licensees may rely on drug and alcohol tests that were conducted at any time before the individual applied for authorization, provided that the individual has been subject to a random drug and alcohol testing program, a behavioral observation program, and an arrest-reporting program that meet the applicable requirements of this part. The NRC has made this change under Goal 5 of the rulemaking to improve the rule by eliminating or modifying unnecessary requirements.

The NRC has added § 26.65(d) [Authorization reinstatement after an interruption of more than 30 days] and (e) [Authorization reinstatement after an interruption of 30 or fewer days] to the final rule, which establish requirements for the pre-access testing of individuals who are applying for an authorization reinstatement. The requirements for pre-access testing of these individuals are less stringent than the requirements for initial authorization and an authorization update. The provision relaxes the pre-access testing requirements in former § 26.24(a)(1), which mandated that all applicants for authorization must be subject to pre-access testing within 60 days before granting authorization. Less stringent pre-access testing requirements are appropriate because these individuals have met the rigorous criteria for initial authorization, established a recent record of successfully maintaining authorization under Part 26, and had only a short break in authorization.

Section 26.65(d) of the final rule specifies pre-access testing requirements for individuals whose authorization has been interrupted for more than 30 days but no more than 1 year. Section 26.65(d)(1)(i) requires the licensee or other entity to administer an alcohol test and collect a urine specimen for drug testing. The final rule, with respect to the proposed rule, clarifies that before granting initial authorization, any required pre-access drug and alcohol tests must be conducted within the 30-day period preceding the day the licensee or other entity grants authorization to the individual. The licensee or other entity is permitted to reinstate the individual's authorization if the alcohol test results are negative before the drug test results are available. Section 26.65(d)(1)(ii) permits the licensee or other entity to maintain the individual's authorization for 5 business days after reinstatement without receiving the drug test results. However, if the licensee or other entity does not receive negative drug test results within 5 business days of reinstating the individual's authorization, the final rule requires the licensee or other entity to administratively withdraw the individual's authorization until negative drug test results are received. These requirements ensure that individuals whose authorization has been interrupted for more than 30 days are subject to pre-access drug and alcohol testing to deter substance abuse and to detect any current substance abuse problem. However, the provisions do not unduly delay authorization reinstatement because these individuals' recent successful histories of maintaining authorization under Part 26 indicate that they are at low risk of engaging in substance abuse.

Section 26.65(d)(2) permits licensees and other entities to forego pre-access testing of these applicants for reinstatement in the circumstances discussed with respect to § 26.65(c)(1) and (c)(2). The discussion with regard to § 26.65(c)(2) also specifies the reasons for the changes from the proposed rule in § 26.65(d)(2)(ii).

The NRC has added § 26.65(e)(1) to the final rule to permit licensees and other entities to forego pre-access testing of applicants whose authorization has been interrupted for 5 or fewer days. This provision is consistent with current licensee practices and recommendations regarding short breaks in authorization in NUREG–1385 and other access authorization requirements. The final rule also has moved the provisions from paragraph (e)(3) of the proposed rule into this paragraph of the final rule to improve clarity in the organization of the final rule, consistent with Goal 3 of the rulemaking. This provision permits licensees and other entities also to forego subjecting an individual to the possibility of selection for pre-access testing if the applicant has been subject to the drug and alcohol testing (including random testing), behavioral observation, and arrest-reporting elements of a Part 26 FFD program throughout the interruption in the individual's authorization. The NRC believes that being subject to these program elements during the interruption period is sufficient to deter substance abuse and provide assurance that substance abuse would be detected. Section 26.65 enhances the deterrent effect of pre-access testing for individuals who have had a very short break in authorization without imposing the burden of requiring that every individual must be tested.

Section 26.65(e)(2) of the final rule requires licensees and other entities to subject applicants whose authorization has been interrupted for 6 to 30 days to the possibility of selection for pre-access testing in order to deter any potential for substance abuse. However, this provision specifies that the licensee or other entity may forego subjecting an individual to the possibility of being selected for pre-access testing if the applicant has been subject to the drug and alcohol testing (including random testing), behavioral observation, and arrest-reporting elements of a Part 26 FFD program throughout the interruption in the individual's authorization.

Section 26.65(e)(2)(i) requires the licensee or other entity to subject the applicant to a one-time chance of being selected for testing at a probability of approximately 4 percent. This probability approximates the likelihood that individuals who are subject to random testing at the 50-percent annual testing rate in § 26.31(d)(2)(vii) are selected for testing at some point within a 30-day period. Section 26.65(e)(2)(ii) clarifies that if an applicant is not selected for pre-access testing under the preceding section, the licensee or other entity is not required to perform a pre-access test. Section 26.65(e)(2)(iii)(A) and (B) specifies requirements for conducting the pre-access testing if an individual is selected for testing under § 26.65(e)(2)(i). The licensee or other entity shall complete an alcohol test and collect a specimen for drug testing before reinstating the individual's authorization. In order to maintain the individual's reinstated authorization,

the final rule requires that the licensee or other entity must receive negative drug test results within 5 business days after reinstatement or administratively withdraw the individual's authorization until negative drug test results are received.

The NRC has deleted from the final rule § 26.65(f) [Time period for testing] of the proposed rule. The proposed provision mandated that specimens that are collected for any pre-access testing required in this section must be collected within the 30-day period preceding the day the licensee grants authorization to an individual. The NRC received a public comment that stated that licensees currently conduct pre-access drug and alcohol testing within the 30-day period preceding the date the licensee grants authorization and that proposed § 26.65(f) only requires licensees to collect a sample in this timeframe. The NRC agrees with the comments and, therefore, has deleted this provision from the final rule to increase efficiency, consistent with Goal 5 of the rulemaking to eliminate unnecessary requirements. However, the NRC has added requirements to § 26.65(c) and (d)(1)(i) to specify that any pre-access testing required in this section must be conducted within the 30-day period preceding the day upon which the licensee grants authorization to an individual, consistent with the proposed rule's intent. Under former § 26.24(a)(1), licensees and other entities were permitted to complete pre-access testing within the 60-day period before authorization is granted. The reason why the final rule shortens this time period to 30 days is discussed with respect to § 26.65(c).

The NRC has added § 26.65(f) [Administrative withdrawal of authorization] (changed from § 26.65(g) in the proposed rule because of renumbering) to the final rule to ensure that the licensee or other entity does not record or report as an unfavorable termination any administrative withdrawal of authorization that may be required under paragraphs (d)(1)(ii) or (e)(2)(iii)(B) of this section. The time a licensee or other entity receives drug test results is not under the applicant's control and does not reflect on the applicant's fitness, trustworthiness, or reliability, if the licensee or other entity is unable to obtain drug test results within the 5 days permitted and must administratively withdraw the individual's authorization. Therefore, subjecting the individual to the severe consequences associated with a record of an unfavorable termination is inappropriate, except if the individual's authorization was subsequently denied or terminated unfavorably by a licensee or entity. However, if the drug test results are positive, adulterated, or substituted and the licensee or other entity terminates the individual's authorization for cause, the termination is then recorded as unfavorable. However, with respect to the proposed rule, the final rule adds a clarification that the individual is required to disclose administrative action if the individual's authorization was subsequently denied or terminated unfavorably. The NRC has made this change to the proposed rule in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

The NRC has added § 26.65(g) [Sanctions] (changed from § 26.65(h) in the proposed rule because of renumbering) to the final rule, which specifies the minimum sanctions to be imposed on an individual whose pre-access test results the MRO confirms as an FFD policy violation. Section 26.65(g)(1) and (g)(2) contains cross-references to the relevant sanctions specified in Subpart D [Management Actions and Sanctions To Be Imposed] to clarify that those sanctions apply to applicants for authorization. For example, if the MRO determines that an individual has submitted an adulterated urine specimen for a pre-access drug test, the licensee or other entity is required to impose the sanction for an attempt to subvert the testing process (i.e., permanent denial of authorization) in § 26.75(b).

The NRC has added § 26.65(g)(3) to the final rule to permit licensees and other entities to grant authorization to an individual whose confirmed positive, adulterated, or substituted test result is a first drug- or alcohol-related violation under a Part 26 program, consistent with former § 26.27(b)(2). However, the final rule permits authorization to be granted only under the stringent requirements contained in § 26.69.

Section 26.67 Random Drug and Alcohol Testing of Individuals Who Have Applied for Authorization

The NRC has added § 26.67 to the final rule, which extends former random testing requirements to individuals who have applied for authorization under Part 26 but who have not yet been granted authorization. The NRC has added the requirements in this section to the access authorization requirements that were established by orders to nuclear power plant licensees dated January 7, 2003, to enhance the effectiveness of FFD programs by increasing the likelihood that substance abuse will be detected before authorization is granted and to deter the potential for substance abuse among applicants. Therefore, the NRC has made these changes to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.67(a) to the final rule, which requires licensees and other entities to conduct random testing of applicants under the requirements of § 26.31(d)(2). The licensee or other entity must add applicants for authorization to the FFD program's normal population of individuals who are subject to random testing, select individuals for testing at the 50-percent annual rate, and otherwise subject applicants to the same random testing requirements as individuals who currently hold authorization under Part 26. An applicant is subject to random testing beginning when the licensee or other entity collects the specimens for any required pre-access test and continues thereafter, if the licensee or other entity grants authorization to the individual.

Licensees and other entities are permitted to forego random testing of applicants in the two circumstances described in § 26.67(a)(1) and (a)(2). Section 26.67(a)(1) permits a licensee or other entity to discontinue random testing of any applicant to whom the licensee or other entity does not grant authorization for any reason, including a termination or denial of authorization or a withdrawal of the application for authorization by the individual or the individual's employer, in the case of a C/V. Section 26.67(a)(2) addresses the circumstance described in § 26.65(b), in which the licensee or other entity is permitted to meet pre-access testing requirements by relying on negative test results from specimens collected under another Part 26 program within 30 days before granting authorization to the individual. Under § 26.67(a)(2), the licensee or other entity shall begin subjecting the applicant to random testing when the licensee or other entity takes the first formal action to process the individual's application for authorization.

The formal actions may include, but are not limited to, the time when the licensee or other entity receives the individual's signed consent form and begins creating a record of the

individual's application that would be accessible to other licensees and entities; conducts a psychological evaluation; begins a suitable inquiry; or takes other actions that are required under NRC regulations to grant authorization. The first formal action that the licensee or other entity takes to process an individual's application for authorization will vary, depending on the licensee's FFD and access authorization program procedures, whether the applicant's FFD training is up-to-date, and other factors. These considerations make it impractical to establish a single point in the authorization process established in the rule when random testing must begin. Therefore, the provision requires the licensee or other entity to begin subjecting the individual to random testing when the licensee or other entity takes the first formal action, but does not define a specific formal action that would initiate random testing of applicants in all cases.

The NRC has added § 26.67(b) to the final rule, which permits licensees and other entities to grant authorization to an individual before random testing is completed if the individual has met all of the requirements for authorization but has been selected for one or more random tests while in applicant status. The final rule does not require the testing to be completed before the licensee or other entity grants authorization to the individual because the primary purpose of randomly testing applicants is to deter substance abuse rather than to provide information for the authorization decision. Pre-access testing provides the necessary information for authorization decision making.

Section 26.67(c) of the final rule cross-references the minimum sanctions to be imposed on an individual whose drug or alcohol results from random testing are confirmed as positive, adulterated, or substituted. The final rule also makes a minor language clarification to the proposed rule by modifying the term ''non-negative'' of this section. Section 26.67(c)(1) and (c)(2) refers to the relevant sanctions specified in Subpart D. Section 26.67(c)(3) continues to permit licensees and other entities to grant authorization to an individual whose confirmed positive, adulterated, or substituted test result is a first drug- or alcohol-related violation under a Part 26 program, consistent with former § 26.27(b)(2). However, the final rule permits authorization to be granted only under the stringent requirements contained in § 26.69.

Section 26.69 Authorization With Potentially Disqualifying Fitness-for-Duty Information

The NRC adds § 26.69 to the final rule to replace and clarify the requirements contained in former § 26.27(b)(4). Former § 26.27(b)(4) established requirements for granting authorization to an individual who has violated an FFD policy and had his or her authorization terminated unfavorably or denied for a period of 3 or more years under the former rule. Consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule, this section of the final rule addresses problems that have arisen in implementing the former rule and clarifies the NRC's intent with respect to several situations that the former rule did not address.

The NRC has added § 26.69(a) [Purpose] to the final rule to describe the purpose of the section and the applicants who are subject to these requirements. The provision requires licensees and other entities to meet the applicable requirements in this section before granting authorization to an individual or permitting an individual to maintain his or her authorization when potentially disqualifying FFD information is obtained about the individual through any means and a previous licensee or other entity has not assessed and favorably resolved the information. Section 26.63(b) permits licensees and other entities to rely on the results of determinations of fitness that previous licensees or other entities conducted, rather than requiring each new licensee or other entity to reevaluate the same information that was reviewed and resolved under another Part 26 program. However, if the potentially disqualifying FFD information was not previously reviewed and favorably resolved by another FFD program under this subpart, licensees and other entities must implement the requirements contained in this section.

Section 26.69(a) also revises the language contained in former § 26.27(b)(2) to recognize that licensees and other entities may decide not to grant authorization to the subject individual and so, in that case, are not required to implement these requirements. At the public meetings discussed in Section I.D, stakeholders noted that some individuals have misinterpreted the former rule as requiring licensees to provide individuals who have violated an FFD policy with the opportunity to seek treatment for a substance abuse problem and to have authorization reinstated. However, although the NRC continues to affirm that individuals who pursue treatment and maintain sobriety may be considered for authorization, both the former and final rules assign the responsibility for making authorization decisions to the licensee or other entity. Therefore, the paragraph clarifies that granting or maintaining the authorization of an individual about whom potentially disqualifying FFD information has been disclosed or discovered is ''at the licensee's or other entity's discretion.''

The NRC has added § 26.69(b) [Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization] to the final rule to define requirements for granting authorization at the licensee's or other entity's discretion to an individual who had confirmed positive drug or alcohol test results and whose authorization was previously terminated unfavorably or denied for 5 years. The requirements in this section apply to:

(1) An applicant who had a first confirmed positive test result on a pre-access test and was consequently denied authorization by a licensee;

(2) An individual who is returning to duty following the 14-day assessment period required in § 26.75(e)(1) (The NRC has moved the provisions in former § 26.26(b)(2) to § 26.75(e)(1));

(3) An individual whose authorization was terminated unfavorably under another Part 26 program and who had an interruption in authorization that was longer than 14 days; and

(4) An individual whose authorization was denied for 5 years under the requirements of § 26.75(c), (d), (e)(2), or (f).

This provision replaces and strengthens the requirements contained in former § 26.27(b)(2) and expands them to address confirmed positive alcohol test results, which were excluded from this process in former § 26.27(b)(5). The paragraph includes confirmed positive alcohol test results for the reasons discussed with respect to § 26.75(e).

The NRC has retained the language of the proposed rule to state that the licensee or other entity shall perform the activities listed in paragraphs (b)(1) through (b)(6) of this section. In the situations presented in this section, the NRC believes that the licensees or other entities will likely conduct these tasks themselves because another licensee has not reviewed and resolved the individual's situation. Therefore, the licensees will have to collect more original data about the individual, rather than relying on that collected by another licensee. However, by retaining

the language of the proposed rule in this section, the NRC does not intend to require that the licensees or other entities must conduct these tasks themselves in these situations. The NRC maintains that the licensee may rely on information collected by others to meet the requirements of § 26.69 if that is the most reasonable way to proceed. For example, if the licensee or other entity uses a background screening company, they would most likely continue to have the company perform the employment history required in this section.

Section 26.69(b)(1) requires the licensee or other entity to obtain and review a self-disclosure and employment history from the applicant to verify that it does not contain any previously undisclosed potentially disqualifying FFD information. The final rule has added ''employment history,'' with respect to the proposed rule, to state the intent that both a self-disclosure and employment history shall be reviewed. When an individual's last period of authorization was terminated unfavorably or denied, licensees and other entities are not permitted to forego obtaining a self-disclosure and employment history under any circumstances because it is important to review the individual's activities during the interruption period. The period of time the self-disclosure must address is the shorter of either the past 5 years or the intervening period after the individual last held authorization.

Section 26.69(b)(2) increases the scope of the suitable inquiry by requiring the licensee or other entity to conduct the suitable inquiry with every employer by whom the applicant claims to have been employed during the period of time addressed in the individual's employment history. The final rule replaces ''self-disclosure'' in the proposed rule with ''employment history'' to clarify that the time period covered is that which the employment history addresses. This extensive suitable inquiry is necessary to determine if any indications exist that the individual has continued to engage in substance abuse. The final rule also requires licensees and other entities to obtain and review any records that other licensees or entities may have developed related to any potentially disqualifying FFD information about the individual from the past 5 years. These records may include, but are not limited to, the results of past suitable inquiries or other investigations, records of arrests or convictions, drug and alcohol test results, treatment records, and the results of determinations of fitness. The SAE uses this information to assess the individual's fitness and the licensee's or other entity's reviewing official uses it to determine whether authorization is warranted.

Section 26.69(b)(3) applies only to individuals whose authorization was denied for 5 years under the former rule or under § 26.75(c), (d), (e)(2), or (f) of the final rule. The paragraph requires the licensee or other entity to verify, before granting authorization, that the individual had not abused alcohol or drugs during the 5-year interruption, at a minimum. The requirement is consistent with the portion of former § 26.27(b)(4) that required licensees to obtain ''satisfactory medical assurance that the person has abstained from drugs for at least 3 years.'' However, the final rule extends the requirement to 5 years to ensure that such an individual is at the lowest risk of recidivism into an active substance abuse problem before the licensee or other entity grants authorization to the individual.

Section 26.69(b)(4) amends the requirement in former § 26.27(b)(2). The former provision mandated that an individual who has a first confirmed positive test result must be referred to the EAP for assessment and counseling before the licensee or other entity may grant authorization to the individual. The final rule makes several changes to the former provision. First, the final rule replaces the term ''management and medical assurance of fitness'' which was used in former § 26.27(b)(2) and (b)(4), with the term ''determination of fitness'' to improve the accuracy of the language in the final rule. The final rule does not use ''management'' because the licensee's or other entity's reviewing official [see the discussion of § 26.69(c)(3) and the definition of ''reviewing official'' in § 26.5] is the individual who licensees and other entities currently designate to make authorization decisions and the reviewing official may not be a manager. In addition, the final rule permits professionals other than a licensed physician to conduct a determination of fitness, for the reasons discussed with respect to § 26.189. The NRC has made these change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Consistent with the intent of the former requirement, the provision requires the licensee or other entity to ensure that an SAE has conducted a determination of fitness, as defined in § 26.189, as part of the authorization decision. Section 26.187 [Substance abuse expert] requires that an SAE must perform determinations of fitness that are conducted for authorization decisions. Section 26.187 also defines the role, responsibilities, and required qualifications of an SAE. Therefore, § 26.69(b)(4) requires that the individual must be referred to an SAE for a determination of fitness. However, the final rule does not require the SAE to be an EAP employee. Permitting licensees and other entities to rely on a professional who meets the required qualifications for an SAE rather than only on EAP personnel, more appropriately focuses this requirement on ensuring that the professional who performs the assessment and treatment planning is qualified, rather than on the professional's organizational affiliation. The NRC received a comment requesting that the rule rely on a Substance Abuse Professional (SAP) to meet the requirement of this section. The NRC acknowledges that the SAP training and credentialing process emphasizes knowledge about the SAP role in programs under 10 CFR Part 40, ''Domestic Licensing of Source Material.'' However, although an SAP under Part 40 meets many of the criteria established in the rule, thorough knowledge of Part 26 requirements is also necessary. Therefore, the NRC has not modified the proposed provision in the final rule.

Section 26.69(b)(4)(i) through (b)(4)(iii) replaces and strengthens the requirement in former § 26.27(b)(2). The former provision stated that ''any rehabilitation program deemed appropriate must be initiated during such suspension period.'' The final rule requires that the individual must be in compliance with or have successfully completed treatment and follow-up testing plans, rather than simply started treatment, in order for the licensee or other entity to grant authorization to the individual and maintain the individual's authorization after it has been granted.

The NRC has added § 26.69(b)(5) to the final rule to impose more stringent pre-access testing requirements on an individual who is being considered for authorization following an unfavorable termination or denial of authorization than those required for individuals whose last period of authorization was terminated favorably. The provision requires negative results from an alcohol test performed within 10 business days before authorization is granted. Similarly, the provision requires negative results from a urine specimen that was collected under direct observation for drug testing within 10 business days before authorization is granted. The provision prohibits the licensee or other entity from granting authorization to the individual before the drug test results are reported to the

licensee's or other entity's MRO. The MRO may then determine whether the drug test results indicate that the individual has not engaged in any further drug abuse [see the discussion of § 26.69(f)]. Completing drug and alcohol testing within 10 business days before granting authorization rather than the 30 days that is permitted in § 26.65 for the other authorization categories provides evidence that the individual has abstained from abusing proscribed substances during the interruption period and that the individual is able to safely and competently perform duties under this part when authorization is reinstated, if the individual's authorization has been interrupted for the 14-day assessment period required under former § 26.27(b)(2) and retained in § 26.75(e)(1). Requiring direct observation of the urine specimen collection is necessary to provide added assurance that the specimen is valid and yields accurate drug test results.

Section 26.69(b)(6) applies only to individuals whose authorization has been unfavorably terminated or denied for at least 14 days for a first confirmed positive drug or alcohol test result. The provision replaces the third sentence of former § 26.27(b)(4). This sentence established requirements and a schedule for followup drug and alcohol testing for an individual whose authorization was denied for 3 years under the former rule. The final rule applies the requirement for followup testing to individuals who have had a first confirmed positive test result for drugs or alcohol. This requirement provides greater deterrence of further drug and alcohol use than former § 26.27(b)(4), which required this followup testing only for the more serious FFD violations that result in a denial of authorization for 3 years or longer. The more stringent requirement provides higher assurance that individuals who are subject to this part are trustworthy, reliable, and fit for duty.

Section 26.69(b)(6) amends the former fixed schedule for followup testing by requiring licensees and other entities to subject the individual to the possibility of being selected for followup testing, during any period in which he or she holds authorization under Part 26, for a period of 3 calendar years after the individual's authorization is restored following termination or denial for the first confirmed positive drug or alcohol test result. The rule requires licensees and other entities to ensure that the individual is subject to unannounced testing at least 15 times within the 3-year period and to verify that the individual's test results are negative. Either random or followup tests, which are both unannounced, may be used to meet this final requirement. The final rule requires licensees and other entities to distribute the unannounced tests over the 3-year period, with at least one unannounced test conducted each quarter.

The NRC has added § 26.69(b)(6)(i) through (b)(6)(iii) to the final rule to address circumstances when an individual is not continuously subject to a Part 26 program during the 3 years following the restoration of authorization. Section 26.69(b)(6)(i) requires that an individual who intermittently holds authorization over the 3-year period must be subject to unannounced testing at least once in each quarter during which the individual is authorized. Section 26.69(b)(6)(ii) permits the licensee or other entity to extend the followup testing period to 5 years, if the requirement for 15 tests over the 3-year period has not been met because the individual has not been authorized a sufficient number of times or for sufficient periods of time during the first 3 years to meet the final 15-test requirement. Section 26.69(b)(6)(iii) permits the licensee or other entity to have an SAE conduct a determination of fitness to determine whether further followup testing is required, if an individual is unable to meet the 15-test requirement after 5 years because of brief and infrequent periods of authorization. The revision of these requirements increase the flexibility with which licensees and other entities may implement followup testing, but retains the former effectiveness of followup testing in detecting and deterring substance abuse.

The NRC has added § 26.69(b)(7) to the final rule, which requires the licensee or other entity to verify that the results of all drug and alcohol tests that are administered to the individual under a Part 26 program following the restoration of the individual's authorization indicate no further drug or alcohol abuse. The provision does not specify that the drug test results must be negative because the metabolites of some drugs, such as marijuana, may be present in an individual's urine for several weeks after the individual has stopped using the drug. If an individual is tested again soon after the original test that resulted in an FFD violation was conducted, the specimen may yield positive results which would not, in fact, reflect new drug use. Therefore, if subsequent drug test results show the presence of the same drug or drug metabolites in the individual's urine as detected in the original confirmed positive test result, the MRO, under § 26.185(o), is required to determine whether the results indicate new drug use or are consistent with results that are expected from the drug use that resulted in the previous confirmed positive test result. The rule adds this requirement in response to inconsistencies in the way some MROs have implemented former requirements related to return-to-duty drug testing. Some MROs have been inappropriately reluctant to declare a second drug test result as negative if any concentration of the drug or drug metabolites that resulted in a first confirmed positive drug test result are detected in the specimen. The change permits an individual who has not engaged in further drug use after a first confirmed positive drug test result to regain authorization at the licensee's discretion rather than be incorrectly denied authorization for 5 years on the basis of a subsequent FFD policy violation, under § 26.75(e)(2).

The NRC has added § 26.69(c) [Granting authorization with other potentially disqualifying FFD information] to the final rule to establish requirements for granting authorization to an individual about whom potentially disqualifying FFD information is discovered or disclosed that was not a confirmed positive, adulterated, substituted, or invalid drug or alcohol test result or 5-year denial of authorization. For example, this type of potentially disqualifying FFD information may include, but is not limited to:

(1) A report of an arrest for an alcohol-related traffic violation;

(2) Information from the suitable inquiry that a previous private-sector employer terminated an individual's employment because of drug- or alcohol-related job performance problems; or

(3) Information obtained from the suitable inquiry or other sources of information indicating that the individual is known to abuse illegal drugs or alcohol or is experiencing significant mental or emotional stress.

This provision is necessary because the former rule did not address the authorization process in these circumstances and the NRC is aware that licensees and other entities have handled these circumstances inconsistently. Therefore, the final rule adds these requirements to establish the NRC's intent with respect to these circumstances and increase consistency between Part 26 programs.

The NRC has added a second sentence to § 26.69(c) in the final rule to clarify that if potentially disqualifying FFD information is obtained about an

individual by any means, the licensee shall perform the activities in paragraphs (c)(1) through (c)(5) of this section before granting authorization to the individual. The NRC has made this change to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.69(c)(1) to the final rule, which requires the licensee or other entity to obtain and review the individual's self-disclosure and employment history. The final rule has added the term ''employment history'' to clarify that the licensee must obtain and review that in addition to the self-disclosure. The final rule also modifies the language of the proposed rule by eliminating reference to § 26.31(b)(3) and instead adding paragraphs (c)(1)(i) through (c)(1)(iii) to § 26.69 to specify exactly the time period that the self-disclosure and employment history must address. The NRC has made this change in response to a public comment suggesting that this provision needed clarification and to meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.69(c)(2) requires the licensee or other entity to conduct a suitable inquiry with every employer for the period that the employment history addresses. In this section, the final rule deletes ''self-disclosure'' and replaces it with the phrase ''employment history required under paragraph 26.63(a) through (e)'' to clarify the time period addressed. If the potentially disqualifying FFD information was identified during the course of conducting a suitable inquiry under § 26.63(f) so that the suitable inquiry was partially completed, § 26.69(c)(2) requires the licensee or other entity to conduct a more complete suitable inquiry by contacting every employer that the individual listed during the interruption period. The provision also requires that if the individual held authorization within the past 5 years, the licensee or entity shall obtain and review any records that other licensees or entities who are subject to this part may have developed with regard to potentially disqualifying FFD information about the individual from the past 5 years. The final rule, with respect to the proposed rule, has added the phrase ''if the individual held authorization within the past 5 years'' to meet Goal 6 of the rulemaking to improve clarity in the language of the rule. This more complete suitable inquiry is necessary to ensure that the licensee or other entity has more information about the individual than is required for individuals whose last period of authorization was terminated favorably in order to make an appropriate authorization decision.

The NRC has added § 26.69(c)(3) to the final rule, which uses the term ''reviewing official'' to refer to the employee whom the licensee or other entity designates to make authorization decisions as discussed with respect to § 26.5. This provision permits the reviewing official to grant or deny authorization based upon his or her review of the circumstances associated with the potentially disqualifying FFD information. Because of the variety of circumstances that may arise, the provision also grants discretion to the reviewing official in deciding whether a determination of fitness is required rather than requiring a determination of fitness in every case. However, if the reviewing official requests a determination of fitness and the professional who performs it recommends any form of treatment or drug and alcohol testing, including the collection of urine specimens under direct observation, § 26.69(c)(4) requires the licensee or other entity to implement the treatment and testing recommendations.

The NRC has added § 26.69(c)(5) to the final rule to require pre-access and random testing of the applicant for authorization. This provision requires the licensee or other entity to verify that the results of pre-access drug and alcohol tests are negative before granting authorization to the individual, to provide evidence that the individual is avoiding substance abuse.

The NRC has added § 26.69(d) [Maintaining authorization with other potentially disqualifying FFD information] to the final rule, which establishes requirements for maintaining an individual's authorization when new potentially disqualifying FFD information is disclosed or discovered that was not a confirmed positive drug or alcohol test result, or 5-year denial of authorization, if the reviewing official determines that maintaining authorization is warranted. A self-disclosure, suitable inquiry, and pre-access testing are not required because the individual would not be applying for authorization. However, the provision requires the reviewing official to consider the circumstances related to the information and, at his or her discretion, ensure that a professional with the appropriate qualifications makes a determination of fitness. The provision mandates that the licensee or other entity must implement any treatment or testing requirements resulting from the determination of fitness. The NRC has added the provision because the former rule did not address maintaining an individual's authorization in these circumstances. Also, the NRC is aware that licensees and other entities have handled these circumstances inconsistently. Therefore, the final rule adds these requirements to establish the NRC's intent with respect to these circumstances and to increase consistency between Part 26 programs.

The NRC has added § 26.69(e) [Accepting followup testing and treatment from another Part 26 program] to the final rule to establish continuity of care requirements for individuals who were subject to a followup testing and/or a substance abuse treatment plan under one Part 26 program and transfer to another FFD program, or leave and then return to the same FFD program.

Section 26.69(e)(1) requires the receiving licensee or other entity to continue the testing and treatment plan to which the individual was subject under the previous FFD program. However, with respect to the proposed rule, the final rule clarifies that the licensee or other entity who imposed the treatment and/or followup testing plan shall ensure that information documenting the treatment and/or followup testing plan is identified to any subsequent licensee or other entity who seeks to grant authorization to the individual. The NRC has made this change to clarify the intent of the provision and in recognition of the need for additional consistency between the final rule and the access authorization requirements. Therefore, this change helps meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.69(e)(1) of the final rule also adds a specification that if it is impractical for the individual to comply with the treatment plan that was developed under another FFD program, the granting FFD program shall ensure that an SAE develops a comparable treatment plan. The NRC has made this change because it received a public comment stating that the proposed provision that required the licensee to assume responsibility for overseeing the continuation of treatment and follow-up testing for an employee who had a positive test result under another FFD program could be burdensome, especially if the individual is applying for authorization at a new site that makes it impossible to use the same treatment providers.

Section 26.69(e)(2) permits the receiving licensee or other entity to

accept and rely on any followup testing that was completed while the individual was subject to the previous Part 26 program to determine how long followup testing must continue. For example, if an individual met all of the requirements for authorization by a new licensee but had completed only 2 of the 3 years of followup testing required under a previous Part 26 program, the granting licensee would then administer the final year of the followup testing. However, the licensee is not required to conduct another 3 full years of followup testing after the individual was authorized. If the transferring individual successfully completed any followup testing and treatment program required under the first FFD program, a previous determination of fitness indicated that the individual is fit for duty, and the individual's authorization by the first licensee or other entity was terminated favorably, this provision permits the receiving licensee or other entity to accept the previous determination of fitness and does not require the granting licensee to develop and implement an additional testing and treatment plan.

The NRC has added § 26.69(f) [Sanctions] to the final rule to clarify the minimum sanctions to be imposed on an individual who has confirmed positive, adulterated, or substituted drug and alcohol test results on any tests that may be required under this section. Section 26.69(f)(1) and (f)(2) cross-references the relevant sanctions specified in Subpart D to establish that those sanctions apply to individuals about whom potentially disqualifying FFD information has been discovered or disclosed.

Section 26.71 Maintaining Authorization

The NRC has added § 26.71 to the final rule to state the requirements for maintaining authorization under this part and has adopted the provisions in this section as proposed without change. Section 26.71(a) of the final rule provides that individuals may maintain authorization under the conditions listed in § 26.71(a)(1) through (a)(4), as follows:

Section 26.71(a)(1) establishes that an individual must comply with the licensee's or other entity's FFD policies to which the individual is subject. This requirement relates, although it does not refer to § 26.27 [Written policy and procedures] that requires the licensee or other entity to prepare a clear and concise statement of its FFD policy and make that policy readily available to all individuals who are subject to the policy. The final rule requires that all individuals who are subject to the FFD policy must have information on the expectations of them and the consequences that may result from a lack of adherence to the policy. Section 26.71 also requires that in order to maintain authorization, an individual must report any legal actions as defined in § 26.5. Finally, although not explicitly specified in § 26.71(a)(1), § 26.33 [Behavioral observation] requires individuals to report any FFD concern to the personnel designated in the FFD policy.

Section 26.71(a)(2) establishes that an individual may maintain authorization if the individual remains subject to a drug and alcohol testing program that complies with the requirements of Part 26, including random testing. Licensees and other entities who are subject to Part 26 are responsible for implementing drug and alcohol testing programs that comply with the requirements in § 26.31 [Drug and alcohol testing]. The failure of a licensee or other entity to maintain a program would terminate the authorizations of individuals who have been granted authorization by the licensee or other entity (see the discussion of § 26.71(b)). Section 26.31 also places certain responsibilities on individuals who are subject to the testing program. In particular, under § 26.31(d)(2)(iii), individuals who are selected for random testing are required to report to the collection site as soon as reasonably practicable after notification within the time period specified in FFD program procedures, as well as to cooperate in the testing process. In appropriate circumstances, an individual's failure to report or cooperate could be the basis for terminating the individual's authorization.

Section 26.71(a)(3) establishes that an individual may maintain authorization if the individual remains subject to a behavioral observation program that complies with the requirements of Part 26. Behavioral observation, as required by § 26.33, is performed by individuals, including coworkers, who have been trained to detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from fatigue or any cause that, if left unattended, might constitute a threat to the health and safety of the public or the common defense and security.

Section 26.71(a)(4) establishes that a condition for maintaining authorization is the individual's successful completion required of FFD training, according to the schedule in § 26.29(c). As specified in § 26.29(c)(1), the final rule requires the individual to complete training before the licensee or other entity grants initial authorization. Thereafter, as specified in § 26.29(c)(2), the rule requires individuals to complete refresher training or pass a comprehensive examination on a nominal 12-month frequency. Section 26.29(d) provides that licensees and other entities may accept the training of individuals who have been subject to another Part 26 program and have either had initial or refresher training or successfully passed a comprehensive examination within the past 12 months that meets the requirements of § 26.29.

Section 26.71(b) of the final rule requires a licensee or other entity to terminate an individual's authorization if the individual is not subject to an FFD program that meets the requirements of Part 26 for more than 30 (consecutive) days. The requirements of the paragraph permits an individual to be away from all elements of a Part 26 program for this period of time in order to accommodate vacations and significant illnesses when the individual is not reasonably available for behavioral observation or to collect specimens for random drug and alcohol testing. The NRC has added this paragraph to the final rule in response to stakeholder requests, and it is consistent with related requirements in the access authorization orders issued to nuclear power plant licensees on January 7, 2003.

Subpart D—Management Actions and Sanctions To Be Imposed

Throughout this subpart, the final rule makes minor clarifications to the proposed rule due to public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The final rule makes other substantive changes in §§ 26.73; 26.75(e)(1) and (h); and 26.77(b)(2) that are discussed with regard to those sections. Otherwise, the final rule has adopted the provisions in this section as proposed without change.

Section 26.73 Applicability

The NRC has added § 26.73 to the final rule to describe the applicability of the subpart. The new § 26.73 specifies, by using applicable cross-references to §§ 26.3 [Scope] and 26.4 [FFD program applicability to categories of individuals], the licensees and other entities, as well as individuals, to whom the requirements of this subpart apply.

Section 26.75 Sanctions

The first sentence of § 26.75(a) of the final rule introduces the purpose of the section, which is to define the minimum

sanctions that licensees and other entities must impose when an individual has violated the drug and alcohol provisions of an FFD policy. The second sentence of the paragraph restates the second sentence of former § 26.27(b). This sentence permits licensees and other entities to impose more stringent sanctions than those specified in the final rule. The final rule adds a cross-reference to paragraph (h) of this section, which establishes limits on the sanctions that licensees and other entities may impose for positive, adulterated, substituted, or invalid drug test results. Adding a cross-reference to paragraph (h) of this section clarifies that the blanket permission to impose more stringent sanctions granted in this paragraph has one exception, as discussed with respect to paragraph (h) of this section. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.75(b) to the final rule to require licensees and other entities to permanently deny authorization to individuals who refuse to be tested or who in any way subvert or attempt to subvert the testing process. This sanction is necessary because acts to subvert the testing process reflect a sufficiently egregious lack of trustworthiness and reliability to warrant permanent denial of authorization. An individual's willingness to subvert or attempt to subvert the testing process provides strong evidence that the individual will also be willing to disregard other rules and regulations, such as safeguards requirements, which ensure the protection of public health and safety and the common defense and security. In addition, if an individual succeeds in subverting the testing process in order to hide substance abuse, the individual may pose an undetected and unacceptable risk to public health and safety or the common defense and security by performing the duties that require him or her to be subject to this part while impaired. Therefore, by deterring acts to defeat the testing process as well as preventing any individuals who engage in them from posing any further risk to public health and safety and the common defense and security, this change meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The final rule specifies three examples of actions that are considered subversion or an attempt to subvert the testing process. These include refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen. However, these examples are not intended to be exhaustive. For example, if a licensee or other entity determines that several individuals colluded to notify potential donors that they would be selected for random testing on a particular day, so that the potential donors could plan to avoid work on that day or take other actions to ensure that their illegal drug use would not be detected, the NRC expects the licensee or other entity to permanently deny authorization to all of the individuals who were involved in the collusion.

The final rule does not include submitting a dilute specimen as an example of a subversion attempt without additional evidence that the donor had diluted the specimen in order to mask the presence of drugs or drug metabolites in the specimen, for the reasons discussed with respect to § 26.185(g). Submitting a dilute specimen, in itself, does not necessarily indicate an attempt to subvert the testing process because there are many legitimate causes for a dilute specimen, including drinking liquids in order to provide a specimen of sufficient quantity, as permitted in Section 2.4(g)(11) in Appendix A of the former rule and in § 26.109(b)(1) of the final rule. Therefore, the final rule does not require licensees and other entities to apply the sanction of permanent denial of authorization for submitting a dilute specimen, unless there is other evidence that the donor had diluted the specimen in an attempt to subvert the testing process.

The NRC used the phrase ''for any test required under this part'' in § 26.75(b) in the proposed rule to indicate that applicants for authorization who subvert or attempt to subvert a pre-access or random test are also subject to permanent denial of authorization. However, the NRC has changed this phrase in the final rule to ''for any test required under 26.31(c).'' This change clarifies the intent of the provision and is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. Although these individuals would not yet be performing any duties that could affect public health and safety or the common defense and security, an attempt to subvert the testing process while in an applicant status provides strong evidence that the individual cannot be trusted to perform those duties. Therefore, it is necessary to ensure that any applicant who subverts or attempts to subvert the testing process is denied authorization.

Section 26.75(c) of the final rule amends former § 26.27(b)(3). Former § 26.27(b)(3) established sanctions for the sale, use, or possession of illegal drugs within a protected area of any nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, or within a transporter's facility or vehicle. The final rule retains the former sanction of a 5-year denial of authorization in these instances and adds two other instances in which a 5-year denial of authorization is required.

First, the final rule requires licensees and other entities to impose a 5-year denial of authorization on any individual who is determined to have consumed alcohol within a protected area of any nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, or within a transporter's facility or vehicle. This change from the former rule is necessary because consuming alcohol causes impairment, which poses the same risks to public health and safety as impairment from illegal drugs. Extending the scope of the former sanction to alcohol consumption is also consistent with the revised FFD program performance objective in § 26.23(d), which is to provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of alcohol as well as illegal drugs. Therefore, by reducing the risk to public health and safety and the common defense and security that the onsite use of alcohol poses, this change meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Second, the final rule adds the phrase ''or while performing the duties that require the individual to be subject to this part'' to address circumstances in which an individual may be performing the duties that require him or her to be subject to this part but is not doing so within the protected area of a nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, or within a transporter's facility or vehicle. As one example, many nuclear power plant licensees' designated collection sites are located outside of the plant's protected area. The intent of the former rule was to prohibit the presence, sale, and use of alcohol or illegal drugs by FFD program personnel at a collection site that is located outside of the protected area, but the former rule did not specifically address such circumstances. The majority of licensees have appropriately interpreted the intent of the former rule, but the final rule adds this phrase to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

In addition, the final rule deletes the list of activities in the paragraph of the former rule that an individual is prohibited from performing. The final rule replaces this list with the summary term ''authorization'' for consistency with the use of this term throughout the final rule. As discussed with respect to § 26.4, the NRC presents the list of duties that require individuals to maintain authorization and to be subject to this part once in that section, rather than repeatedly throughout the rule, for consistency with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.75(d) of the final rule amends a portion of former § 26.27(c) that required licensees or other entities to record as a removal ''for cause'' an individual's resignation that occurs before the licensee removes the individual for violating the FFD policy. This portion of the former provision has raised implementation questions from licensees regarding the appropriate action to take in these circumstances. Licensees have questioned whether the former requirement was intended to deny authorization to an individual for some period of time, as required under former § 26.27(b)(2) through (b)(4), permanently deny authorization to the individual, or merely to record the resignation. Therefore, the final rule clarifies the intent of the former provision as follows:

The final rule establishes the sanction of a 5-year denial of authorization for an individual who resigns before a licensee or other entity terminates the individual's authorization or denies authorization to an applicant for a first violation of the FFD policy involving a confirmed positive drug or alcohol test result. The paragraph establishes a 5-year denial of authorization because the confirmed positive drug or alcohol test result in combination with such a resignation, is a strong indication that the individual has an active substance abuse problem. However, because the individual resigned or withdrew his or her application for authorization, the individual would not be available for the SAE to evaluate the seriousness of his or her substance abuse problem and devise an appropriate treatment plan, as required under § 26.189 [Determination of fitness]. Therefore, prohibiting the individual from being granted authorization for a 5-year period gives the individual an opportunity to seek treatment and establish a 5-year history of sobriety, which is required to regain authorization under § 26.69 [Authorization with potentially disqualifying fitness-for-duty information]. This prohibition also ensures that such an individual is not granted authorization without having demonstrated that he or she has overcome the substance abuse problem. Therefore, the NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

In addition, for any type of FFD policy violation, this provision requires the licensee or other entity to record the fact that the individual had resigned or withdrawn his or her application for authorization, the nature of the FFD policy violation, and the sanction that would have been imposed if the individual had not resigned or withdrawn. Recording this information is necessary to ensure that any licensees or other entities who may consider granting authorization to the individual in the future are aware of the individual's behavior and the nature of the FFD policy violation. Subsequent licensees and other entities will then be able to ensure that the minimum requirements of this section are met. For example, if the FFD policy violation was a third confirmed positive drug or alcohol test result, § 26.75(g) prohibits a subsequent licensee or other entity from granting authorization to the individual under any circumstances. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has moved the portion of former § 26.27(c) that referred to a refusal to provide a specimen for testing to § 26.75(b) of the final rule to meet Goal 6 of this rulemaking, regarding organizational clarity.

Section 26.75(e) of the final rule amends former § 26.27(b)(2) and expands its scope to include alcohol. The NRC no longer excludes the abuse of alcohol from the sanctions specified in this section for several reasons. First, although the possession and use of alcohol are legal for adults and do not adversely reflect on an individual's trustworthiness and reliability, a perceived need to conceal an untreated active alcohol abuse problem could cause an individual to be vulnerable to influence to act in ways that are adverse to the common defense and security. Second, alcohol-related impairment in the nuclear workplace poses an undue potential risk to public health and safety that is comparable to the risk imposed by impairment from the use of drugs. Third, some licensees have not imposed appropriately stringent sanctions on individuals who have abused alcohol in a manner that could cause the individual to be impaired while performing the duties that require individuals to be subject to this part. Therefore, in order to deter individuals from abusing alcohol and ensure that individuals who may be impaired from alcohol are not permitted to perform the duties that require individuals to be subject to this part, this final rule imposes the same sanctions for abusing alcohol as those required for abusing drugs. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.75(e)(1) retains but amends the intent of the second sentence of former § 26.27(b)(2). The former § 26.27(b)(2) stated that licensees and other entities must remove an individual from performing activities under this part for at least 14 days following a first confirmed positive test result. However, the final rule requires licensees and other entities to immediately unfavorably terminate the individual's authorization for at least 14 days from the date of the unfavorable termination, rather than ''remove'' the individual. With respect to the proposed rule, the final rule adds a clarification that the 14-day termination begins on the date of the unfavorable termination. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity in this provision to illustrate the NRC's intent. At the public meetings discussed in Section I.D, the stakeholders indicated that the term ''remove'' is confusing because it could be interpreted as requiring licensees and other entities to terminate the individual's employment, which is not the intent of this paragraph. The stakeholders suggested using the phrase ''terminate the individual's authorization'' to more accurately characterize the required action. This change is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The stakeholders also requested that the agency eliminate from § 26.75(e)(1) the requirements in the former paragraph related to referring the individual to the EAP for assessment and counseling. The stakeholders noted that many licensees terminate an individual's employment at the same time that they terminate the individual's authorization after a first confirmed positive test result. They suggested that if the licensee or other entity terminates the individual's employment and does not intend to provide the individual with an opportunity to regain authorization, it is inappropriate to require the licensee or other entity to provide assessment and counseling services to the individual. However, some licensees have interpreted the

former provision as requiring them to provide EAP services to individuals whom they no longer employ. The NRC concurs that the intent of the former rule is for licensees and other entities to provide assessment and counseling services only in those instances when the licensee or other entity desires to reinstate the individual's authorization. Therefore, the NRC has made this change, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule also moves the requirements in former § 26.27(b)(2) that were related to permitting the individual to regain authorization to Subpart C [Granting and Maintaining Authorization] of the final rule instead of retaining them in § 26.75(e)(1) because § 26.75(e)(1) addresses sanctions for FFD policy violations, rather than FFD requirements for granting authorization. Subpart C addresses the requirements for granting authorization to an individual after his or her authorization has been terminated unfavorably for a first confirmed positive drug or alcohol test result in § 26.69(b). The NRC has made this change to meet Goal 6 of this rulemaking to improve organizational clarity in the rule.

Section 26.75(e)(2) increases the length of the period for which licensees and other entities must deny an individual's authorization for a second confirmed positive drug or alcohol test result from 3 years in former § 26.27(b)(vii) to 5 years in the final rule. This change provides greater assurance that individuals who have had a second confirmed positive drug or alcohol test result are able to abstain from substance abuse for at least 5 years before a licensee or other entity may again consider granting authorization to them. The 5-year period is based on the research literature indicating that individuals who abstain from substance abuse for 5 years after treatment are less likely to relapse than individuals who have been able to abstain for 3 years. In addition, the more stringent sanction for a second confirmed positive drug or alcohol test result provides greater deterrence to recidivism than the former 3-year period. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.75(f) of the final rule amends former § 26.27(b)(5). Former § 26.27(b)(5) stated that the sanctions for confirmed positive drug test results in former § 26.27 [Written policy and procedures] did not apply to the misuse of alcohol, valid prescriptions, and over-the-counter drugs, but required licensee FFD policies to establish sanctions that are sufficient to deter the misuse of those substances. The final rule requires the same minimum sanctions for alcohol abuse as those required for drug abuse. Impairment caused by alcohol abuse creates a risk to public health and safety that is fundamentally similar to the risk posed by the use of illegal drugs. However, some licensees have imposed lesser sanctions for alcohol violations, an approach that is inconsistent with the NRC's intent. Therefore, the final rule rectifies this situation by explicitly requiring the same minimum sanctions for the abuse of alcohol as currently required for the use of illegal drugs. The NRC has made this change to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

In addition, § 26.75(f) of the final rule requires licensees and other entities to impose the same sanctions as mandated for the abuse of illegal drugs if the MRO determines that the misuse of prescription drugs or over-the-counter medications resulting in a positive drug or alcohol test result represents substance abuse. The MRO makes this determination under § 26.185(j). Misuse of prescription and over-the-counter medications may include, for example, the use of a spouse's or other family member's prescription medications that may cause impairment, such as some pain relievers, or the excessive use of some over-the-counter cold and cough preparations containing alcohol or other active ingredients that may cause impairment. However, an individual who has a substance abuse problem may use the same substances. For example, an individual who has become addicted to opiates may use a spouse's or other family member's codeine tablets or other opiates that were prescribed for pain relief to assist the addicted individual in avoiding withdrawal symptoms. Under this provision, if the MRO determines that an individual's use of a prescription or over-the-counter medication represents substance abuse, the licensee or other entity is required to impose the minimum sanctions specified in this section for a confirmed positive drug or alcohol test result, as appropriate. If the MRO determines that the misuse of a prescription or over-the-counter medication does not represent substance abuse, the final rule requires the licensee or other entity to impose the sanctions for substance misuse that the licensee or other entity specifies in the FFD policy.

The final rule also retains but revises the requirement in the last sentence of former § 26.27(b)(5). Section 26.75(f) retains the former requirement that sanctions for the misuse of prescription and over-the-counter drugs must be sufficient to ''deter abuse of legally obtainable substances'' because such misuse may lead to impairment on the job. However, the final rule eliminates the phrase ''as a substitute for abuse of prescribed drugs'' in the last sentence of former § 26.27(b)(5) because it unnecessarily limited the circumstances in which sanctions for the misuse of prescription and over-the-counter drugs must be imposed. The NRC has made these changes to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.75(g) of the final rule amends former § 26.27(b)(4). The NRC has moved the portions of the former paragraph that established requirements for granting authorization to an individual who has violated the licensee's or other entity's FFD policy to § 26.69 in Subpart C of the final rule for organizational clarity because § 26.75(g) only addresses sanctions for FFD policy violations. This provision retains the portion of the former paragraph that required licensees and other entities to permanently deny authorization to an individual who has repeatedly violated a licensee's or other entity's FFD policy. The final rule requires the permanent denial of an individual's authorization if he or she has another confirmed positive drug or alcohol test result after he or she has had authorization denied for 5 years under other paragraphs in this section. Requiring this more stringent sanction meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs because this provides reasonable assurance that individuals are trustworthy and reliable, as demonstrated by avoiding substance abuse, and increases the assurance that only individuals who are fit for duty are permitted to perform the duties listed in § 26.4.

Section 26.75(h) and (i) of the final rule amends former § 26.24(d)(2). The former provision permitted licensees to temporarily suspend an individual's authorization or take other administrative action if an individual has a positive drug test result for marijuana or cocaine metabolites that is identified through initial testing at the licensee testing facility. For organizational clarity, consistent with Goal 6 of this rulemaking, the final rule divides the former paragraph into two paragraphs to separate the requirements related to the conditions under which licensees and other entities may and

may not take action on the basis of initial test results.

Section 26.75(h) prohibits licensees and other entities from taking administrative actions or imposing sanctions on an individual based on a positive test result from any initial drug test result reported by an HHS-certified laboratory. This section also permits licensees and other entities to take administrative actions on the basis of positive initial drug test results for marijuana and cocaine from a licensee testing facility. However, in order for the licensee or other entity to take action, the final rule requires that the urine specimen that yields a positive, adulterated, or substituted drug test result(s) must also appear to be a valid specimen, based on the results of validity screening or initial validity test results at the licensee testing facility. In addition, this section prohibits licensees and other entities from imposing sanctions or taking other actions in response to adulterated, substituted, or invalid screening or initial validity test results from a specimen in which no drug metabolites were detected. The NRC has added this prohibition because the procedures, instruments, and devices used in conducting validity screening and initial validity tests have not yet been proven to be sufficiently accurate and reliable to support management actions or sanctions without confirmatory testing. Permitting licensees and other entities to take actions on the basis of validity screening or initial validity test results risks imposing substantial burdens on individuals from false positive, adulterated, substituted, or invalid test results. Therefore, the NRC has added this prohibition to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

With respect to the proposed rule, the final rule adds a provision that the licensee or other entity may not subject an individual to administrative action based upon validity testing results indicating that a specimen is of questionable validity. This change is based on analysis of public comment, which is discussed with respect to the term ''questionable validity'' in § 26.5 [Definitions].

Section 26.75(i)(1) through (i)(4) retains the requirements in former § 26.24(d)(2)(i) through (iv) that established the conditions under which licensees and other entities may take administrative actions on the basis of a positive initial drug test result for marijuana or cocaine metabolites from a licensee testing facility. The final rule adds a requirement for specimen validity testing (see the discussion of § 26.31(d)(3)(i) with respect to the addition of validity testing requirements in this rule and the requirement that the specimen for which action will be taken must appear to be valid, based on validity screening or initial validity test results from the licensee testing facility). The final rule also revises the terminology used in the former provision to be consistent with the terminology used throughout the final rule (see the discussion of § 26.5 with respect to the new terminology adopted in the final rule) and updates the cross-references to other sections of the rule to be consistent with the organization of the final rule. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.77 Management Actions Regarding Possible Impairment

The NRC has added § 26.77 [Management actions regarding possible impairment], which amends the requirements of former § 26.27(b)(1). The former section required licensees and other entities to remove impaired workers, or those whose fitness may be questionable, from performing activities within the scope of this part. The former provision also permitted licensees and other entities to return the individuals to duty only after the individuals were determined to be fit to safely and competently perform their duties. The final rule retains the intent of the former provision, but the terminology used in the section is consistent with the terminology used throughout the final rule. The NRC has updated cross-references to other sections of the rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. In addition, the agency has added several new requirements.

The NRC has added § 26.77(a) to the final rule to introduce and describe the purpose of the section, which is to prescribe the management actions that licensees and other entities must take when an individual shows indications that he or she is not fit to safely and competently perform their duties. The NRC has added this paragraph to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.77(b) of the final rule retains the portion of former § 26.27(b)(1) that required the licensee or other entity to take immediate action to prevent an individual from performing the duties that require him or her to be subject to this part if an individual appears to be impaired, or his or her fitness is questionable. This section of the final rule adds cross-references to § § 26.27(c)(3), 26.207, and 26.209 (updated from the proposed rule) because those provisions provide exceptions to the requirement for immediate action. Section 26.27(c)(3) permits licensees and other entities to use individuals who have consumed alcohol if they are needed to respond to an emergency and the licensee or other entity establishes controls and conditions under which the individual may perform work safely. Sections 26.207 and 26.209 contain the provisions for waivers and exceptions and self-declarations, which exempt individuals from the work hour controls of Subpart I [Managing Fatigue] under certain circumstances. The NRC has added the cross-references to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule also revises some terminology used in the former provision in response to stakeholder requests during the public meetings discussed in Section I.D. The stakeholders indicated that, because the former rule requires them to ''remove'' individuals whose fitness may be questionable, some FFD programs have interpreted the former paragraph as requiring them to terminate the individual's authorization. This was not the intent of the former provision. In this instance, the intent of the rule was for licensees and other entities to prevent the individual from performing the duties that would require the individual to be subject to this part in order to ensure that any potential impairment could not result in errors or lapses in judgment that may pose a risk to public health and safety or the common defense and security until the cause of the problem could be identified and resolved. Therefore, the final rule replaces the phrase, ''removed from activities within the scope of this part,'' with the phrase, ''prevent the individual from performing the duties,'' and makes other minor changes to the wording of the former requirement to clarify the intent of the provision. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.77(b)(1) retains the intent of former § 26.24(a)(3). This provision requires licensees and other entities to conduct drug and alcohol testing for cause. The final rule requires for-cause testing based upon a ''reasonable suspicion'' that the individual may be impaired from possible substance abuse. Reasonable suspicion of substance abuse could be based upon an observed

behavior, such as unusual lack of coordination or slurred speech, or a physical condition, such as the smell of alcohol. If the only basis for a reasonable suspicion is the smell of alcohol, then alcohol testing is required. However, the final rule does not require the licensee or other entity to perform a drug test unless other physical or behavioral indicators of possible impairment are present.

The stakeholder comments received during the public meetings discussed in Section I.D reported that many of the for cause tests they perform are initiated as a result of a security officer or other person reporting that an individual smells of alcohol without behavioral indications of impairment. They also noted that the very large majority of the for-cause drug tests that they conduct in these circumstances yields negative results, including those instances in which the alcohol test results are positive. The stakeholders suggested that the former requirement to conduct drug tests in these circumstances imposes a significant burden because the drugs tests impose costs, not only for collecting and testing the urine specimens, but also because they cannot permit the individual to resume performing his or her duties until the drug test results are available, which may take several days. The stakeholders argued that the burden is unnecessary because the drug tests yield positive results so infrequently and, therefore, do not serve their intended purpose of detecting drug abuse. Based on these stakeholders' arguments and the FFD program performance data that support them, the NRC concurs that drug testing is unnecessary when the smell of alcohol is the only indication that for cause testing is required, and has eliminated it from the final rule. The final rule continues to require drug testing if there are behavioral or physical indications of impairment in addition to the smell of alcohol.

The NRC has added § 26.77(b)(2) to apply only to nuclear power plant licensees and C/Vs who are subject to Subpart I. With respect to the proposed rule, the final rule modifies the language of this provision to improve its clarity and to more clearly specify the NRC's intent. This section permits these entities to forego drug and alcohol testing and the determination of fitness process required by § 26.189 if a fatigue assessment conducted under § 26.211 confirms that the individual's observed behavior or physical condition is solely a result of fatigue. This section applies only to licensees and C/Vs who are subject to Subpart I because licensees not subject to Subpart I would not have the requisite training to evaluate whether the observed behavior is caused by fatigue. The NRC has made this change to meet Goal 2 of this rulemaking to ensure against worker fatigue at nuclear power plants and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.77(b)(3) to specify the actions that licensees and other entities must take when there are indications that an individual may be impaired, other than behavior or a physical condition that creates a reasonable suspicion of substance abuse (or fatigue, in the case of licensees who are subject to Subpart I). Consistent with former § 26.27(b)(1), the final rule permits the licensee or other entity to return the individual to duty only after identifying and resolving the cause of the impairing condition and making a determination of fitness indicating that the individual is fit to safely and competently perform his or her duties (see the discussion of § 26.189 for more details regarding the determination of fitness process). This section does not require licensees and other entities to unfavorably terminate an individual's authorization for illness, fatigue, temporary mental and emotional stress, or other conditions that may affect an individual's fitness, but prohibits the licensee or other entity from assigning the impaired individual to perform the duties that require him or her to be subject to this subpart until a determination is made that the individual is fit to return to duty. The NRC has made this change to meet Goal 2 of this rulemaking to ensure against worker fatigue at nuclear power plants and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.77(c) of the final rule updates former § 26.27(d) to be consistent with current NRC notification procedures.

Subpart E—Collecting Specimens for Testing

Throughout Subpart E, the final rule makes minor clarifications to the proposed rule because of public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The final rule also makes more substantive changes to the proposed rule in this subpart because of public comment or to improve clarity in the organization and language of the rule. The substantive changes in this subpart can be found in §§ 26.81; 26.85(c)(1), (c)(2), and (e); 26.87(e); 26.89(a)(2) and (c); 26.91(e)(4); 26.109(b)(1); and 26.111(a), (c) and (d). These changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed without change.

Section 26.81 Purpose and Applicability

This added section describes the purpose of Subpart E, which is to establish requirements for collecting specimens for drug and alcohol testing. The new section assists in locating provisions within the rule and is consistent with Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

The NRC revised the title of this section from ''Purpose'' in the proposed rule to ''Purpose and applicability'' in the final rule to reflect other modifications to this paragraph that the agency has made in response to public comments that the applicability of the proposed rule's requirements was unclear. This paragraph specifies that the requirements of Subpart E apply to the licensees and other entities in § 26.3(a) through (d) to the extent that a C/V conducts drug and alcohol testing on which a licensee or other entity in § 26.3(a) through (d) relies. The provision further specifies the applicability of Subpart E's requirements by also listing the categories of individuals who are subject to the subpart. These include the categories of individuals listed in § 26.4(a) through (e). In addition, licensees and other entities may choose to conduct specimen collections and alcohol testing under the requirements of this subpart for the categories of individuals specified in § 26.4(f) and (g). However, §§ 26.4(j), 26.31(b)(2), and Subpart K [FFD Programs for Construction] permit licensees and other entities to rely on specimen collections and alcohol testing that are conducted under the requirements of 49 CFR Part 40, ''Procedures for Transportation Workplace Drug Testing Programs'' (65 FR 41944; August 9, 2001), for the reasons discussed with respect to those sections. In these instances, § 26.81 permits the specimen collections and alcohol testing to be performed under DOT's procedures, rather than those contained in Subpart E, for individuals who are subject to another Federal or State FFD program in § 26.4(j), FFD program personnel in § 26.31(b)(2), and the categories of individuals identified in § 26.4(f). These changes meet Goal 6 of the rulemaking to improve clarity in the organization and language of the rule.

Section 26.83 Specimens To Be Collected

The NRC has added § 26.83, which specifies the types of specimens that licensees and other entities must collect for initial and confirmatory drug and alcohol testing.

Section 26.83(a) requires licensees and other entities to collect either breath or oral fluids (i.e., saliva) for initial alcohol tests. The final rule continues to require collecting only breath specimens for confirmatory alcohol testing. The final rule permits the use of oral fluids (i.e., saliva) for initial alcohol tests because devices for testing oral fluids for alcohol have matured sufficiently to provide valid and reliable initial test results. Circumstances may arise, such as collecting a specimen of oral fluids from a donor who has impaired lung functioning, in which the use of these devices is more efficient than collecting breath specimens for both donors and the FFD program. Therefore, the permission to collect oral fluids for initial alcohol testing meets Goal 3 of this rulemaking to improve the efficiency of FFD programs. Additionally, other Federally mandated alcohol testing programs permit the use of these devices for initial alcohol testing. Therefore, adding permission to collect oral fluids for initial alcohol testing to the final rule is consistent with Goal 1 of the rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The final rule eliminates the use of blood as a specimen for alcohol testing at the donor's discretion, which was permitted in former § 26.24(g) and Section 2.2(d)(4) in Appendix A to Part 26. The final rule eliminates the former provisions related to blood alcohol testing for several reasons. Since the former rule was first promulgated, licensees have repeatedly raised questions related to the proper interpretation of a confirmatory alcohol test result using an evidential breath testing device (EBT) and an alcohol test result derived from a blood specimen when the results from the two types of testing differ. Specifically, if a confirmatory alcohol test result using an EBT is positive, but the result from testing a blood specimen is negative, licensees have asked which test result they should rely on in determining whether the donor has violated the FFD policy. Although the NRC's original intent was that the result from the blood test was to be definitive, delays in obtaining a blood specimen sometimes resulted in blood test results that fell below the alcohol cutoff level of 0.04 percent BAC due to alcohol metabolism during the period of the delay. Some licensees have been reluctant to apply sanctions for a positive alcohol test result in these instances even though alcohol metabolism over time explains the lower test result from the blood sample. Further, experience has shown that few donors request testing of a blood sample. Data gathered from a sampling of representative FFD programs show that individuals requested an average of fewer than one blood test per program within the period reviewed (January–May 2002). Additionally, the use of EBTs for confirmatory alcohol tests has consistently withstood legal challenge. The added protection of donors' rights that the NRC envisioned when promulgating the provisions for voluntary testing of blood specimens has not been realized in practice. The former requirement has also been costly for licensees. Licensees must ensure that an individual who is trained to draw blood is available to do so should a donor request blood testing. Based on information provided by stakeholders at the public meetings discussed in the preamble to the proposed rule, the NRC determined that the costs associated with retaining this provision are not justified because of the very few instances in which donors have requested blood alcohol testing. Therefore, the agency has deleted from the final rule references to collecting and testing blood specimens for alcohol.

Section 26.83(b) retains, but makes explicit, the implied requirement in the first sentence of former § 26.24(b) (and other provisions that are interspersed throughout the former rule) for licensees and other entities to collect only urine specimens for drug testing. When the former rule was promulgated, it was unnecessary to establish an explicit requirement to collect and test only urine specimens for drugs in Part 26 programs because methods for testing other specimens were not available and the HHS Guidelines only addressed testing urine specimens. Since that time, methods for testing alternate specimens, such as oral fluids, sweat, and hair, have become commercially available and HHS has published proposed revisions to its guidelines (69 FR 19673; April 13, 2004) that would permit the use of alternate specimens for drug testing in Federal workplace drug testing programs. The NRC is considering permitting the use of alternate specimens for drug testing when HHS has published final revisions to its guidelines related to these types of specimens. The revised HHS Guidelines will establish acceptable collection procedures and testing methods. However, HHS has not yet published final guidelines for collecting and testing these alternate specimens. Therefore, it is necessary to add § 26.83(b) to the final rule to clarify that the NRC intends to continue prohibiting the collection and drug testing of specimens other than urine in this rulemaking except as permitted under § 26.31(d)(5) [Medical conditions]. The reasons are as discussed with respect to that section.

Section 26.85 Collector Qualifications and Responsibilities

This added section replaces the collector qualifications and training requirements specified in the definition of ''collection site person'' in the former rule and in former Sections 1.2, 2.2(d), and 2.4(b) in Appendix A to Part 26. This section retains the intent of the former provisions, but the final rule groups the requirements together to improve organizational clarity. In addition, the final rule amends the former collector qualifications and training requirements to increase the consistency of Part 26 with the requirements of other Federal agencies and incorporates the lessons learned from those programs as discussed with respect to Goal 1 of this rulemaking.

Section 26.85(a) [Urine collector qualifications] provides more detailed requirements for urine collector qualifications and training than are contained in the former definition of ''collection site person'' and former Section 2.2(d) in Appendix A to Part 26. The final rule requires urine collectors to be knowledgeable of the requirements of this part, the FFD policy and procedures of the licensees or other entities for whom they perform collections, and to keep current on any changes to urine collection procedures. These changes increase the consistency of urine collector qualification requirements with those of other Federal workplace drug testing programs as well as consistency in urine collection procedures among FFD programs that are subject to this subpart.

Section 26.85(a) retains the requirements in former Section 2.2(d) that urine collectors must receive training to perform their duties and demonstrate proficiency in applying the requirements of this section before serving as a collector. Section 26.85(a)(1) through (a)(4) lists the topics that the final rule requires collector training to address. Section 26.85(a)(1) requires collectors to be trained in the steps that are necessary to complete a collection correctly and the proper

completion and transmission of the custody-and-control form to the licensee testing facility or HHS-certified laboratory, as appropriate. Section 26.85(a)(2) requires training in methods to address ''problem'' collections. These may include, but are not limited to, collections involving ''shy bladder'' (see the discussion of proposed § 26.119 [Determining ''shy'' bladder] for an explanation of this term and the procedures involved) and attempts by a donor to tamper with a specimen. Section 26.85(a)(3) requires the training to instruct collectors on correcting collection problems. These may include, but are not limited to, a donor refusing to cooperate with the collection process or an incident in which a urine specimen is spilled. Section 26.85(a)(4) requires training so that a collector is knowledgeable in maintaining the integrity of the specimen collection and transfer process, and ensuring that donors' privacy and modesty are maintained. The NRC added these requirements to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.85(a)(4) retains the portion of former Section 2.2(d)(1) in Appendix A to Part 26 that required collector training to emphasize the collector's responsibility for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the donor, and avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

The NRC added § 26.85(b) [Alcohol collector qualifications] to specify requirements related to alcohol collector qualifications and training. Portions of this section are the same as the requirements for urine collectors in § 26.85(a), including the first three sentences of § 26.85(b), and (b)(4) and (b)(5). The agency added these requirements here for the same reasons discussed with respect to the first three sentences of § 26.85(a), and (a)(3) and (a)(4), respectively. The final rule repeats the requirements that are applicable to both urine and alcohol collectors in each of these paragraphs because some FFD programs may not train collectors to perform both types of collections. Repeating the requirements makes it easier to locate the requirements that apply to urine or alcohol collectors and meets Goal 6 of the rulemaking to improve clarity in the organization of the rule.

Section 26.85(b)(1) and (b)(3) requires alcohol collectors to receive training that addresses the alcohol testing requirements of this part and methods to address ''problem'' collections. These include, but are not limited to, collections involving ''shy lung'' problems or attempts by a donor to tamper with a specimen. In contrast to § 26.85(a)(2), which addresses ''shy bladder'' problems in urine collections, the final rule does not incorporate the related DOT procedures for evaluating ''shy lung'' problems in alcohol collections. During the public meetings discussed in the preamble to the proposed rule, stakeholders requested that the proposed rule incorporate DOT's ''shy bladder'' procedures, but did not believe that adding DOT's ''shy lung'' procedures to the final rule is necessary. The stakeholders reported that donors have not experienced problems related to ''shy lung,'' based on their experience implementing the breath testing requirements of Part 26 since the rule was first promulgated. Therefore, § 26.85(b)(3) requires alcohol collectors to be able to implement the ''shy lung'' procedures established by any FFD program for whom the collectors are providing collection services, but does not establish requirements for responding to ''shy lung'' problems in the rule.

The final rule adds § 26.85(b)(2) to require alcohol collectors to be trained in the operation of the particular alcohol testing device(s) (i.e., the ASDs and EBTs) to be used in conducting alcohol tests, consistent with the most recent version of the manufacturers' instructions. The final rule adds this requirement because the NRC is aware that some FFD programs did not implement device manufacturers' recommended changes to instructions for using the testing devices. Although the NRC staff is not aware of any testing errors or instances in which donors have challenged the results of alcohol tests that were not performed in accordance with the most recent version of the device manufacturer's instructions, the final rule adds this requirement to ensure that alcohol test results continue to be accurate and cannot be challenged on this basis. The changes are also consistent with the alcohol collector training requirements of other Federal agencies.

Section 26.85(c) [Alternative collectors] amends the last sentence of former Section 2.2(d)(2) in Appendix A to Part 26. The former provision permitted medical personnel to perform specimen collections without receiving the required training for non-medical collectors. The final rule permits medical personnel to conduct specimen collections for the purposes of this subpart only under the conditions specified in § 26.85(c)(1) through (c)(5). These conditions may include, but are not limited to, the collection of specimens for post-event testing by a nurse or medical technician at a hospital. The final rule limits the circumstances in which an untrained medical professional, technologist, or technician may perform collections for a licensee or other entity because the experience of other Federal agencies has shown that medical personnel who are untrained in specific collection procedures have committed errors in collections that resulted in unnecessary legal challenges to test results. At the same time, the NRC is also aware that licensees and other entities may occasionally have to rely on these individuals to collect specimens for drug and alcohol testing, as discussed with respect to § 26.4(i)(1). Therefore, the final rule permits untrained medical personnel to collect specimens to facilitate the collection of specimens for testing in rare circumstances in which a qualified collector could not reasonably be expected to be available, but otherwise requires medical personnel who do not meet the criteria specified in § 26.85(c)(1) through (c)(5) to receive the same training as non-medical collectors. The NRC made this change to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, by reducing the likelihood of errors and legal challenges to test results. In addition, the final rule also makes minor changes to the organization of this paragraph in response to a public comment indicating a lack of clarity in the same provision in the proposed rule.

The NRC has eliminated former Section 2.2(d)(4) in Appendix A to Part 26, which required that donors must be informed of the option to request blood testing. The agency eliminated the former requirement because the final rule no longer permits donors to request blood testing for alcohol, as discussed with respect to § 26.83(a).

Section 26.85(d) amends former Section 2.7(o)(5) [Personnel available to testify at proceedings] in Appendix A to Part 26. This section required the licensee testing facility and HHS-certified laboratory to make available qualified individuals to testify in administrative or disciplinary proceedings related to drug and alcohol test results. The final rule adds an explicit requirement for collection site personnel to be available to testify at proceedings because the former provision implied, but did not explicitly state this requirement. When the rule was first published, licensee testing facilities and collection sites were

typically co-located at a site. However, this is no longer the case. In some current FFD programs, alcohol testing and urine specimen collections occur at the collection site, but initial testing of urine specimens is performed at a licensee testing facility that may not be co-located with the collection site. Therefore, the NRC has added this paragraph to retain the former rule's original intent that licensees and other entities must make available collection site personnel to testify, as needed, in administrative and/or legal proceedings related to an alcohol or drug test result. For organizational clarity, the final rule moves the requirements in the former paragraph that addressed the availability of personnel to testify in proceedings related to drug test results from the licensee testing facility to § 26.139(c) of Subpart F [Licensee Testing Facilities] and those related to HHS-certified laboratories to § 26.153(f)(2) of Subpart G [Laboratories Certified by the Department of Health and Human Services].

The NRC added § 26.85(e) to the final rule in response to a public comment noting that the proposed rule did not include a requirement for licensees and other entities to ensure that personnel files are maintained for collectors. The new paragraph establishes requirements for personnel files for collectors to document their training and other qualifications for the positions they hold. This documentation may be necessary in administrative and/or legal proceedings related to an alcohol or drug test result.

Section 26.87 Collection Sites

The NRC has reorganized requirements related to specimen collection sites in the former rule and grouped them together in this section. Requirements related to collection sites were distributed among several different sections in Appendix A to Part 26 of the former rule. The agency made this change to improve organizational clarity in the rule.

Section 26.87(a) amends former Section 2.4(a) in Appendix A to Part 26. This former section required FFD programs to designate collection sites and ensure that they are fully equipped to collect specimens for testing. The final rule deletes references to blood specimens because the final rule no longer provides donors with the option to request blood testing for alcohol for the reasons discussed with respect to § 26.83(a). The final rule adds a requirement for collection sites to be capable of alcohol testing that the former section implied but did not explicitly state. The agency made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule. This section retains the permission in the former rule for licensees and other entities to use properly equipped mobile collection facilities.

Section 26.87(b) revises the first sentence of former Section 2.4(f) in Appendix A to Part 26 to require visual privacy for donors while the donor and collector are viewing the results of an alcohol test and retains the former requirement for individual privacy during urine specimen collections, except if the urine specimen collection must be conducted under direct observation. The new requirement for visual privacy while viewing alcohol test results increases the consistency of Part 26 with the alcohol testing procedures of other Federal agencies and assures greater privacy for donors who are subject to FFD programs that did not provide visual privacy under the former rule. The NRC made this change to meet Goal 7 of this rulemaking to protect the privacy of individuals who are subject to Part 26. For organizational clarity, the final rule moves the former requirements in Section 2.4(f) in Appendix A to Part 26 that are related to collecting a specimen under direct observation to § 26.115 [Collecting a urine specimen under direct observation].

Section 26.87(c) retains only the portion of former Section 2.7(m) in Appendix A to Part 26 that required licensees' and other entities' contracts for collection site services to permit unfettered NRC, licensee, and other entity access to collection sites for unannounced inspections. The final rule moves the portions of the former section that apply to HHS-certified laboratories to § 26.153(f) of Subpart G for organizational clarity. In addition, § 26.87(c) adds a requirement that licensees' and other entities' contracts for collection site services must permit unfettered NRC, licensee, and other entity access to all information and documentation that is reasonably relevant to inspections and audits. The final rule adds this requirement for access to documentation for consistency with the HHS Guidelines, which also require collection sites to provide information and documentation as part of inspections and audits. Therefore, this change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. The agency also added the term ''audit'' to this section because, although the NRC conducts inspections, licensees and other entities are required to conduct audits under § 26.41 [Audits and corrective action]. Adding this term to this paragraph increases the clarity of its language, consistent with Goal 6 of the rulemaking.

Section 26.87(d) revises former Section 2.4(c) in Appendix A to Part 26 to clarify requirements for assuring collection site security and the integrity of specimen collection procedures. For organizational clarity, the final rule groups requirements related to assuring the security of a licensee's or other entity's designated collection site in this paragraph. For the same reason, the final rule moves to § 26.87(f) the requirements contained in former Section 2.4(c) in Appendix A to Part 26 that address assuring collection security when a designated collection site is inaccessible and there is an immediate requirement to collect a urine specimen. Section 26.87(d) includes other clarifying changes to former Section 2.4(c) in Appendix A to Part 26, in response to stakeholder requests at the public meetings discussed in Section IV.D.

Section 26.87(d)(1) retains the first sentence of former Section 2.4(e) in Appendix A to Part 26 and permits only authorized personnel to have access to any part of a collection site in which specimens are collected and stored. For organizational clarity, the final rule moves this requirement to this section because it addresses the topic of collection site security.

Section 26.87(d)(2) amends the second sentence of former Section 2.4(c) in Appendix A to Part 26. The former provision required collection sites to be secure, and the final rule adds examples of acceptable methods to assure collection site security. The NRC added these examples in response to stakeholder requests during the public meetings discussed in the preamble to the proposed rule. The stakeholders noted that the requirement that collection sites ''must be secure'' has raised many implementation questions. Therefore, the final rule adds examples of acceptable means to ensure collection site security, including, but not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection site when it is not occupied. The agency made this change to meet Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.87(d)(3) amends the third sentence in former Section 2.4(c) in Appendix A to Part 26. The former provision required that the portion of any facility that is not dedicated solely to drug and alcohol testing must be secured during testing. The final rule

retains that requirement and combines it with the third sentence of former Section 2.4(c)(1) in Appendix A to Part 26. The provision requires the protection of the facility against unauthorized access during the collection. The final rule replaces the phrase, ''in the case of a public restroom,'' in the last sentence of former Section 2.4(c)(1) in Appendix A to Part 26, with the phrase, ''if a collection site cannot be dedicated solely to collecting specimens,'' to clarify that a specimen may be collected at locations other than public restrooms. The NRC makes these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The agency has added § 26.87(e) to specify the steps that licensees and other entities must take to deter dilution and adulteration of specimens during urine collections. This section retains and amends portions of former Section 2.4(g) in Appendix A to Part 26.

Section 26.87(e)(1) relaxes the former requirement in Section 2.4(g)(1) of Appendix A to Part 26 to use a bluing agent in any source of standing water, such as a toilet bowl or tank. The final rule permits licensees and other entities to use colors other than blue. However, the final rule prohibits use of a yellow coloring agent because it precludes the collector's ability to determine whether a donor had diluted the specimen with water from a source of standing water in the stall or room in which the donor provides a specimen. The relaxation does not affect the accuracy of drug tests but gives FFD programs increased flexibility in the choice of coloring agents. The agency made this change in response to stakeholder requests during the public meetings discussed in the preamble to the proposed rule and to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.87(e)(2) retains the second sentence of former Section 2.4(g)(1) in Appendix A to Part 26, which requires sources of standing water to be secured, but shortens it without changing the intended meaning of the requirement. The agency made this change to improve clarity in the language of the rule.

The final rule adds § 26.87(e)(3) to require that chemicals or products that could be used to adulterate a urine specimen must be secured or removed from the collection site. The paragraph also requires the collector to inspect the enclosure to ensure that no potential adulterants are available before the donor enters the stall or enclosure. The agency intends these requirements to prevent possible donor attempts to subvert the testing process by adulterating a urine specimen with materials that are available at the collection site. This provision meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs. The provision is also consistent with the related requirements of other Federal agencies.

Section 26.87(f) reorganizes former Section 2.4(c)(1), portions of Section 2.4(c)(2), and Section 2.4(g)(10) in Appendix A to Part 26 to prescribe acceptable procedures for collecting specimens at locations other than a designated collection site in unusual circumstances, such as a specimen collection for post-event testing at a hospital. The final rule groups these requirements together in a single paragraph and separates them from those related to collecting specimens at a designated collection site in § 26.87(d) and (e) to make it easier to locate these requirements within the rule. The NRC made this change to improve organizational clarity in the rule.

Section 26.87(f)(1) amends former Section 2.4(c)(1) in Appendix A to Part 26, which established requirements for securing a location that is not a designated collection site but will be used for a specimen collection(s). The final rule requires either an individual to guard access to a public rest room while the collection is occurring or the posting of a sign to ensure that no unauthorized personnel enter the area during the collection. The former rule required only the posting of a sign. However, stationing an individual to guard access is at least as effective. The final rule permits an individual to guard access to the collection area in response to stakeholder requests for this flexibility during the public meetings discussed in the preamble to the proposed rule. This change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.87(f)(2) retains the third sentence of former Section 2.4(g)(10) in Appendix A to Part 26 that requires using a water-coloring agent, if possible, to deter a possible dilution or adulteration attempt when a collection must occur at a location other than the licensee's or other entity's designated collection site.

Section 26.87(f)(3) retains the requirement in the second sentence of former Section 2.4(g)(10) that the collector must be the same gender as the donor in the exceptional event of a specimen collection occurring at a location other than the FFD program's designated collection site. However, if a collector of the same gender is unavailable, the rule permits another person of the same gender who is instructed in the requirements of Subpart E [Collecting Specimens for Testing] to assist in the collection. The provision requires either the collector or the observer to remain outside the area in which the donor will provide the urine specimen to protect the donor's privacy and the integrity of the collection process. The rule requires documentation of the observer's identity on the custody-and-control form so that the observer may be located should any subsequent questions arise with respect to the collection in a review under § 26.39 [Review process for fitness-for-duty policy violations] or legal proceedings. The flexibility to rely on a person of the same gender as an observer, if a collector of the same gender is unavailable, is consistent with the procedures of other Federal agencies and reduces potential embarrassment to the donor. Therefore, this change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, and Goal 7 to protect the privacy of individuals who are subject to Part 26.

Section 26.87(f)(4) requires the collector, once he or she is in possession of the donor's specimen, to inspect the area in which the specimen donation occurred for any evidence of a subversion attempt by the donor. This paragraph amends the fifth and sixth sentences of former Section 2.4(g)(10) in Appendix A to Part 26 that described the required sequence of actions during a specimen collection and specified that a donor is permitted to flush the toilet after a specimen donation. The final rule eliminates the option for the donor to flush the toilet and directs the collector to instruct the donor not to flush the toilet. The change reduces the possibility that a donor could dispose of evidence of a subversion attempt by flushing it down the toilet. Section 26.87(f)(4) directs the collector to inspect the toilet bowl and area once he or she receives the specimen from the donor. The final rule adds these provisions to reduce the opportunities for a donor to subvert the testing process at a location that is not a designated collection site to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs. The requirements also meet Goal 1 to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.87(f)(5) amends the portions of former Section 2.4(c)(2) in Appendix A to Part 26 that defined requirements for maintaining control of

specimens that are not collected at a designated collection site. The final rule permits an ''authorized individual,'' including, for example, a security officer or hospital medical technician, to maintain physical custody and control of specimens, rather than only the collector, as the former rule required. The licensee or other entity must designate the ''authorized individual'' and ensure that he or she is instructed in his or her responsibilities for maintaining custody and control of the specimen. The authorized individual's custody of the specimen must be documented on the custody-and-control form to ensure that the individual may be located should any subsequent questions arise with respect to the collection in a review under § 26.39 or legal proceedings. This change continues to ensure specimen integrity and security, but responds to industry experience, as described by stakeholders at the public meetings discussed in the preamble to the proposed rule. The stakeholders reported that it is sometimes difficult in unusual circumstances, such as the hospital setting, for the collector to maintain physical custody of the specimen until it is prepared for transfer, storage, or shipping. Therefore, the NRC made this change to meet Goal 5 of this rulemaking, to improve Part 26 by eliminating or modifying unnecessary requirements, while also continuing to meet Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.89 Preparing To Collect Specimens for Testing

This added section describes the preliminary steps that the collector and donor must take before specimens will be collected for drug and alcohol testing. This section reorganizes and amends portions of the former Appendix A to Part 26, and adds several new requirements. The final rule presents these requirements in a new section to facilitate locating them within the final rule to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.89(a) provides more detailed requirements than those contained in former Section 2.4(g)(3) in Appendix A to Part 26 for actions to be taken if an individual does not appear for testing. The former rule required the collector to contact an ''appropriate authority'' to determine the actions to take if a donor does not appear for testing. At the public meetings discussed in the preamble to the proposed rule, some stakeholders indicated that the lack of specificity in the former rule with respect to the actions that the ''appropriate authority'' must take in these circumstances has led some FFD programs to interpret this provision as requiring the imposition of the sanctions for a ''refusal to test'' on an individual who fails to appear, including situations in which there is clear evidence that the individual had not been informed that he or she was required to appear for testing or was otherwise not at fault for the failure. This was not the NRC's intent. Therefore, under this new provision, when informed that an individual who was selected for testing has not appeared at the required time, FFD program management must ensure that the circumstances are investigated and determine whether the individual's absence or tardiness represents an attempt to avoid testing and, therefore, subvert the testing process. The final rule requires the licensee or other entity to impose the sanctions specified in § 26.75(b) for a refusal to test only if the investigation identifies evidence that the individual's failure to appear for testing was a subversion attempt. If the investigation does not identify evidence of a subversion attempt, the final rule prohibits the licensee or other entity from imposing sanctions and requires testing the individual at the earliest reasonable and practical opportunity after the individual is located. The NRC has added these more detailed requirements to strengthen the rule's effectiveness in preventing subversion by ensuring that a failure to appear for testing is investigated to increase the likelihood of detecting a willful attempt to avoid testing. In addition, the requirements prevent an individual from being subject to a permanent denial of authorization, as required under § 26.75(b), if the individual's failure to appear is determined to be outside of the individual's control or otherwise not a result of a willful attempt to avoid testing. The agency has made these changes to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs, and Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.89(b) reorganizes and expands former Section 2.4(g)(2) in Appendix A to Part 26, which required the collector to ensure that an individual who arrives at the collection site for testing is positively identified. The final rule adds more detailed requirements for the reasons discussed with respect to each requirement.

Section 26.89(b)(1) retains the requirement in former Section 2.4(g)(2) in Appendix A to Part 26 for the collector to positively identify the donor before beginning a collection. This section specifies the types of photo identification that the licensee or other entity may accept to establish a donor's identity.

Section 26.89(b)(2) amends the portion of former Section 2.4(g)(2) in Appendix A to Part 26 that directed the collector to stop the collection if the individual cannot be positively identified. The amended provision directs the collector to proceed with the collection and inform FFD program management that the donor did not present acceptable photo identification. This paragraph requires FFD management to take the necessary steps to determine whether the lack of identification is an attempt to subvert the testing process. However, the provision retains the former requirement for the collector to delay the collection until the individual can be identified if it is a pre-access test. The NRC has made these changes for several reasons.

First, lessons learned from implementing the former rule have indicated that the large majority of failures to present acceptable identification result from miscommunication or other errors that are easily resolved. However, stopping or delaying the specimen collection may alter test results (e.g., if an individual has consumed alcohol, the individual's alcohol test result would show a lower BAC after a delay or may not be detected if testing is not conducted). Therefore, collecting the specimens first and then resolving the individual's identity ensures that test results are available and accurate from donors who are currently authorized and whose identity the licensee or other entity has previously confirmed. Therefore, this change meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Second, the former requirement to stop the collection without investigating the reasons that the individual is unable to present acceptable identification does not ensure that an attempt by an individual to subvert the testing process is detected. For example, an individual who has engaged in substance abuse could delay specimen collection by claiming to have ''forgotten'' his or her photo identification in his or her car or locker. Permitting the individual to leave the collection site to obtain his or her identification provides an opportunity for the individual to obtain an adulterant or substitute urine that he or she could then use to subvert the testing process. Steps that FFD program management could take to investigate

the reasons that the individual did not present acceptable identification in this instance could include assigning a security officer to accompany the individual to his or her car or locker to verify the individual's claim, as well as to ensure that the individual does not have the opportunity to bring an adulterant or substitute urine back to the collection site. Therefore, the new requirement strengthens the effectiveness of FFD programs in detecting attempts to subvert the testing process.

The final rule modifies the proposed rule to permit an individual's supervisor, except for pre-access tests, to positively identify an individual who appears for testing without acceptable photo identification. The NRC made this change in response to a public comment, which noted that under many FFD programs, supervisors are trusted to notify donors that they have been selected for random testing, and, therefore, it is reasonable to trust supervisors also to verify a donor's identity. The change increases the consistency of Part 26 with access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003 (Goal 4 of this rulemaking).

Section 26.89(b)(3) retains the former requirement to delay the specimen collection until the individual presents acceptable identification if it is a pre-access test, at the request of stakeholders during the public meetings discussed in the preamble to the proposed rule. The stakeholders noted that the former requirement to delay pre-access testing until the individual presents acceptable photo identification does not present a risk to public health and safety or the common defense and security from a possible subversion attempt because the individual does not yet have access to sensitive information, radiological materials, or safety systems and equipment. Furthermore, stakeholders noted that retaining the former provision saves licensees and other entities from the expense associated with collecting and testing a specimen from the wrong individual. Therefore, the NRC believes it is reasonable to retain the former requirement as it relates to pre-access tests.

Section 26.89(b)(4) updates former Section 2.4(g)(4) and 2.4(g)(23)(ii) in Appendix A to Part 26, in which, before any specimens are collected, donors were required to list the prescription and over-the-counter medications they had used within the 30 days before testing. To be consistent with the privacy requirements of the Americans with Disabilities Act [Pub. L. 101–336, July 26, 1990], the final rule eliminates the requirement to list medications prior to specimen collection and testing. The final rule requires donors to provide medication information to the MRO only in the event of positive, adulterated, substituted, or invalid confirmatory validity and/or drug test result to enhance their rights to privacy under the rule. This revised requirement is also consistent with the procedures of other Federal agencies and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.89(b)(4) also adds a requirement for the collector to explain the testing procedure to the donor. Former Section 2.2(d)(3) in Appendix A to Part 26 required providing individuals who are subject to testing with standard written instructions setting forth their responsibilities. However, the NRC is aware that individuals typically receive these instructions as part of the training that is required under former § 26.21 [Policy communications and awareness training] rather than at the collection site before starting the specimen collection process. This was not the intent of Section 2.2(d)(3) in Appendix A to Part 26. Rather than retaining and clarifying the former provision for standard written instructions that some individuals may have difficulty comprehending, the final rule adopts the related practices of other Federal agencies, which require the collector to explain the testing procedure to the donor. This change ensures that individuals are informed of the testing process in which they must participate and their responsibilities. It also meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 1, by enhancing the consistency of Part 26 with the requirements of other Federal agencies.

The NRC added § 26.89(c) to ensure that the donor is aware of his or her responsibilities to cooperate with the specimen collection process. This paragraph responds to reports from stakeholders at the public meetings discussed in the preamble to the proposed rule that some donors have attempted to obstruct or delay the collection process on the basis that the former rule implied, but did not explicitly state, the donor's responsibility to cooperate with the collection process. Therefore, the new provision eliminates that basis for obstructing or delaying collections, which improves the effectiveness and efficiency of FFD programs, consistent with Goal 3 of this rulemaking.

This section also requires the collector to inform the donor that a failure to cooperate in the specimen collection process is considered a refusal to test and may result in a permanent denial of authorization under § 26.75(b). In response to public comment, the final rule adds examples to those in the proposed rule describing behavior that may be determined to be a refusal to test. In addition to leaving the collection site before the collection is complete, the final rule adds behaving in a confrontational manner that disrupts the testing process; admitting to the collector that the donor has substituted, diluted, or adulterated the specimen; or the collector finds that the donor has a device, such as a prosthetic appliance, the purpose of which is to interfere with providing an actual urine specimen. Other examples could include a donor refusing to permit the collector to examine the contents of the donor's pockets or the donor refusing to wash his or her hands when directed by the collector. The final rule does not provide an exhaustive list of behaviors that comprise a refusal to test because they are too numerous to list. However, the NRC has added these examples for increased clarity in the rule. Informing donors of the potential consequences of failing to cooperate in the collection process, in advance, is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26. The requirements of this section also meet Goal 1 to improve the consistency of NRC requirements with those of other Federal agencies.

Section 26.89(d) retains the last two sentences of former Section 2.4(e) in Appendix A to Part 26. These provisions require the collector to conduct only one urine specimen collection at a time and define the point at which the collection process ends, which is when the donor has left the collection site. The NRC has retained these provisions in this paragraph because they relate to the topic of this section, which is preparing for specimen collections, to ensure that collectors are aware of this requirement before they begin collecting any specimens. The change improves the organizational clarity of the rule.

Section 26.91 Acceptable Devices for Conducting Initial and Confirmatory Tests for Alcohol and Methods of Use

This added section amends requirements in the former rule that addressed alcohol testing devices and

methods of use. The requirements in the former rule that are related to this topic appeared in former § 26.24(g) and Sections 2.4(g)(18) and 2.7(o)(3)(ii) in Appendix A to Part 26. This section combines these requirements, amends the former requirements, and adds others. The final rule groups these requirements in one section to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

The agency added § 26.91(a) [Acceptable alcohol screening devices] to permit the use of alcohol screening devices (ASDs) for initial testing and establish requirements for the ASDs that may be used. Acceptable ASDs include alcohol saliva analysis devices and breath testing devices that are listed on the most recent version of NHTSA's Conforming Products List (CPL) for ASDs (66 FR 22639; May 4, 2001, and subsequent amendments). Former Section 2.7(o)(3)(ii) in Appendix A to Part 26 limited FFD programs to using only evidential-grade breath testing devices. However, permitting FFD programs to use ASDs listed on NHTSA's CPL for initial alcohol testing is consistent with other Federal agencies' procedures for workplace alcohol testing. Therefore, the change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Further, permitting the use of some ASDs for initial alcohol testing provides increased flexibility in conducting initial alcohol tests. Licensees and other entities may find that, over time, it is less expensive to use a particular ASD than to continue using EBTs for all initial alcohol tests. The option to use alcohol saliva analysis devices also may reduce the burden of alcohol testing for some donors, such as individuals who have impaired lung functioning. The final rule's permission to use ASDs that are listed on NHTSA's CPL for ASDs for initial alcohol testing meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements by increasing FFD programs' flexibility in administering initial alcohol tests.

Section 26.91(b) [Acceptable evidential breath testing devices] amends former Section 2.7(o)(3)(ii) in Appendix A to Part 26 and establishes new requirements for the EBTs that licensees and other entities must use for confirmatory alcohol breath testing. The new section requires licensees and other entities to use EBTs that are listed on the most recent version of NHTSA's CPL for evidential breath testing devices without an asterisk (67 FR 62091; October 3, 2002, and subsequent amendments) when conducting confirmatory alcohol tests, and permits licensees and other entities to use these EBTs for conducting initial alcohol tests. The EBTs that are listed without an asterisk incorporate many improvements in EBT technology and have been shown to accurately detect BACs at the 0.02 percent level. Therefore, they are the appropriate instruments to use for confirmatory testing at the revised alcohol cutoff levels specified in § 26.103 [Determining a confirmed positive test result for alcohol].

Further, because these EBTs have been shown to provide valid, reliable, and legally defensible results in other Federal programs that also require workplace alcohol testing, the new requirement to use these EBTs permits two additional changes to the alcohol testing procedures contained in former Section 2.4(g)(18) in Appendix A to Part 26: (1) Collecting only one breath specimen for the initial alcohol test and one for the confirmatory test in §§ 26.95(c) and 26.101(c), rather than the two specimens that were required for each test under the former rule; and (2) conducting both the initial and confirmatory tests (if a confirmatory test is required) using the same EBT in § 26.101(d). As discussed further with respect to §§ 26.95(c) and 26.101(c) and (d), these changes to the former alcohol testing requirements improve the efficiency of alcohol testing while continuing to provide valid, reliable, and legally defensible results that are necessary to protect donor's rights under workplace alcohol testing programs. The use of these improved EBTs is similarly required for confirmatory alcohol testing and permitted for initial testing under 49 CFR Part 40. Therefore, this change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines; Goal 3 to improve the efficiency of FFD programs; and Goal 5 to improve Part 26 by eliminating or modifying unnecessary requirements.

The NRC added § 26.91(c) [EBT capabilities] to specify the required capabilities of the EBTs that licensees and other entities may use for initial alcohol testing and must use for confirmatory alcohol tests. The EBT capabilities listed in § 26.91(c)(1) through (c)(3) are necessary to ensure that a confirmatory alcohol test result can be uniquely associated with the instrument used, the time of testing, and the donor. These capabilities are necessary to establish an unimpeachable chain of custody for confirmatory alcohol test results as well as permit the accurate identification of any test results that may have been affected by instrument malfunctions that are discovered later through additional quality assurance checks. The EBT capabilities listed in § 26.91(c)(4) and (c)(5) ensure that test results will be accurate by requiring collectors to verify before each test that the instrument is functioning properly and there will be no carryover effects from previous testing. With respect to the proposed rule, the final rule revises the language of proposed § 26.91(c)(6) to clarify that EBTs must have the capability to support a calibration check using an external standard in response to public comments that the intended meaning of the proposed provision was unclear. Commenters were unfamiliar with the meaning of the term, ''external calibration check,'' and stated that the proposed provision implied that the EBT itself must be capable of performing an external calibration check to be acceptable for testing under this part. This was not the NRC's intent. As discussed with respect to § 26.91(e)(1), EBT manufacturers must submit a quality assurance plan to NHTSA that, among other attributes, specifies the minimum frequency with which the EBT must be subject to an external calibration check. An external calibration check simulates delivering a breath sample with a known alcohol concentration to the EBT to verify that the EBT is reading within acceptable limits. The external standards used for the calibration checks are typically either wet bath (i.e., a solution of ethanol in water) or dry gas (i.e., a mixture of pressurized gas, usually ethanol in nitrogen) and are delivered to the EBT through a regulator or other device that simulates a human breath exhalation. Calibrating devices may be included in an EBT ''kit'' or sold separately. Section 26.91(c)(6) of the final rule clarifies that EBTs used for confirmatory alcohol testing must be capable of being calibrated using external standards, rather than implying that the EBTs must be self-calibrating with external standards. The capabilities specified in § 26.91(c)(4) through (c)(6) improve the effectiveness and efficiency of confirmatory alcohol testing by limiting the need to cancel test results due to instrument errors, as required under § 26.91(e)(3). Using EBTs that have the required capabilities for confirmatory alcohol tests protects donors' rights to accurate test results, provides greater assurance that test results will withstand any legal challenges, and improves FFD

programs' abilities to identify tests that instrument errors may have affected. Therefore, these requirements meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC added § 26.91(d) [Quality assurance and quality control of ASDs] to establish quality assurance and quality control requirements for ASDs. These requirements are necessary to ensure that initial tests that are conducted using an ASD do not yield false negative test results. If an ASD provides a false negative test result, the test would not detect a donor who has an alcohol concentration that exceeds the cutoff levels established in this part, and the donor may be permitted to perform duties while impaired, potentially creating an unacceptable risk to public health and safety or the common defense and security. The final rule continues to require confirmatory testing if initial alcohol test results are positive, so false positive test results from an ASD lead to confirmatory testing, which provides accurate test results. False positive test results from initial testing reduce the efficiency of FFD programs and inconvenience donors by causing them to be subject to unnecessary confirmatory testing, but do not pose any risks to public health and safety or the common defense and security. However, confirmatory testing is not required if the result of an initial alcohol test result is negative. Therefore, the quality assurance and quality control requirements contained in this paragraph are necessary to maintain the effectiveness of FFD programs, which is Goal 3 of this rulemaking.

The agency added § 26.91(d)(1) to require FFD programs to implement the most recent version of the quality assurance plan that a manufacturer has submitted to NHTSA for any ASD that the licensee or other entity uses for initial alcohol testing. To obtain NHTSA approval for an ASD, the manufacturer of the device must submit a quality assurance plan that (1) specifies the methods that must be used for quality control checks, (2) the temperatures at which the ASD must be stored and used, (3) the shelf life of the device, (4) environmental conditions (e.g., temperature, altitude, humidity) that may affect the ASD's performance, (5) instructions for its use and care, (6) the time period after specimen collection within which the device must be read, where applicable, and (7) the manner in which the reading is made. This paragraph requires licensees and other entities who intend to use an ASD to obtain and implement the most recent version of the manufacturer's quality assurance plan to ensure that the ASD will not provide false negative test results from improper storage or use. As discussed with respect to § 26.91(d), the new provision is necessary to maintain the effectiveness of FFD programs that rely on ASDs for initial alcohol testing.

The NRC added § 26.91(d)(2) to prohibit licensees and other entities from using an ASD that fails the quality control checks that are specified in the most recent version of the manufacturer's quality assurance plan or that has passed its expiration date. This prohibition is necessary to ensure that test results from using the ASD are accurate both to protect public health and safety and donors' rights to accurate test results under the rule.

The NRC added § 26.91(d)(3) to require licensees and other entities to follow the device use and care requirements that are specified in § 26.91(e) for any ASD that tests breath specimens. The agency added this requirement because some ASDs test specimens of oral fluids while others test breath specimens, and some ASDs that test breath specimens also appear on NHTSA's CPL for evidential breath testing devices (67 FR 62091: October 3, 2002, and subsequent amendments). Those ASDs that do test breath specimens and are used for confirmatory testing have more detailed quality assurance and quality control provisions because their results must be legally defensible.

Section 26.91(e) [Quality assurance and quality control of EBTs] establishes new quality assurance and quality control requirements for EBTs. The new requirements are consistent with those of other Federal agencies that require workplace alcohol testing and, therefore, update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.91(e)(1) adds a requirement that licensees and other entities must implement the most recent version of the manufacturer's instructions for the use and care of the EBT consistent with the quality assurance plan submitted to NHTSA for the EBT, including the required frequency for conducting calibration checks using external standards (''external calibration checks''). An EBT manufacturer is required to submit to NHTSA a quality assurance plan that addresses methods used to perform external calibration checks on the EBT, the tolerances within which the EBT is regarded as being in proper calibration, and the intervals at which these checks must be performed. The final rule requires licensees and other entities to perform calibration checks using external standards at the manufacturer's recommended intervals, at a minimum. These calibration intervals take into account factors such as frequency of use, environmental conditions (e.g., temperature, humidity, altitude), and type of operation (e.g., stationary or mobile). Therefore, this provision is intended to ensure that the EBT will not provide false test results from improper storage or use.

Section 26.91(e)(2) adds a requirement for licensees and other entities to use only calibration devices appearing on NHTSA's CPL for ''Calibrating Units for Breath Alcohol Tests'' when conducting external calibration checks. This requirement is necessary to ensure that the calibrating units used by licensees and other entities meet minimum standards and provide accurate results.

The final rule adds § 26.91(e)(3) to address circumstances in which an EBT fails an external calibration check. This section requires the licensee or other entity to take the EBT out of service and prohibits its use until it has been repaired and passes an external calibration check. An EBT that has failed an external calibration check must be taken out of service to avoid inaccurate reporting of breath alcohol test results that could result either in the imposition of sanctions on a donor who has not abused alcohol or the failure to identify a donor who has.

The NRC moved and amended the requirement in proposed § 26.91(e)(3) to cancel any positive confirmatory alcohol test results that were obtained from an EBT that fails an external calibration check and also to cancel the results of any tests that were conducted with that EBT subsequent to its last successful external calibration check. The final rule retains this requirement in § 26.91(e)(4)(i), but presents it as one of two options licensees and other entities must implement if an EBT fails an external calibration check. The final rule adds a second option for handling circumstances in which an EBT fails an external calibration check in § 26.91(e)(4)(ii). This new section permits licensees and other entities to conduct an external calibration check of the EBT after each positive confirmatory alcohol test result. If the EBT fails the check, the provision requires the collector to cancel the donor's test result and perform another initial and confirmatory alcohol test, if necessary, using a different EBT. The requirements to cancel tests from an EBT that has failed an external calibration check are necessary to protect donors' right to accurate testing under the rule because

positive test results from an EBT that has failed an external calibration check are questionable and donors should not be subject to sanctions on the basis of these test results.

The NRC added § 26.91(e)(4)(ii) in response to a public comment on proposed § 26.91(e)(3). The commenter stated that canceling donors' positive confirmatory test results from an EBT that fails an external calibration check may not adequately protect donors' rights under the rule, if a licensee or other entity performs external calibration checks at the manufacturers' recommended intervals. The commenter noted that most EBT manufacturers' recommended intervals for conducting external calibration checks are 1 month, which could result in several canceled tests, if an EBT has yielded false positive test results that are only discovered when the EBT fails the monthly check. However, if the licensee or other entity has already imposed sanctions on a donor for a positive confirmatory alcohol test result from the EBT, the donor will experience the adverse consequences of those sanctions, which may include job loss, before the licensee or other entity identifies the instrument malfunction and cancels the donor's confirmed positive test result.

The NRC considered several options to address this concern, including requiring more frequent external calibration checks, but could not identify a technical basis for establishing schedules that would be more appropriate for every EBT on the NHTSA list than those recommended by the EBT manufacturers. Further, the agency recognizes that canceling tests imposes a burden on licensees and other entities as well as on donors and expects that licensees and other entities will likely choose to conduct external calibration checks more often than recommended by the EBT manufacturers to avoid canceling multiple tests. Therefore, the final rule retains the proposed requirement as an option in § 26.91(e)(4)(i), but adds a second option for handling circumstances in which an EBT fails an external calibration check in § 26.91(e)(4)(ii). Under the latter provision, it is unnecessary for a licensee or other entity to cancel any previous donors' confirmed positive alcohol test results from using the EBT because the licensee or other entity will perform the external calibration check after every positive confirmatory test result and no other donors will have been affected by false positive test results from an EBT that fails the check. Under this option, a donor will not be subject to adverse consequences for a false positive test result because the malfunction will be detected before the licensee or other entity imposes any sanctions. The NRC has added this provision to meet Goal 7 of the rulemaking to protect donors' privacy and other rights (including due process) under the rule.

The final rule renumbers as § 26.91(e)(5) the provision contained in § 26.91(e)(4) of the proposed rule. This section requires an EBT manufacturer or a maintenance representative or other individual who is certified by the manufacturer, a State health agency, or other appropriate State agency to inspect, maintain, and calibrate the EBT. This new provision ensures that qualified personnel perform inspection, maintenance, and calibration of EBTs (1) to ensure that the EBTs used in Part 26 programs continue to provide accurate test results, and (2) because the experience of other Federal agencies that require workplace alcohol testing has demonstrated that such stringent EBT inspection, maintenance, and calibration requirements are necessary to withstand legal challenges to alcohol test results. The final rule adds ''or other individual who is certified'' to the proposed provision because some licensees and other entities may choose to obtain the required certification for their FFD program personnel or other employees, and the NRC does not intend to prohibit this practice.

Section 26.93 Preparing for Alcohol Testing

This added section expands on former Section 2.4(g)(18) in Appendix A to Part 26, which specified procedures for alcohol testing. The final rule provides more detailed procedures than the former paragraph to increase the consistency of these procedures with those of other Federal workplace alcohol testing programs as well as consistency among the alcohol testing procedures of Part 26 programs. The agency added more detailed requirements for the reasons discussed in Section IV.B.

Section 26.93(a) contains more detailed procedures for implementing the requirement in the first sentence of former Section 2.4(g)(18) in Appendix A. That provision instructed collectors to delay alcohol breath testing for 15 minutes if the donor has engaged in any of the activities listed (e.g., smoking, regurgitation of stomach contents from vomiting). Section 26.93(a)(1) through (a)(6) requires the collector to provide the donor with more detailed information about mouth alcohol and the testing process than was required under the former rule and document that the information is provided. Providing more detailed requirements for the 15-minute waiting period improves the effectiveness and efficiency of the alcohol testing process by reducing false positive test results that are due to residual mouth alcohol or other substances that could potentially trigger a false positive result. Section 26.93(a)(1) retains the former requirement for the collector to ask the donor about behaviors such as eating and drinking that may have occurred within the 15 minutes before an alcohol test and adds a requirement for the collector to advise the donor to avoid these activities during the collection process. Section 26.93(a)(2) permits alcohol testing to proceed if the donor states that none of the activities listed in § 26.93(a)(1) has occurred, while § 26.93(a)(3) retains the former requirement for a 15-minute waiting period before a donor may be tested if he or she had engaged in the activities listed in § 26.93(a)(1). Section 26.93(a)(4) adds a requirement for the collector to explain that it is to the donor's benefit to avoid the activities listed in § 26.93(a)(1) during the collection process. Section 26.93(a)(5) adds a requirement for the collector to explain to the donor that initial and confirmatory alcohol tests will be conducted at the end of the waiting period regardless of whether the donor has engaged in any of the activities listed in § 26.93(a)(1). Section 26.93(a)(6) adds a requirement for the collector to document that he or she has communicated the instructions to the donor. The additional requirements for the collector to communicate with the donor about the potential effects on test results of the activities listed in § 26.93(a)(1) ensure that donors clearly understand the reasons for avoiding those activities and the potential consequences of engaging in them to protect their rights to accurate test results under the rule. The requirement for the collector to document that the instructions were communicated to the donor ensures that the collector does not inadvertently omit the instructions and, therefore, improves the legal defensibility of the collection procedure, should a donor challenge it.

The final rule adds § 26.93(b) to require collectors to minimize delays in administering for-cause drug and alcohol tests and complete alcohol testing before collecting a specimen for drug testing. These requirements decrease the likelihood that a donor's test results will fall below the program's cutoff levels as a result of metabolic

processes over time, which could prevent the detection of proscribed alcohol consumption and drug use. Delays between the time at which a donor reports for testing and the time at which testing occurs continue to be permitted for tests conducted under conditions other than for cause, because, in contrast to for-cause testing, there is no reason to believe that an individual may have used drugs or alcohol in violation of the FFD policy. Therefore, there is no basis for a concern that metabolic processes may cause inaccurate test results. The new provision is consistent with the related regulations of other Federal agencies.

Section 26.95 Conducting an Initial Test for Alcohol Using a Breath Specimen

Section 26.95 replaces portions of former Section 2.4(g)(18) in Appendix A to Part 26 that specified procedures for conducting an initial test for alcohol. Collectors follow the procedures in this section when using ASDs that test breath specimens and EBTs. The new section increases the consistency of Part 26 with the procedures of other Federal agencies for workplace alcohol testing. Consistent with other agencies' procedures, the final rule eliminates the requirement in former Section 2.4(g)(18) in Appendix A to Part 26 for collecting a second breath specimen for the initial alcohol test. The experience of other Federal agencies indicates that the former Part 26 requirement for two breath specimens is unnecessary to obtain a valid, reliable, and legally defensible test result if the procedures specified in the new section are followed. Therefore, the final rule amends the former procedures to reduce the burden on FFD programs and donors that is associated with collecting two breath specimens for the initial alcohol test, while continuing to ensure that breath alcohol testing provides accurate results.

The agency added § 26.95(a) to require the collector to start breath testing as soon as reasonably practical after the donor indicates that he or she has not engaged in any activities that may result in the presence of mouth alcohol or after the 15-minute waiting period, if required. The final rule adds the phrase, ''as soon as reasonably practical,'' to this paragraph in response to stakeholder comments at the public meetings discussed in the preamble to the proposed rule. The intent of the provision is for the collector to conduct the initial alcohol test as soon as the individual has received the instructions specified in § 26.93 [Preparing for alcohol testing] to ensure the accuracy of the test result. Delays in conducting the test increase the possibility that the donor may inadvertently engage in a behavior that could result in the presence of mouth alcohol as well as permit the donor's metabolism to lower the alcohol concentration in the specimen if the donor has consumed alcohol. However, the stakeholders noted that when preparing for outages, in which it is sometimes necessary to test large numbers of individuals, collectors often provide the instructions in § 26.93 to groups of donors at the same time and it is not feasible to test each one immediately after providing the instructions. Therefore, the final rule adds the phrase, ''as soon as reasonably practical,'' to permit reasonable delays in testing associated with outage planning.

Section 26.95(b)(1) permits the donor to select a mouthpiece to be used for his or her test, at the collector's discretion. The rule does not require the collector to permit the donor to select the mouthpiece. However, this practice may increase the donor's confidence in the integrity of the testing process by assuring the donor that the selection of the mouthpiece is random if he or she is concerned that a collector may attempt to subvert the testing process by selecting a mouthpiece that had been contaminated with alcohol or other means of tampering with the testing device. The NRC is not aware of any instances in Part 26 programs in which a donor has accused a collector of altering an alcohol testing device. However, the experience of other Federal agencies who similarly require workplace alcohol testing indicates that taking steps to reduce potential donor concerns about the integrity of the testing process increases donors' willingness to participate in the testing procedures and reduces the potential for legal challenges.

In § 26.95(b)(2), the NRC has added a requirement for the collector to open the mouthpiece packaging and insert it into the device in view of the donor for the same reason described with respect to § 26.95(b)(1).

Section 26.95(b)(3) requires the donor to blow into the mouthpiece for at least 6 seconds in order to obtain an adequate breath sample. The NRC deleted the requirement to obtain the specimen from the end of the breath exhalation in former Section 2.4(g)(18) in Appendix A to Part 26 because it is unnecessary, based on improvements to breath-testing technology.

Section 26.95(b)(4) requires the collector to show the test result to the donor. This requirement is consistent with current industry practices and is intended to increase donor confidence in the integrity of the testing process by ensuring that both the donor and the collector have access to the same information about the donor's test result. The requirement is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, by ensuring that donors are aware of the information used by the collector to determine whether an alcohol test result is positive or negative.

Section 26.95(b)(5) requires the collector to ensure that the test result record can be associated with the donor and is maintained securely, consistent with the many provisions throughout the former and final rules that the chain of custody must be maintained for specimens and the associated documentation of test results. Sections 26.129 [Assuring specimen security, chain of custody, and preservation] and 26.159 [Assuring specimen security, chain of custody, and preservation] establish similar requirements for urine specimens at licensee testing facilities and HHS-certified laboratories, respectively.

The NRC has added § 26.95(c) to require the collection of only one breath specimen for the initial test unless problems in the collection require repetition of the collection. Problems in the collection may include, but are not limited to, device malfunctions or a donor's inability to provide an adequate breath specimen on the first try. If a repeat collection is required, the collector must rely on the result from the first successful collection in determining the need for confirmatory alcohol testing. If the procedures specified in this paragraph are followed, relying on one breath specimen for the initial test, rather than the two required in the former rule, increases the consistency of Part 26 collection procedures with those of other Federal agencies, in accordance with Goal 1 of this rulemaking. The new requirement also reduces the time required for breath specimen collections without compromising the accuracy, validity, or reliability of the test results. Therefore, the provision also meets Goal 3 to improve the efficiency of FFD programs.

Section 26.97 Conducting an Initial Test for Alcohol Using a Specimen of Oral Fluids

The NRC added this section to establish requirements for conducting initial alcohol tests using an ASD for testing oral fluids specimens. The final rule permits licensees and other entities to rely on ASDs that test oral fluids for

the reasons discussed with respect to § 26.83(a). The procedures for conducting alcohol testing of oral fluids with an ASD incorporate the related requirements from 49 CFR Part 40 and have been added to the final rule to ensure that initial alcohol tests of oral fluids provide accurate and legally defensible test results.

The agency has added § 26.97(a) to specify the procedures that the collector must follow in using an ASD for testing oral fluids.

Section 26.97(a)(1) requires the collector to check the expiration date on the device and show it to the donor. Because some devices degrade during storage, this step is necessary to assure both the donor and the collector that the device can be expected to function properly.

Section 26.97(a)(2) requires the collector to open an individually wrapped or sealed package containing the device in the presence of the donor for the reasons discussed with respect to § 26.95(b)(1).

Section 26.97(a)(3) requires the collector to offer the donor a choice of using the device or having the collector use it. If the donor chooses to use the device, the collector must provide instructions for its proper use. The final rule requires the collector to offer the donor the choice of using the device to increase the donor's confidence in the integrity of the testing process, as discussed with respect to § 26.95(b)(1).

Section 26.97(a)(4) requires the collector to gather oral fluids in the proper manner if the donor chooses not to use the device, or in cases in which a second test is necessary because the device failed to activate. In addition, the collector is required to wear single-use examination or similar gloves while doing so and change them following each test. Section 26.97(a)(5) requires the collector to follow the manufacturer's instructions to ensure that the device has activated. The NRC has added the requirements in these sections to ensure that the collection is properly conducted. The requirement to use single-use examination gloves ensures that the collector and donor are protected from possible infection from exposure to body fluids.

The NRC added § 26.97(b) to specify the procedures that the collector must follow if the first attempt to conduct the test using the ASD fails for any reason, including, but not limited to, the ASD failing to activate or because the device is dropped on the floor.

Section 26.97(b)(1) requires the collector to discard the device and conduct another test using a new device that has been under the collector's control if the first attempt fails. The final rule requires the second device to have been under the collector's control to ensure that the donor or another individual has no opportunity to substitute the new device with another that has been altered to provide a false negative test result. This provision is necessary to protect the integrity of the collection process.

Section 26.97(b)(2) requires the collector to record the reason for the new test. This requirement ensures that the information is available, should any questions arise with respect to the collection procedure in a review conducted under § 26.39 or legal proceedings.

Section 26.97(b)(3) requires the collector to offer the donor the choice of using the device or having the collector use it, unless the collector concludes that the donor was responsible for the new test needing to be conducted. The final rule requires the collector to offer the donor the choice of using the device for the reasons discussed with respect to § 26.95(b)(1). The requirement for the collector to use the device if he or she concludes that the donor was responsible for the second test needing to be conducted enhances the efficiency of the collection procedure by ensuring that the second collection is conducted properly.

Section 26.97(b)(4) requires the collector to repeat the collection procedures outlined in § 26.97(a) for the second collection.

If the second collection attempt fails, § 26.97(c) directs the collector to use an EBT to perform the initial alcohol test instead. The final rule requires the collector to use an EBT to perform the initial test after two failed attempts at testing oral fluids specimens to ensure that a valid test result is obtained to enhance the efficiency of the collection procedure by changing the method used to conduct the test.

If the specimen collection using the ASD for testing oral fluids is successful, § 26.97(d) instructs the collector to follow the device manufacturer's instructions for reading the result and show the result to the donor. The final rule prohibits the collector from reading the result sooner than instructed by the device manufacturer because some devices require several minutes after specimen collection to provide an accurate result, but no more than 15 minutes in all cases. The requirement for the collector to show the test result to the donor is intended to increase donor confidence in the integrity of the testing process by ensuring that both the donor and the collector have access to the same information about the donor's test result. This paragraph also requires the collector to record the test result and document that an ASD was used to ensure that the information is available, should any questions arise with respect to the collection procedure in a review conducted under § 26.39 or legal proceedings.

To protect collectors and donors from any possible biohazards, the final rule adds § 26.97(e) to prohibit the reuse of any devices, swabs, gloves, and other materials used in collecting oral fluids.

Section 26.99 Determining the Need for a Confirmatory Test for Alcohol

Section 26.99 amends the requirements in former § 26.24(g) and the portion of Section 2.7(e)(1) in Appendix A to Part 26 that addressed cutoff levels for alcohol testing. The final rule amends the former requirements for consistency with a new approach to determining positive alcohol test results in § 26.103. The NRC adopted the new approach because some licensees have not taken appropriate action when a donor has obtained alcohol test results just below the 0.04 percent BAC cutoff level after the donor has been at work for several hours. A BAC below 0.04 percent after the donor has been at work for several hours allows very little doubt that the donor has had an unacceptably high BAC, and has probably been impaired, at some time during the work period. Therefore, the final rule establishes new cutoff levels for alcohol testing in §§ 26.99 and 26.103 that take into account the average rate at which individuals metabolize alcohol over time. In § 26.99(a), the agency decreased the cutoff level for the initial alcohol test result from 0.04 to 0.02 percent BAC and requires a confirmatory alcohol test if a donor's initial test result is 0.02 percent BAC or higher. In addition, § 26.99(b) requires the collector to record the time at which the initial alcohol test result is obtained, so that the length of time during which the donor has been in a work status can be calculated to determine whether a confirmatory test result is positive, in accordance with § 26.103. These changes to the initial alcohol test cutoff level and testing procedure are necessary to support the provisions of § 26.103, which require the collector to declare an alcohol test as positive if the donor's confirmatory test result is 0.03 percent or higher after the donor has been on duty for 1 hour, or 0.02 percent or higher after the donor has been on duty for 2 hours. The revised lower cutoff level for the initial test of 0.02 percent BAC permits licensees and other entities to identify donors who

have had a BAC of 0.04 percent or higher while in a work status, and to initiate confirmatory testing for those individuals.

Section 26.101 Conducting a Confirmatory Test for Alcohol

The NRC added this section to provide detailed procedures for conducting confirmatory breath alcohol tests. These procedures incorporate the related requirements from 49 CFR Part 40, which the NRC has added to the final rule to ensure that confirmatory breath alcohol tests provide accurate and legally defensible test results when using the EBTs that are required in § 26.91(b) [Acceptable evidential breath testing devices] and relying on one breath specimen for confirmatory testing, as is required in § 26.91(c).

Section 26.101(a) requires licensees and other entities to conduct the confirmatory test as soon as possible following the initial alcohol test, and in all cases, no later than 30 minutes after the initial test. The final rule adds this requirement to reduce the possibility that alcohol metabolism will cause a confirmatory test to provide a result falling below the applicable cutoff level. Former Section 2.4(g)(18) in Appendix A to Part 26 did not require conducting a confirmatory test as soon as possible after obtaining a positive initial alcohol test result, although licensees follow this practice. However, the agency had added a 30-minute limit because some FFD program personnel may be tested under DOT procedures, as permitted in § 26.31(b)(2), and an EBT that is suitable for confirmatory testing may not be immediately available at the collection site, such that transport to another collection site is required. The 30-minute interim period is unnecessary at licensees' and other entities' collection sites because licensees' and other entities' collection sites must have the capability to conduct confirmatory tests with an EBT, as required under § 26.87(a). Therefore, except in these unusual circumstances, licensees and other entities are expected to continue their current practice of conducting the confirmatory test immediately after a donor's initial test result is determined to be positive.

The NRC added § 26.101(b) to specify procedures for conducting a confirmatory alcohol test.

Sections 26.101(b)(1) and (b)(2) require the collector to conduct an air blank before beginning the confirmatory test and verify that the air blank reading is 0.00. These steps are necessary to ensure that the EBT is functioning properly before the test begins.

Section 26.101(b)(3) requires the collector to take the EBT out of service if a second air blank test reading is above 0.00. This step is necessary because a reading above 0.00 on an air blank test indicates that the EBT is not functioning properly and may provide inaccurate test results.

The NRC has added § 26.101(b)(4) through (b)(7) to specify requirements for handling the EBT's mouthpiece; reading the test number displayed on the EBT; blowing into the EBT; and showing, recording, and documenting the result displayed on the EBT, respectively. The need for these steps is the same as for those discussed with respect to the related steps in § 26.95 [Conducting an initial test for alcohol using a breath specimen]. However, the final rule does not permit the donor to insert the mouthpiece into the EBT for the confirmatory test because it is necessary to ensure that the confirmatory test is conducted strictly in accordance with the proper procedures to produce a result that meets evidential standards. Meeting evidential standards is necessary if any questions arise with respect to the collection procedure in a review conducted under § 26.39 or legal proceedings.

Section 26.101(c) requires that only one breath specimen must be collected for the confirmatory alcohol test, unless problems in the collection require that the collection be repeated. If a repeat collection is required, the collector must rely on the result from the first successful collection in determining the confirmatory test result. As discussed under § 26.95(c), if the specified procedures are followed, relying on one breath specimen for the initial test rather than the two required in the former rule increases the consistency of Part 26 collection procedures with those of other Federal agencies. This also reduces the time required for breath specimen collections without compromising the accuracy, validity, or reliability of the test results. This section also prohibits licensees and other entities from combining or averaging results from more than one test in order to arrive at the confirmatory test result. These calculations, required by former Section 2.4(g)(18) in Appendix A to Part 26, are no longer necessary because of the mandatory use of the EBTs specified in § 26.91(b). The change meets Goal 3 of this rulemaking to improve the efficiency of FFD programs.

Section 26.101(d) amends the portion of former Section 2.4(g)(18) in Appendix A of Part 26 that required using a different EBT to conduct the confirmatory alcohol test than used for initial alcohol testing. The final rule permits the use of the same EBT for both initial and confirmatory alcohol testing, instead of requiring the use of two different EBTs. The licensee or other entity must obtain one breath specimen for initial alcohol testing and one for confirmatory testing, if necessary, but is permitted to conduct both tests using the same EBT. The NRC has made this change because improvements in EBT technology assure that valid and reliable test results may be obtained from a single EBT if the specimen collection and quality assurance procedures in this part are followed. Reducing the number of breath specimens required for alcohol testing not only reduces the costs associated with alcohol testing, but also reduces the burden on donors that the collection process imposes. Use of the same EBT for initial and confirmatory testing is consistent with the procedures of other Federal agencies for workplace alcohol testing.

Section 26.103 Determining a Confirmed Positive Test Result for Alcohol

Section 26.103 amends the cutoff level for determining whether a confirmatory alcohol test result is positive, as specified in former § 26.24(g) and Section 2.7(f)(2) in Appendix A to Part 26. This section establishes new cutoff levels that take into account the length of time the donor has been in a work status for the reasons discussed with respect to § 26.99 [Determining the need for a confirmatory test for alcohol]. Section 26.103(a)(1) retains the 0.04 percent BAC in former § 26.24(g) and Section 2.7(f)(2) in Appendix A to Part 26 as the cutoff level for a confirmed positive alcohol test result at any time regardless of the length of time the donor has been in a work status. Sections 26.103(a)(2) and (a)(3) establish new cutoff levels for positive alcohol test results that are above the 0.02 percent BAC cutoff level on the initial test and do not meet or exceed the 0.04 percent BAC cutoff level on confirmatory testing but indicate that the donor had a BAC of 0.04 percent or greater while in a work status or consumed alcohol while on duty. The cutoff levels and time periods in § 26.103(a)(2) and (a)(3) are based on the average rate at which normal metabolic processes reduce an individual's BAC over time, which is about 0.01 percent BAC per hour. Therefore, a donor whose BAC is measured as 0.03 percent after the donor has been in a work status for 1 hour would have had a BAC of approximately 0.04 percent when he or she reported for work an hour ago.

Through the same metabolic processes, a donor whose BAC is measured as 0.02 percent after he or she has been in a work status for 2 hours would also have had a BAC of approximately 0.04 percent when he or she reported for work 2 hours ago. These changes improve the effectiveness of FFD programs by ensuring that confirmatory alcohol testing identifies donors who have been impaired from alcohol use while on duty and, therefore, may have posed a risk to public health and safety.

The NRC added § 26.103(b) to strengthen FFD programs by requiring licensees and other entities to address circumstances in which a donor's confirmatory alcohol test result is greater than 0.01 percent BAC when the individual has been in a work status for 3 hours or more, but his or her BAC falls below the cutoff levels in § 26.103(a). The final rule requires the collector to declare the test as negative because NHTSA has not thoroughly evaluated some of the EBTs that licensees and other entities are permitted to use for confirmatory alcohol testing under the final rule for accurately estimating BAC levels below 0.02 percent. However, if an individual has an alcohol test result above 0.01 percent BAC and has been in a work status for 3 hours or more, the test result provides a reason to believe that the individual has been impaired while on duty. Therefore, the provision requires the licensee or other entity, after testing, to ensure that the donor's alcohol use is evaluated, a determination of fitness is performed, and the determination of fitness indicates that the donor is fit to safely and competently perform his or her duties before the individual is permitted to perform the duties that require him or her to be subject to this part. This change strengthens the effectiveness of FFD programs by ensuring that the alcohol use of individuals who may have been impaired when reporting for duty is assessed to determine whether such individuals' alcohol use is problematic and may pose a future risk to public health and safety and the common defense and security.

The NRC has deleted former Section 2.4(g)(19) in Appendix A to Part 26, which established requirements for collecting a blood specimen for alcohol testing, in its entirety because the final rule no longer permits blood testing for alcohol, at the donor's discretion, for the reasons discussed with respect to § 26.83(a).

Section 26.105 Preparing for Urine Collection

This section is added to describe the preliminary steps for collecting a urine specimen for drug testing. For organizational clarity, this section reorganizes the requirements in former Section 2.4(g)(5) through (g)(7) in Appendix A to Part 26 by separating alcohol and urine specimen collection procedures into separate sections of the final rule. The section also establishes several new requirements that the agency has added to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.105(a) revises former Section 2.4(g)(5) in Appendix A to Part 26. The final rule retains the former requirement for the donor to remove any unnecessary outer garments and belongings that might conceal items or substances that could be used to tamper with a urine, breath, or blood specimen. However, the final rule eliminates the references to blood and breath specimens in the former paragraph because the final rule no longer permits donors to request blood testing for alcohol. This paragraph also eliminates reference to breath specimens because the final rule presents requirements related to preparing for alcohol testing in a separate section (§ 26.93) for organizational clarity.

The NRC added § 26.105(b) to require the donor to empty his or her pockets and display the items contained in them. The new requirement for the collector to examine the articles in the donor's pockets increases the likelihood of detecting items (e.g., a vial of powdered urine, bleach, a portable heating unit, a false penis or any other tube or device that may be used to replicate the function of urinary excretion) that could be used to adulterate or substitute the specimen in a subversion attempt. The rule requires the collector to use his or her judgment in determining whether an item found in the donor's pockets indicates a clear intent to attempt to subvert the testing process. For example, whereas a container of urine found in a donor's pocket would be clear evidence of an intent to subvert the testing process, a container of eye drops, which could be used to adulterate the specimen, would, in most cases, be unlikely to indicate an intent to subvert the testing process. Should the collector identify an item that indicates a possible intent to subvert the testing process, this section requires him or her to contact the FFD program manager or MRO in order to obtain direction regarding the need for a directly observed collection. If the collector identifies an item that could be used to tamper with the specimen, but does not indicate an intent to subvert testing, then the collector must secure the item and continue with the collection. The agency added these requirements to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, as well as Goal 3 to improve the effectiveness of FFD programs, by improving the ability of the collector to identify attempts to subvert the drug testing process. Adding the requirement for the donor to permit the collector to make this examination ensures that donors understand that they must cooperate with the examination.

Section 26.105(c) retains former Section 2.4(g)(6) in Appendix A to Part 26, which required the individual to be instructed to wash his or her hands prior to urination. The final rule makes two minor editorial changes to the former provision for clarity in the language of the final rule. The final rule clarifies that the collector is to instruct the donor to wash and dry his or her hands and replaces the term ''individual'' with the term ''donor.''

Section 26.105(d) retains former Section 2.4(g)(7) in Appendix A to Part 26 and requires the donor to remain in the presence of the collection site person and not to have access to any source of water or other materials that could be used to tamper with the specimen. The final rule makes two minor editorial changes to the former provision for clarity in the language of the rule. The final rule replaces the term ''collection site person'' with the simpler term ''collector'' and the term ''individual'' with the term ''donor.''

The NRC added § 26.105(e) to permit the donor, at the collector's discretion, to select the specimen collection container that he or she will use. Permitting the donor to select the collection kit is not required. However, this practice may increase the donor's confidence in the integrity of the testing process by assuring the donor that the selection of the collection kit is random if he or she is concerned that a collector may attempt to subvert the testing process by selecting a kit that had been contaminated with a substance that would produce a positive, adulterated, substituted, or invalid test result in order to entrap the donor. The importance of providing assurance to the donor regarding the integrity of the collection process is discussed with respect to § 26.95(b)(1). This paragraph also prohibits the donor from taking collection kit materials (such as the specimen label) other than the collection container, into the private area used for urination. This prohibition ensures that a donor could not tamper

with the other collection kit materials and thereby disrupt the chain of custody for the urine specimen.

This section is consistent with the related requirements of other Federal agencies and so meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines, as well as Goal 3 to improve the effectiveness of FFD programs, by improving the ability of the collector to identify attempts to subvert the drug testing process. The final rule adds the new provision requiring the donor to permit the collector to make this examination in response to stakeholder requests at the public meetings discussed in the preamble to the proposed rule to ensure that donors understand that they must cooperate with the examination.

Section 26.107 Collecting a Urine Specimen

Section 26.107 amends former Section 2.4(g)(8), (g)(9), and (g)(12) in Appendix A to Part 26 to update the rule's urine specimen collection procedures and incorporate advances in other relevant Federal rules and guidelines, consistent with Goal 1 of this rulemaking.

The NRC added § 26.107(a)(1) to specify the instructions that the collector is required to provide to the donor. This paragraph requires the collector to instruct the donor to go into the room or stall used for urination, provide a specimen of the quantity that the licensee or other entity has predetermined, refrain from flushing the toilet, and return with the specimen as soon as the donor has completed the void. The final rule requires the collector to provide these instructions to the donor so that the donor understands his or her responsibilities with respect to the urine collection procedure. In addition, the instructions are necessary to implement other provisions of the final rule. For example, the quantity of urine that the collector instructs the donor to provide is based on the requirements of the licensee's or other entity's drug testing program, as discussed with respect to § 26.109 [Urine specimen quantity]. The collector instructs the donor not to flush the toilet so that the collector may inspect the private area in which the donor voided after receiving the specimen, as discussed with respect to § 26.109(c). The collector must instruct the donor to return with the specimen as soon as the donor has completed the void in order to minimize the possibility that the urine specimen cools and its temperature falls below the acceptable specimen temperature range specified in § 26.111(b).

Section 26.107(a)(1) further amends former Section 2.4(g)(8) in Appendix A to Part 26. The former provision stated that the individual may provide his or her urine specimen in the privacy of a stall or otherwise partitioned area that protects individual privacy. For clarity, this paragraph replaces ''may'' in the former rule with ''shall'' to indicate that the area in which the donor will urinate must provide for individual privacy. The final rule also adds an exception to the former requirement for privacy in the case of a directly observed collection. The agency made this change for greater accuracy in the rule language because the requirement for individual privacy does not apply in the case of a directly observed collection, as discussed with respect to § 26.115.

The NRC added § 26.107(a)(2) to further emphasize the requirement in former Section 2.4(g)(8) in Appendix A to Part 26 that donors must be afforded individual privacy when providing a urine specimen. The new paragraph requires that, unless the specimen is to be collected under direct observation, no one other than the donor may go into the private area in which the donor will urinate. Although the NRC is not aware of any instances in Part 26 programs in which the former requirement for individual privacy has been compromised, the experience of other Federal agencies has indicated that such emphasis is necessary.

Section 26.107(a)(3) permits the collector to set a reasonable time limit for the donor to void. Rather than establishing a specific time limit, the final rule permits the collector to rely on his or her professional judgment in order to ensure that individuals who may experience difficulty in voiding have sufficient time to provide a specimen while also permitting collectors to prevent donors from disrupting the testing process by taking an unduly long time to provide a specimen. In § 26.85(a), the rule specifies new training and qualification requirements to ensure that collectors are able to exercise professional judgment appropriately. At the public meetings discussed in the preamble to the proposed rule, stakeholders reported incidents in which donors appeared to be attempting to disrupt the testing process by spending an unduly long time providing a specimen and challenged the collector's authority to set a time limit. The new paragraph clarifies that collectors have the authority to set a reasonable time limit for voiding. In addition, this paragraph increases the consistency of Part 26 with the procedures implemented by other Federal agencies in accordance with Goal 1 of this rulemaking.

Section 26.107(b) amends former Section 2.4(g)(9) in Appendix A to Part 26. The former provision required the collector to note any unusual behavior or appearance in the permanent record book and on the custody-and-control form. This section clarifies the intent of the former requirement, which raised implementation questions from licensees, by specifying that the collector must pay careful attention to the donor during the collection process so that the collector can note any conduct that may indicate an attempt to substitute or tamper with the specimen. This section also provides examples of the types of behavior that may indicate a subversion attempt and requires the collector to contact FFD program management if he or she observes such behavior. This section requires FFD program management to determine whether a directly observed collection is necessary under § 26.115.

The NRC added § 26.107(c) to specify the actions to be taken by the collector and donor to complete the specimen collection procedure. The first sentence of § 26.107(c) retains the instruction in former Section 2.4(g)(12) in Appendix A to Part 26 that prohibits the donor from washing his or her hands until the specimen has been delivered to the collector. This paragraph also adds a requirement for the collector to inspect the private area for any evidence of a subversion attempt prior to flushing the toilet. This additional requirement is consistent with existing industry practices and the procedures of other Federal agencies. It is intended to increase the likelihood of detecting subversion attempts if the donor leaves any physical evidence in the toilet bowl or private area where the donor voided, which could include, but is not limited to, an empty vial that contains an adulterant, powdered urine spilled on the floor, or the remains of an adulterant in the toilet bowel.

Section 26.109 Urine Specimen Quantity

Section 26.109 amends former Section 2.4(g)(11) in Appendix A to Part 26. The former provision established 60 milliliters (mL) as the minimum quantity of urine that an FFD program must collect from donors and the procedures to be followed if a donor is unable to provide the specified quantity. The final rule reduces to 30 mL the basic quantity of urine to be collected.

Section 26.109(a) introduces a new term ''the predetermined quantity.'' The licensee or other entity establishes a

predetermined quantity of urine that each donor is requested to provide, depending on the characteristics of the licensee's or other entity's testing program. The final rule requires the predetermined quantity to include at least 30 mL of urine, but licensees and other entities may request a larger quantity of urine if—

The specimen will be initially tested at a licensee testing facility;

Testing will be conducted for additional drugs beyond those required in § 26.31(d)(1);

Split specimen procedures will be followed; or

The licensee's or other entity's program includes some combination of these characteristics.

The NRC has reduced the 60-mL quantity that was required in former Section 2.4(g)(11) in Appendix A to Part 26 to 30 mL to decrease the burden on donors, while ensuring that a sufficient quantity of urine is available to complete initial validity and drug tests, confirmatory validity and drug tests (if required), and any retests that may be requested by the donor and authorized by the MRO under § 26.165(b). NRC staff discussions with representatives of HHS-certified laboratories indicated that advances in testing technologies allow for these minimum testing and retesting procedures to be completed on a 30-mL specimen. Therefore, a 60-mL specimen is no longer necessary to achieve the NRC's minimum objectives of conducting validity and drug tests on each specimen for the five classes of drugs specified in § 26.31(d)(1), as well as retesting of the specimen, if required.

Section 26.109(a) also specifies the additional quantity of urine, above the basic 30 mL, to be collected when the testing program follows split specimen procedures. The rule requires licensees and other entities to collect an additional 15 mL for transfer into Bottle B of a split specimen for storage and possible testing. (As discussed with respect to § 26.113(b), the final rule replaces the terms, ''primary specimen'' and ''split specimen,'' in the former rule with the terms, ''Bottle A'' and ''Bottle B,'' for clarity in the language of the rule and consistency with the terminology used by other Federal agencies.) This additional 15 mL is sufficient to permit the HHS-certified laboratory to conduct validity and drug tests of the specimen in Bottle B, at the donor's request, and is consistent with the quantity required in the related provisions of other Federal agencies. Therefore, if a licensee's or other entity's testing program follows split specimen procedures, but does not include initial tests at the licensee testing facility or testing for additional drugs beyond those specified in § 26.31(d)(1), then the predetermined quantity for this testing program is 45 mL (30 mL for basic testing + 15 mL for the split specimen). The predetermined quantity must be larger than 45 mL if the testing program also includes initial tests at a licensee testing facility and testing for additional drugs.

Section 26.109(a) also permits licensees and other entities to include in the predetermined quantity the additional amount of urine that is necessary to support testing for additional drugs beyond those specified in § 26.31(d)(1). Licensees and other entities must consult with the HHS-certified laboratories they use to identify the quantity of urine required to test for the additional drugs. For example, if the licensee's or other entity's testing program does not include initial tests at a licensee testing facility and does not follow split specimen procedures, then the predetermined quantity for that testing program consists of the 30-mL basic quantity plus the additional amount of urine needed to test for additional drugs. As another example, if a licensee's or other entity's testing program includes initial tests at a licensee testing facility, follows split specimen procedures, and tests for additional drugs, then the predetermined quantity consists of the 30-mL basic quantity plus 15 mL for the split specimen plus the additional amount required by the licensee testing facility and HHS-certified laboratory to test for the additional drugs.

Section 26.109(a) also permits licensees and other entities to include in the predetermined quantity the additional amount of urine that is necessary to perform initial validity and drug tests at the licensee testing facility, if initial tests are performed there. For example, one licensee testing program currently requires an additional 10 mL of urine for initial testing at the licensee testing facility, but does not test for other drugs or follow split specimen procedures. In this program, the predetermined quantity that collectors must request the donor to provide is 40 mL. As another example, if a licensee's or other entity's testing program includes initial tests at the licensee testing facility, does not test for additional drugs, and follows: split specimen procedures, the predetermined quantity may be 55 mL (30 mL for basic testing + 15 mL for the split specimen + 10 mL for initial testing at the licensee testing facility). If this program also tests for additional drugs, the predetermined quantity may be larger than 55 mL.

The final rule adds § 26.109(b) to establish the actions that the collector must take if a donor provides a specimen that is less than the 30-mL basic quantity. NRC staff discussions with representatives of HHS-certified laboratories indicated that 30 mL is sufficient to meet the NRC's primary objectives of detecting drug use and subversion attempts through initial validity and drug testing, and for confirmatory validity and drug tests, if required, at an HHS-certified laboratory for the panel of drugs for which testing is required in § 26.31(d)(1). The 30-mL quantity also ensures that sufficient urine is available for retesting the specimen for validity and for drugs and drug metabolites, should the donor request such retesting, as permitted in § 26.165(b). Therefore, the 30-mL basic quantity is necessary to achieve the NRC's drug-testing objectives, although it is insufficient to permit testing for additional drugs, initial testing at licensee testing facilities, or splitting the specimen, which this part does not require.

Section 26.109(b)(1) amends the portions of former Section 2.4(g)(11) in Appendix A to Part 26 that prescribed collector actions if a donor provides an insufficient specimen. The final rule requires the collector to ''encourage'' the donor to drink a reasonable amount of liquid in order to provide a specimen of at least 30 mL, rather than ''allow'' the donor to drink additional liquid as required under the former rule. The NRC made this change to enhance the efficiency of FFD programs, consistent with Goal 3 of this rulemaking, by potentially reducing the time required to obtain a specimen of the required quantity from the donor and, thereby, to complete the collection, should the donor choose to comply. However, this paragraph establishes a limit on the amount of liquid that the individual is permitted to consume to avoid the potential for ''water intoxication,'' which is a physical response to consuming too many liquids that may cause harm to the donor. Although the limit of 24 ounces of water over a 3-hour period in the proposed rule is the same limit imposed in the HHS Guidelines, the NRC raised the limit in the final rule to 40 ounces over a 3-hour period for consistency with the DOT limit, in response to public comment. This limit continues to be conservative to ensure that individuals who may have a medical condition that makes them more subject to water intoxication, such as some forms of renal disease, or who are taking some medications, would not be placed at risk. The final rule retains

the former requirement in Section 2.4(g)(11) in Appendix A to Part 26 to collect successive specimens in separate containers.

The NRC added § 26.109(b)(2) to require the collector to end the specimen collection process as soon as the donor provides a specimen of at least 30 mL in a subsequent attempt. This requirement reduces the burden on donors who may have some difficulty providing a urine specimen while meeting the NRC's objectives of obtaining a specimen of sufficient size to support initial and confirmatory validity and drug testing, as well as retesting of the specimen.

Section 26.109(b)(2) also specifies that the licensee or other entity may not impose any sanctions if a donor provides a subsequent specimen that is less than the licensee's or other entity's predetermined quantity, as long as the specimen quantity is at least 30 mL. Imposing sanctions for failing to provide sufficient urine to support initial testing at the licensee's testing facility, split specimen procedures, or testing for additional drugs is inappropriate, because a specimen of at least 30 mL is sufficient to meet the NRC's objectives and, therefore, could not be considered a refusal to test.

Section 26.109(b)(2) also requires the collector to forward a subsequent specimen that is greater than 30 mL, but less than the licensee's or other entity's predetermined quantity, to the HHS-certified laboratory for testing, rather than permit the specimen to be tested at the licensee testing facility. This provision is necessary to ensure that a sufficient quantity of urine is available for validity and drug testing and retesting at the HHS-certified laboratory, if required, consistent with the NRC's objectives. However, if the subsequent specimen is equal to or greater than the licensee's or other entity's predetermined quantity, the licensee or other entity is permitted to follow the FFD program's normal testing procedures. Following normal testing procedures in this instance is permissible because there is sufficient urine to implement the FFD program's testing procedures (e.g., split specimen procedures, testing for additional drugs, initial testing at a licensee testing facility), while continuing to ensure that sufficient urine is available for testing and retesting at the HHS-certified laboratory, if required.

The agency added § 26.109(b)(3) to require the implementation of ''shy bladder'' procedures if a donor is unable to provide a 30-mL specimen within 3 hours of the initial attempt to provide a specimen, for the reasons discussed with respect to § 26.119. Requirements for implementing ''shy bladder'' procedures are contained in that section.

The NRC added § 26.109(b)(4) to establish additional requirements for specimen collections when a donor provides a specimen of less than 30 mL.

This section eliminates the requirement in former Section 2.4(g)(11) in Appendix A to Part 26 to combine successive specimens from a donor in order to obtain a specimen of 60 mL. The final rule prohibits the practice of combining specimens to ensure that successive specimens neither contaminate nor dilute a specimen that will be tested. In addition, the prohibition increases the consistency of Part 26 with the related requirements of other Federal agencies (Goal 1 of this rulemaking).

Section 26.109(b)(4) also requires the collector to discard any specimens of less than 30 mL unless there is reason to believe that a specimen may have been altered. Examples of reasons to believe that a donor may have attempted to alter the specimen may include, but are not limited to: (1) Observation of powder (that could be an adulterant or powdered urine) spilled in the private area in which the donor urinated or on the donor's clothing; (2) unexpected sounds from the private area while the donor should be voiding, such as the sound of something being unwrapped or dropping to the floor; (3) observation that the donor's pocket appears to contain an item that was not visible before the donor entered the private area (that the donor may have previously had taped to his body); and (4) an unusual color or lack of clarity in the urine specimen. The final rule requires the collector to discard specimens of less than 30 mL when there is no reason to believe that the specimens have been subject to tampering because they are not used for testing and there is no reason to retain them.

If the collector suspects that a specimen has been altered and the suspect specimen is equal to or greater than 15 mL, the rule requires the collector to forward the suspect specimen to the HHS-certified laboratory for testing, consistent with former Section 2.4(g)(16) in Appendix A to Part 26. NRC staff discussions with representatives of HHS-certified laboratories indicate that 15 mL is the minimum quantity necessary for HHS-certified laboratories to perform the initial and confirmatory (if necessary) validity and drug testing required in this part, although it is insufficient to support retesting of the specimen at the donor's request. When the collector has observed donor conduct or specimen characteristics that indicate there is a reason to believe that the donor may have altered the specimen, the NRC's interest in assuring that the testing process is not subverted takes precedence over the donor's ability to request retesting of the specimen. Any results of validity testing that confirm that the specimen was adulterated or substituted, in combination with the collector's observations, provide clear evidence that a donor has tampered with the specimen and thereby attempted to subvert the testing process.

This section also amends former Section 2.4(g)(17) in Appendix A to Part 26. The former provision required a directly observed collection whenever there is a reason to believe that a donor has or may attempt to alter a specimen. The amended provision requires the collector to contact FFD program management to determine whether a directly observed collection is required, but does not require a directly observed collection in every circumstance. At the public meetings discussed in the preamble to the proposed rule, the stakeholders requested flexibility in the decision to collect another specimen under direct observation. They noted that numerous instances have occurred in which a collector identified incontrovertible evidence that the donor intended to or had tampered with a specimen and that, in such cases, drug testing would not provide additional information that justifies the costs associated with conducting a directly observed collection and testing the additional specimen. The NRC believes that the presence of drugs and drug metabolites in a specimen that is collected under direct observation establishes a clear motive for an alleged attempt to tamper with a specimen and adds further evidence supporting the imposition of sanctions on the donor for attempting to subvert the testing process. However, the NRC believes that such additional evidence is unnecessary when there is incontrovertible evidence that the donor intends to or has attempted to tamper with a specimen. Therefore, the final rule permits FFD program management to determine whether an additional specimen collection under direct observation must be conducted. The agency has made this change to meet Goal 3 of this rulemaking to improve the efficiency of FFD programs, by reducing the number of directly observed collections required under the rule.

Section 26.111 Checking the Acceptability of the Urine Specimen

Section 26.111 amends former requirements for assessing specimen validity at the collection site, which appeared in Section 2.4(g)(13) through (g)(17) in Appendix A to Part 26. In general, the NRC has made changes in this section to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. In addition, the NRC changed the heading of this section from ''Checking the validity of the urine specimen'' in the proposed rule to ''Checking the acceptability of the urine specimen,'' in response to a public comment which noted that ''acceptability'' more accurately characterizes the purpose of the requirements in this section.

Section 26.111(a) amends former Section 2.4(g)(13) in Appendix A to Part 26. The former provision required the collector to measure the temperature of the specimen immediately after the urine specimen is collected. The new provision requires the collector to measure the temperature of any specimen that is 15 mL or more. The final rule does not mandate measuring the temperature of smaller specimens because the collector is required to discard them, as discussed with respect to § 26.109(b)(4). This paragraph also replaces former Section 2.4(g)(14) in Appendix A to Part 26, which established the acceptable specimen temperature range and required conducting a second specimen collection under direct observation if a specimen's temperature falls outside the acceptable range. The final rule increases the range of acceptable specimen temperatures from 90.5°F–99.8°F in the former provision to 90°F–100°F for consistency with the temperature range specified in the HHS Guidelines. The wider acceptable temperature range provides increased protection against false low or false high temperature readings and, therefore, protects donors from the imposition of sanctions based on inaccurate specimen temperature readings. The portion of former Section 2.4(g)(14) that specified collector actions if there is a reason to believe that the individual may have tampered with the specimen has been moved to § 26.111(d) for organizational clarity.

In response to a public comment, the final rule eliminates the requirement in § 26.111(a), which appeared in both the former and proposed rules, for the collector to offer the donor an opportunity to provide a measurement of body temperature. In addition, the final rule deletes § 26.111(b) in the proposed rule entirely and has renumbered the paragraphs in this section accordingly. The NRC has made these changes in response to public comments, which reported that DOT's experience indicates that there are often discrepancies when comparing the temperature provided by a specimen container temperature strip and that provided by a device that measures body temperature. Further, with the increase in the range of acceptable specimen temperatures, as discussed with respect to § 26.111(a), a measurement of body temperature is less useful to counter a reason to believe that the donor has altered the specimen (e.g., humans who have a body temperature at or below 90°F would be suffering from severe hypothermia). Therefore, eliminating the opportunity for a donor to provide a measure of body temperature in this paragraph meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.111(b) amends former Section 2.4(g)(15) in Appendix A to Part 26. The former provision required the collector to inspect the specimen's color, determine whether there were any signs of contaminants, and record any unusual findings in the permanent record book. The final rule amends this provision by deleting reference to the permanent record book and requiring the collector to use the custody-and-control form to record this information. The NRC has made this change because the final rule no longer requires collection sites to maintain a permanent record book, consistent with the elimination of the requirement to maintain a permanent record book in the HHS Guidelines. The final rule also makes minor editorial revisions to the former provision by incorporating the related language from the HHS Guidelines. The agency made these changes to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with the regulations of other Federal agencies.

Section 26.111(c) replaces and amends the first sentence of former Section 2.4(g)(14) in Appendix A to Part 26. The former provision required a second specimen to be collected under direct observation if the temperature of the first specimen submitted by a donor fell outside of the acceptable specimen temperature range. The final rule eliminates the requirement for a second specimen collection under direct observation if the specimen temperature falls outside of the required range, although licensees and other entities could, at their discretion, continue this practice. Instead, the new provision requires the collector to contact the FFD program manager, if the collector has a reason to believe the donor has attempted to subvert the testing process based on observed donor behavior, the specimen temperature, unusual specimen characteristics, or other observations. The FFD program manager, at his or her discretion, may consult with the MRO to determine whether the collector's observations provide sufficient evidence that a subversion attempt has occurred to warrant the imposition of sanctions. If the MRO and/or FFD program manager determine that a subversion attempt has occurred on the basis of the collector's observations, the final rule permits the licensee or other entity to impose the sanctions for a subversion attempt in § 26.75(b) without conducting a directly observed collection. However, at the FFD program manager's or the MRO's discretion, a second specimen may be collected under direct observation. The rule permits a second specimen to be collected under direct observation to provide further information to assist the MRO in determining whether or not a subversion attempt has occurred. For example, positive drug test results from a second specimen that is collected under direct observation provide additional evidence that the donor attempted to tamper with his or her first specimen to hide drug use. The NRC has made this change in response to stakeholder requests, for the reasons discussed with respect to proposed § 26.109(b)(4).

The NRC also added permission in § 26.111(c) for a donor to volunteer to submit another specimen under direct observation to counter any reason to believe that he or she may have altered the first specimen. The agency added this permission in response to a public comment suggesting this change and because it is consistent with Goal 7 of the rulemaking to protect donor's rights (including due process) under the rule.

Section 26.111(d) replaces and revises former Section 2.4(g)(16) in Appendix A to Part 26. The former provision required forwarding all urine specimens that are suspected of being adulterated or diluted to the HHS-certified laboratory for testing. The final rule adds a third reason, suspicion that a specimen has been substituted, for forwarding a specimen to the HHS-certified laboratory. As discussed with respect to § 26.31(d)(3)(i), substitution entails replacing a valid urine specimen with a drug-free specimen. The NRC has made this change for consistency with the addition of substitution to the final

rule as another method of attempting to subvert the testing process for which licensees and other entities are required to impose sanctions, as discussed with respect to § 26.75(b). This paragraph also adds a provision that specifically prohibits testing any suspect specimen at a licensee testing facility to (1) limit the potential for specimen degradation during the time period required to conduct testing at the licensee testing facility; (2) decrease the time required to obtain confirmatory validity test results if the specimen, in fact, has been altered; and (3) ensure that a sufficient quantity of urine is available for conducting validity tests at more than one HHS-certified laboratory if, for example, the specimen contains a new adulterant or an adulterant that the licensee's or other entity's primary laboratory is not capable of identifying (see § 26.161(g)). Only suspect specimens of 15 mL or more must be sent for testing, rather than all specimens. The final rule establishes this lower limit on specimen quantity to ensure that there is sufficient urine available for the HHS-certified laboratory to conduct all of the validity and drug tests on the specimen that are required under this part. In response to a comment, this paragraph of the final rule also adds a requirement to send specimens of 15 mL or more, collected under direct observation in accordance with § 26.111(c), to an HHS-certified laboratory for initial and confirmatory testing.

Section 26.111(e) requires collectors and the HHS-certified laboratory to preserve as much of a suspect specimen as possible. The NRC has added this requirement to provide increased assurance that a sufficient quantity of urine is available to support further testing, in the event that further testing of the specimen is necessary, and to enhance the consistency of Part 26 with the related provisions of other Federal agencies.

The agency also added § 26.111(f) to inform donors and collectors of the characteristics of a specimen that is acceptable for testing at an HHS-certified laboratory. This paragraph incorporates the related provision from the HHS Guidelines.

Section 26.113 Splitting the Urine Specimen

Section 26.113 updates former Sections 2.4(g)(20) and 2.7(j) in Appendix A to Part 26. This section amends collection site procedures for split specimens in the former rule and groups them together in one section within the final rule for organizational clarity.

Section 26.113(a) of the final rule revises the same provision in the proposed rule, in that the NRC has deleted the phrase ''who are subject to this part'' to provide additional clarity to the language of the rule, in response to public comment. The NRC deleted this phrase because not all of the licensees and entities who are subject to Part 26 are required to meet the requirements of this section.

For organizational clarity, the NRC has added § 26.113(b) to group together in one paragraph the steps that the collector and donor must follow for the split specimen collection procedure. These steps were embedded in former Section 2.4(g)(20) and portions of Section 2.7(j) in Appendix A to Part 26. The final rule also replaces the terminology used in the former rule that referred to the split specimen as an ''aliquot,'' and uses the terms, ''Bottle A'' and ''Bottle B,'' to refer to the primary and split specimen, respectively. The agency made these changes for increased clarity in the language of the rule and consistency with the terminology used in other relevant Federal rules and guidelines.

In response to a public comment, the NRC revised proposed § 26.113(b)(1) to delete the option of using a specimen bottle to collect a urine specimen to eliminate the possibility of problems arising from collecting urine in two different types of containers. The final rule retains the requirement for the collector to instruct the donor to void into a specimen container to clarify that the donor is not required to divide a specimen into Bottle A and Bottle B while urinating. This paragraph incorporates the related provision in the HHS Guidelines.

Section 26.113(b)(2) amends the portions of former Section 2.7(j) in Appendix A to Part 26 that specified the amount of urine to be poured into the split specimen bottles. The rule replaces the implied requirements in the second and third sentences of Section 2.4(j), which referred to the split specimens as ''halves'' of the specimen that was collected, with updated requirements that are consistent with those established in § 26.109 and the related provisions in the HHS Guidelines. This paragraph requires the collector to ensure that Bottle A contains 30 mL and that Bottle B contains a minimum of 15 mL of urine. As discussed with respect to § 26.109, advances in urine testing technologies since the agency first promulgated Part 26 permit a reduction in the quantity of urine that must be collected from donors in order to conduct the testing this part requires. Therefore, 30 mL of urine is now a sufficient quantity for conducting all of the testing that may be required under this part and 15 mL is sufficient for conducting testing of the specimen in Bottle B.

In response to public comment, the NRC has revised this paragraph in the final rule to more clearly specify that the specimen in Bottle A must be used for drug and validity testing even if there is less than 15 mL of urine available for Bottle B. The agency added this clarification to the final rule because, in the experience of other Federal agencies, some collection sites have discarded any specimen of less than 45 mL and conducted another collection to obtain a sufficient amount of urine to fill both Bottles A and B. Following this practice would reduce the efficiency of FFD programs and unnecessarily increase the burden on donors who are subject to testing. The final rule incorporates this clarification from the HHS Guidelines to ensure that Part 26 programs do not adopt this inefficient and burdensome practice.

Section 26.113(b)(3) retains the portion of former Section 2.4(g)(20) in Appendix A to Part 26 that requires the donor to observe the process of splitting the specimens and maintain visual contact with the specimen bottles until they are sealed and prepared for storage or shipping.

The NRC added § 26.113(c) to establish priorities for using the specimen that has been collected. The paragraph permits the licensee testing facility to test aliquots of the specimen at a licensee testing facility or to test for additional drugs beyond those required under § 26.31(d)(1), but only if the donor has provided a specimen of at least the predetermined quantity, as discussed with respect to § 26.109. As discussed with respect to § 26.113(b)(2), the final rule requires the collector first to ensure that 30 mL of urine is available for Bottle A and 15 mL for Bottle B. If the donor has provided more than 45 mL of urine and the additional amount is sufficient to support testing at the licensee testing facility, testing for additional drugs, or both, the final rule permits the remaining amount of urine to be subject to such testing. However, if the donor has provided only 45 mL of urine, the final rule requires that the 15 mL of urine that remains after 30 mL has been retained for Bottle A must be used for Bottle B rather than to conduct testing at the licensee testing facility or testing for additional drugs. The final rule establishes this priority because the FFD program has established the expectation among donors in this instance that the FFD program will follow split specimen procedures and

that Bottle B will be available for retesting at the donor's request. Reserving the 15 mL of urine for Bottle B is also consistent with the principle that is established in the last sentences of §§ 26.135(b) and 26.165(a)(4) that control over testing of the specimen contained in Bottle B resides with the donor.

Section 26.115 Collecting a Urine Specimen Under Direct Observation

Section 26.115 groups together in one section the former rule's requirements that apply to collecting a urine specimen under direct observation. The NRC has made this organizational change because requirements that address this topic were dispersed throughout the former rule. This section also incorporates more detailed procedures for collecting specimens under direct observation that are based on related requirements from other relevant Federal rules and guidelines. More detailed procedures are necessary because devices and techniques to subvert the testing process have been developed since Part 26 was first published that are difficult to detect in many collection circumstances, including under direct observation, such as a false penis or other realistic urine delivery device containing a substitute urine specimen and heating element that may be used to replicate urination. Therefore, the agency has made these changes to increase the likelihood of detecting attempts to subvert the testing process and increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor.

Section 26.115(a) amends and combines former Section 2.4(f), 2.4(g)(17), and (g)(25) in Appendix A to Part 26. The former provisions established requirements for collecting a urine specimen under direct observation. This paragraph of the final rule assigns responsibility for approving a directly observed collection to the MRO or FFD program manager, rather than a ''higher level supervisor'' of the collector, as stated in former Section 2.4(b)(25) in Appendix A to Part 26. This change ensures that an individual who is thoroughly knowledgeable of the requirements of this part, and the emphasis that the NRC places on maintaining the individual privacy of donors, makes the decision to conduct a directly observed collection. The change is also consistent with revised requirements in the HHS Guidelines related to who may authorize a directly observed collection.

The final rule also lists the circumstances that constitute a reason to believe that a donor may dilute, substitute, adulterate, or otherwise alter a specimen, and that warrant the invasion of individual privacy associated with a directly observed collection.

Section 26.115(a)(1) amends former Section 2.4(f)(2) in Appendix A to Part 26, which stated that a directly observed collection may be performed if the last urine specimen provided by the donor yielded specific gravity and creatinine concentration results that were inconsistent with normal human urine. The new paragraph amends the former provision in several ways.

First, the final rule eliminates the limitation in the former paragraph that a specimen may be collected under direct observation if ''the last urine specimen'' provided by the individual yielded specific gravity and creatinine concentration results that are inconsistent with normal human urine. The final rule permits a directly observed collection if the donor had presented a specimen with characteristics that are inconsistent with normal human urine ''at this or a previous collection.'' The change is consistent with § 26.75(b), which requires that an individual who has subverted or attempted to subvert any test conducted under Part 26 must be subject to a permanent denial of authorization. Because § 26.75(b) requires permanent denial of authorization to a donor who has engaged in a subversion attempt, individuals whose last specimen had characteristics that are inconsistent with normal human urine are not subject to further testing under the rule. However, instances may arise in which a licensee or other entity is aware that an individual engaged in a subversion attempt under a drug testing program that the NRC does not regulate. If the licensee or other entity is considering granting authorization under Part 26 to the individual, then a directly observed collection is warranted to ensure that the donor does not have an opportunity to tamper with the specimen and, therefore, that drug test results will be accurate. The amended language of the new provision permits collecting a specimen under direct observation in these circumstances.

Second, the final rule updates the former provision by replacing the specific gravity and creatinine concentration values in the former paragraph with references to a urine specimen that ''the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO reported to the licensee or other entity that there is no adequate medical explanation for the result.'' The NRC made this change for consistency with the addition of more detailed requirements for validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). Section 26.161 [Cutoff levels for validity testing] specifies the cutoff concentrations and specimen characteristics that require the HHS-laboratory to report a specimen as substituted, adulterated, or invalid. Section 26.185 [Determining a fitness-for-duty policy violation] specifies the requirements for the MRO's review of these test results.

Section 26.115(a)(2) combines and updates former Sections 2.4(f)(1) and 2.4(g)(14) in Appendix A to Part 26. The former provisions stated that the presentation of a specimen that falls outside of the required temperature range is sufficient grounds to conduct a directly observed collection. The new paragraph retains the requirement in former Section 2.4(f)(1) in Appendix A to Part 26, which specified that a directly observed collection may be conducted at any time the specimen's temperature falls outside of the required temperature range. However, the final rule deletes the provisions of the proposed rule that addressed measuring the donor's body temperature for the reasons discussed with respect to § 26.111(a).

Section 26.115(a)(3) updates former Section 2.4(f)(3) in Appendix A to Part 26. The former provision permitted a directly observed collection if a collector observed donor conduct that clearly and unequivocally demonstrates an attempt by the donor to substitute the specimen. The final rule adds references to attempts to dilute and adulterate a specimen, in addition to substitution, as behaviors that demonstrate a subversion attempt, consistent with the NRC's heightened concern in the final rule for ensuring specimen validity, as discussed with respect to § 26.31(d)(3)(i). As discussed with respect to § 26.107(b), donor conduct that clearly and unequivocally demonstrates an attempt to alter a specimen may include, but is not limited to, possession of a urine specimen before the collection has occurred; possession of a vial, or vials, filled with chemicals that are subsequently determined to be urine or an adulterant; possession of a heating element; or evidence that the coloring agent used by the licensee or other entity in a source of standing water at the collection site (see § 26.87(e)(1)) discolors the specimen.

Section 26.115(a)(4) updates former Section 2.4(f)(4) in Appendix A to Part 26. The former provision permitted

directly observed collections if a donor had previously been determined to have engaged in substance abuse and the specimen was being collected as part of a rehabilitation program and/or pre-access testing following a confirmed positive test result. This paragraph updates the former requirement by adding a cross-reference to § 26.69 [Authorization with potentially disqualifying fitness-for-duty information], which establishes requirements for granting or maintaining the authorization of an individual about whom potentially disqualifying FFD information has been discovered or disclosed. Several provisions in § 26.69 permit or require directly observed collections, including § 26.69(b)(5), which requires specimens to be collected under direct observation for pre-access drug testing of individuals who have been subject to sanctions under the rule. For organizational clarity, this paragraph replaces the former requirement with a cross-reference to § 26.69, rather than repeat the applicable requirements in this section.

Section 26.115(b) amends the requirement in former Section 2.4(g)(25) in Appendix A to Part 26 that the collector must obtain permission from a ''higher level supervisor'' before conducting a directly observed collection, as discussed with respect to § 26.115(a). The NRC has added the second sentence of this paragraph to require that, once the decision has been made to conduct a directly observed collection based on a reason to believe that the donor may alter a specimen, the collection must occur as soon as reasonably practical. Although the NRC is not aware of any occasions in Part 26 programs in which a directly observed collection has been unreasonably delayed, the new requirement ensures that test results from the directly observed collection provide information about the presence or absence of drugs and drug metabolites in the donor's urine. If a collection is delayed for a day or more, metabolism may cause the concentration of drugs and drug metabolites in the donor's urine, if any are present, to fall below the cutoff levels established in this part or by the FFD program and, therefore, not be detected by testing. Positive, adulterated, substituted, or invalid test results from a specimen collected under direct observation provide evidence to support a conclusion that the individual had attempted to subvert the testing process in order to mask drug abuse, whereas negative test results may counter the reason to believe that the individual had attempted to subvert the testing process. Therefore, conducting the directly observed collection as soon as reasonably practical ensures that test results from the specimen provide relevant and useful information. The requirement is also consistent with those of other relevant Federal rules and guidelines.

The agency added § 26.115(c) to require the collector to inform the donor of the reason(s) for the directly observed collection so that the donor is aware of the nature of the concern that has initiated a directly observed collection. The final rule includes this requirement for two reasons: (1) knowing the reason for a directly observed collection may increase a donor's willingness to cooperate in the procedure in order to counter the reason to believe that the donor has or may attempt to alter the specimen, and (2) informing the donor of the reason for a directly observed collection meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 by ensuring that the donor is aware of the concern that has initiated the collection. This paragraph also meets Goal 1 of this rulemaking by improving consistency with the requirements of other relevant Federal rules and guidelines.

The NRC added § 26.115(d) to establish recordkeeping requirements related to the directly observed collection. This provision requires the collector to record on the specimen's custody-and-control form that the specimen was collected under direct observation and the reason(s) for the directly observed collection. This requirement ensures that the HHS-certified laboratory and the MRO have this information available when the specimen is tested and the MRO conducts his or her review of the test results, as is required under § 26.185. This information is important in an MRO's decision to request the laboratory to test a specimen that appeared to have been diluted, as permitted under § 26.185(g)(2), in order to compare the results from testing the dilute specimen with those obtained from testing the specimen that was collected under direct observation. Positive, adulterated, substituted, or invalid test results from the dilute specimen and the presence of the same drugs or drug metabolites in the specimen collected under direct observation provide evidence that the donor diluted the first specimen in an attempt to mask drug use. This section is also consistent with the requirements of other relevant Federal rules and guidelines.

Section 26.115(e) retains and combines the former requirements in Sections 1.2, 2.4(b), 2.4(g)(14), (g)(17), and (g)(25) in Appendix A to Part 26. These provisions required that the individual who observes the specimen collection must be of the same gender as the donor. Consistent with the former requirements, the final rule permits another individual of the same gender to serve as the observer if a qualified urine collector of the same gender is not available as long as the observer receives the instructions specified in § 26.115(f). The final rule combines the former requirements in this paragraph for organizational clarity.

The NRC added § 26.115(f) to specify the procedures that must be followed in conducting a directly observed collection by either a qualified collector or an individual of the same gender who may serve as the observer. These more detailed procedures are necessary because devices and techniques to subvert the testing process have been developed since Part 26 was first published that can be used under direct observation without detection. Therefore, the agency made these changes to increase the likelihood of detecting attempts to subvert the testing process and, thereby, increase the effectiveness of directly observed collections in assuring that a valid specimen is obtained from the donor.

The NRC added § 26.115(f)(1) to specify that the observer must instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed. This requirement ensures that the observer is able to detect the use of an anatomically correct urine delivery device.

The agency added § 26.115(f)(2) to specify the action to be observed during the collection. This paragraph is consistent with the requirements of other Federal agencies and is intended to ensure that the urine specimen is obtained from the donor's body.

The rule adds § 26.115(f)(3) to prohibit an observer who is not the collector from touching the specimen container. The new provision is consistent with the related requirements of other Federal agencies and is intended to protect the observer from any potential claims by a donor that the observer had altered the specimen.

The new § 26.115(f)(4) requires the collector to record the observer's name on the custody-and-control form if the observer is not the collector. This mandate is consistent with the related requirements of other Federal agencies

and is intended to ensure that the observer's identity is documented should future questions arise regarding the collection.

The NRC added § 26.115(g) to clarify that a donor's refusal to participate in the directly observed collection constitutes a refusal to test and, therefore, is considered to be an act to subvert the testing process under § 26.75(b). Former Section 2.4(j) in Appendix A to Part 26 required the collector to inform the MRO, and the MRO to inform licensee management, if a donor failed to cooperate with the specimen collection process, including, but not limited, to a refusal to provide a complete specimen, complete paperwork, or initial the specimen bottles. The former requirement did not specifically mention that a refusal to participate in a directly observed collection is also an instance of a failure to cooperate. In addition, the former rule did not require the licensee or other entity to impose sanctions on a donor for refusing to be tested. Therefore, the final rule adds a provision that both clarifies the NRC's original intent by stating that a refusal to participate in a directly observed collection constitutes a refusal to test and updates the former requirement by adding a cross-reference to the sanction of permanent denial of authorization that is required under § 26.75(b).

The agency added § 26.115(h) to specify the actions that a collector must take if a directly observed collection was required but not performed. The collector must report the omission to the FFD program manager or designee, who ensures that a directly observed collection is immediately performed. Although the concentrations of any drugs, drug metabolites, or blood alcohol in the donor's specimens may fall below the cutoff levels that are specified in this part or in the licensee's or other entity's FFD policy if several days have elapsed since the directly observed collection should have occurred, testing a specimen collected several days later increases the likelihood of detecting any subsequent drug or alcohol use. In addition, the metabolites from using some drugs, such as marijuana, linger in an individual's body. Therefore, conducting a directly observed collection may result in detecting these metabolites. However, because elapsed time reduces the concentrations of drugs, drug metabolites, or alcohol in the donor's specimens, the final rule requires a directly observed collection to be performed immediately. This section uses the term ''immediately'' to indicate that the licensee or other entity may be required to call in the donor and a collector to perform the directly observed collection, if the donor and collectors are not on site when the oversight is identified. This requirement increases consistency with the related requirements of other Federal agencies and is intended to provide instructions for correcting an oversight that the former rule did not address.

Section 26.117 Preparing Urine Specimens for Storage and Shipping

A new § 26.117 reorganizes and presents together in one section former requirements for safeguarding specimens and preparing them for transfer from the collection site to the licensee's testing facility or the HHS-certified laboratory for testing. The NRC made this organizational change because requirements that address these topics were dispersed throughout the former rule and grouping them together in a single section in the final rule makes them easier to locate.

Section 26.117(a) amends former Section 2.4(g)(20) in Appendix A to Part 26, which required the donor and collector to maintain visual contact with specimens until they were sealed and labeled. The final rule eliminates reference to blood specimens because donors are no longer permitted to request blood testing for alcohol under the final rule, as discussed with respect to § 26.83(a). The new paragraph also amends the requirements in the second sentence of the former provision. For organizational clarity, the final rule moves to § 26.113 [Splitting the urine specimen] procedural requirements for observing the splitting of a specimen and sealing the split specimen bottles. However, this provision broadens the former requirement, which addressed only split specimens, to require the donor to observe the transfer of any specimen or aliquot that the collector transfers to a second container and the sealing of the container(s). This requirement is necessary because some FFD programs who operate licensee testing facilities may transfer an aliquot of the urine specimen to a second container for initial testing at the licensee testing facility, while preserving the primary specimen in the first or another container. The final rule requires the donor to observe these actions to ensure that the specimen or aliquot(s) that are transferred belong to the donor and that the identity and integrity of the specimen are maintained.

Section 26.117(b) retains former Section 2.4(g)(21) in Appendix A to Part 26. This provision requires the donor and collector to remain present while the procedures for sealing and preparing the specimen (and aliquots, if applicable) for transfer are performed.

Section 26.117(c) retains the meaning of former Section 2.4(g)(22) in Appendix A to Part 26. This provision establishes requirements for labeling and sealing the specimen(s), but the final rule splits the former requirement into several sentences for increased clarity in the language of the provision.

For organizational clarity, § 26.117(d) retains and combines former Section 2.4(g)(23) and 2.4(g)(23)(i) in Appendix A to Part 26. These provisions required the donor to certify that the specimen was collected from him or her. However, the final rule deletes former Section 2.4(g)(23)(ii), which required the donor to have an opportunity to list on the custody-and-control form any medications he or she had taken within the past 30 days for the reasons discussed with respect to § 26.89(b)(3).

The final rule deletes former Section 2.4(g)(24) in Appendix A to Part 26, which required the collector to enter into the permanent record book all information identifying the specimen. The agency eliminated this requirement because the final rule no longer requires collection sites to maintain a permanent record book, consistent with the elimination of the requirement to maintain a permanent record book in the HHS Guidelines. Collection sites are permitted to use other means of tracking specimen identity, including, but not limited to, bar coding.

Section 26.117(e) amends former Section 2.4(g)(26) in Appendix A to Part 26. The former provision required the collector to complete the chain-of-custody forms for both the aliquot and the split sample and certify proper completion of the collection. The final rule eliminates reference to the aliquot and split sample in the former section to clarify the intent of this requirement, which is that the collector must complete the appropriate chain-of-custody forms for all of the sealed specimen and aliquot containers, not simply those resulting from a split specimen procedure. For example, if an FFD program follows split specimen procedures and conducts initial testing at a licensee testing facility, the donor's urine specimen may be divided into Bottle A, Bottle B, and another container that would be used for tests at the licensee testing facility. This section retains the former requirement for the collector to certify proper completion of the collection.

Section 26.117(f) amends former Section 2.4(g)(27) in Appendix A to Part 26. The former provision stated that the specimens and chain-of-custody forms

''are now ready for transfer'' and must be appropriately safeguarded if they are not immediately prepared for shipment. The final rule replaces the first sentence of the former provision, which stated that the specimens and forms are ready for transfer, with a requirement for the collector to package the specimens and forms for transfer to the HHS-certified laboratory or licensee testing facility. This change improves the clarity in the rule's language because it is necessary for the collector to package the specimens and chain-of-custody forms for transfer before they are ready to be transferred. This section retains the second sentence of the former provision.

Section 26.117(g) retains former Section 2.4(g)(28) in Appendix A to Part 26. This provision requires the collector to maintain control of the specimens and custody documents and ensure they are secure, if he or she must leave the workstation or collection site for any reason. The final rule makes minor editorial changes to some of the terminology used in the former section for consistency with the terminology used throughout the final rule, as discussed with respect to § 26.5 [Definitions], but retains the intended meaning of the former requirements.

Section 26.117(h) retains the requirements in former Section 2.4(c)(2) in Appendix A to Part 26 related to maintaining specimen security until the specimens are sent from the collection site to the licensee testing facility or the HHS-certified laboratory for testing. For organizational clarity, the NRC moved the former paragraph to this section of the final rule because requirements for maintaining specimen security apply at this point in the specimen collection process. Likewise, the agency has moved the portion of the former section that applies to situations in which it is impractical to maintain continuous physical security of a collection site to § 26.87(f)(5) because § 26.87(f) addresses those circumstances.

Section 26.117(i) updates the specimen packaging requirements in former Section 2.7(i) in Appendix A to Part 26 by replacing the former section with the related provision from the HHS Guidelines. For organizational clarity, the rule moves § 26.117(j) to the first sentence of the former section, which directs collection site personnel to arrange to transfer the specimens to the licensee testing facility or HHS-certified laboratory. Section 26.117(j) addresses transfer and storage requirements, while § 26.117(i) addresses packaging requirements. This section also eliminates the initial phrases in the second sentence of the former provision, which listed the conditions under which specimens were transferred offsite (e.g., shipping specimens that test as ''presumptive positive'' on initial testing at the licensee testing facility, special processing of suspect specimens), because they are redundant with other portions of the final rule. For organizational clarity, the rule moves new requirements related to transferring specimens from a licensee testing facility to an HHS-certified laboratory for further testing to § 26.129(g) in Subpart F. The final rule also eliminates the third sentence of the former section, which required the collector to sign and date the tape used to seal the container. The NRC eliminated this requirement because licensees and other entities now transfer specimens using courier services who offer other means of tracking the sender and the date that a container of specimens is shipped. Program experience has shown these other means to be equally effective. This new section retains the intended meaning of the former requirements for the collector to place the specimens in a second container that minimizes the possibility of damage during shipment and seal them so that tampering will be detected. At the request of stakeholders during the public meetings discussed in the preamble to the proposed rule, the final rule adds shipping bags to the former set of examples of acceptable shipping containers that protect the specimens from damage. Also at the request of stakeholders, the final rule deletes the last sentence of the former section, which required the collector to ensure that chain-of-custody documents were attached to the container used to ship the specimens to the licensee testing facility or laboratory. The stakeholders requested this change because their practice is to seal a specimen's custody-and-control documentation inside the shipping container to ensure that it cannot be altered. The NRC endorses this practice as providing greater protection for donors and, therefore, adopts this change.

Section 26.117(j) amends and combines the first sentence of former Section 2.4(i) in Appendix A to Part 26 with the requirements applicable to the short-term storage of specimens at collection sites in former Section 2.7(c) in Appendix A to Part 26. The NRC moved to this section the first sentence of former Section 2.4(i) in Appendix A to Part 26 for the reasons discussed with respect to § 26.117(i). Under this section, as a result of advances in testing technologies, the rule no longer requires short-term refrigerated storage of specimens within 6 hours of collection. However, the final rule continues to require licensees and other entities to protect specimens from any conditions that could cause specimen degradation. Collection site personnel are required to refrigerate specimens that are not transferred or shipped to the licensee testing facility or the HHS-certified laboratory within 24 hours of collection. The final rule also requires that any specimens that may have been substituted or adulterated must be refrigerated as soon as they are collected because some adulterants may interfere with drug testing results unless the specimen is refrigerated. The final rule establishes a time limit of 2 business days for receipt of specimens at the licensee testing facility or HHS-certified laboratory after shipment from the collection site to further protect against potential specimen degradation.

Section 26.117(k) amends the portions of former Section 2.4(h) in Appendix A to Part 26 that required a specimen's custody-and-control form to identify every individual in the chain of custody. The final rule does not require couriers to meet the requirements in former Section 2.4(h), which stated that each time a specimen is handled or transferred, the date and purpose of the transfer must be documented on the chain-of-custody form and every individual in the chain of custody must be identified. Couriers are not required to meet these requirements because custody-and-control forms for individual specimens are packaged inside the shipping container, where they are inaccessible to couriers, so that it is impractical to expect them to sign the forms when handling the specimen shipping containers. This new paragraph codifies licensees' and other entities' practice of relying on courier services' normal package tracking systems to maintain accountability for specimen shipping containers, which is consistent with the HHS Guidelines and standard forensic practices. The final rule also eliminates the former requirement, contained in the last sentence of Section 2.4(h) in Appendix A to Part 26, to minimize the number of persons handling specimens because this requirement cannot be enforced.

Section 26.119 Determining ''Shy'' Bladder

The agency has adapted a new § 26.119 from the DOT Procedures at 49 CFR 40.193 [What happens when an employee does not provide a sufficient amount of urine for a drug test?] to specify procedures for determining whether a donor who does not provide a urine specimen of 30 mL within the 3 hours that is permitted for a specimen

collection is refusing to test or has a medical reason for being unable to provide the required 30 mL specimen. This new section responds to stakeholder requests during public meetings discussed in the preamble to the proposed rule. The stakeholders reported that some donors have had difficulty providing the minimum 60 mL of urine required in former Section 2.4(g)(11) for medical reasons, but the former rule did not establish procedures for handling such circumstances. As a result, some FFD programs have adopted the DOT ''shy bladder'' procedures, but stakeholders preferred that the final rule incorporate the requirements to (1) clarify that the NRC accepts the procedures, (2) inform donors of the procedures that they are required to follow if they have medical reasons for being unable to provide a sufficient quantity of urine for testing, (3) enhance consistency among Part 26 programs, and (4) enhance the consistency of Part 26 procedures with the procedures that collectors must follow when conducting tests under DOT requirements. The NRC expects that fewer donors will be subject to ''shy bladder'' problems under the final rule because § 26.109 reduces the minimum quantity of urine required from 60 mL in the former rule to 30 mL. However, because some donors' medical problems may also interfere with their ability to provide 30 mL of urine, the final rule incorporates the DOT procedures. These procedures are intended to protect the due process rights of individuals who are subject to Part 26. That is, this section establishes procedures for ensuring that there is a legitimate medical reason that a donor was or is unable to provide a urine specimen of the required quantity so that the licensee or other entity has a medical basis for not imposing sanctions on the individual. In addition, the MRO is authorized to devise alternative methods of drug testing, if it appears that the donor's medical problem prevents him or her from being able to provide sufficient urine for drug testing in future tests.

The agency has added § 26.119(a) to require that a licensed physician, who has appropriate expertise in the medical issues raised by the donor's failure to provide a sufficient specimen, must evaluate a donor who was unable to provide a urine specimen of at least 30 mL. The rule permits the MRO to perform the evaluation if the MRO possesses the appropriate expertise. If not, the rule requires the MRO to review the qualifications of the physician and agree to the selection of that physician. These requirements for the physician who performs the evaluation to be qualified in the relevant medical issues ensure that the results of the evaluation are valid.

This section also requires that the evaluation must be completed within 5 calendar days of the unsuccessful collection. The agency has established the time limit of 5 calendar days as a trade off between the need to provide the donor with sufficient time to locate a qualified physician, obtain an appointment, and for the physician to complete the evaluation (i.e, the donor's right to due process), and the public's interest in a rapid determination of whether the donor had attempted to subvert the testing process by refusing to provide a sufficient specimen. DOT's experience indicates that 5 days is sufficient to complete the evaluation.

The final rule adds § 26.119(b) to specify the information that the MRO must provide to the physician who is selected to perform the evaluation if the MRO does not perform it. Sections 26.119(b)(1) and (b)(2) require the MRO to inform the physician that the donor was required to take a drug test under Part 26 but was unable to provide a sufficient quantity of urine for testing and explain the potential consequences to the donor for a refusal to test. These requirements ensure that the evaluating physician understands the context in which he or she is being asked to perform the evaluation. Section 26.119(b)(3) also requires the MRO to inform the physician that he or she must agree to follow the procedures specified in § 26.119(c) through (f) if he or she performs the evaluation. This requirement ensures that the physician understands and consents to follow the procedures specified in this section.

The NRC added § 26.119(c) to describe the conclusions that the physician must provide to the MRO following the evaluation. Under § 26.119(c)(1), the physician may determine that a medical condition has, or with a high degree of probability could have, precluded the donor from providing the required quantity of urine. Or, under § 26.119(c)(2), the physician may determine that there is an inadequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the donor from providing a sufficient quantity of urine. The final rule limits the physician's conclusions to one of these two alternatives to ensure that the results of the evaluation are relevant to and useful for determining whether sanctions must be imposed on the donor for a refusal to test.

The agency added § 26.119(d) to define the physical and psychological conditions that constitute a medical condition that could have precluded the donor from providing a 30-mL specimen as well as to provide examples of conditions that do not constitute a legitimate medical condition. Legitimate medical conditions include an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder that precluded the donor from providing a 30-mL specimen. Unsupported assertions of ''situational anxiety'' or dehydration are examples of conditions that could not be considered legitimate medical conditions. The final rule adds this section to provide necessary guidance to the evaluating physician.

The final rule adds § 26.119(e) to require the evaluating physician to provide a written statement of his or her findings and conclusion from the evaluation. By implication, if the MRO performs the evaluation, the MRO provides this written statement. The written statement is necessary to communicate the results of the evaluation and create a record of it, should any question arise later with respect to the determination.

This section also requires that the physician must provide only the information that is necessary to support the physician's conclusion. The NRC has added this requirement to protect the donor's privacy by ensuring that the physician documents only the medical information that is necessary to support the determination.

The NRC added § 26.119(f) to require the physician to inform the MRO, in the written statement, whether any medical condition that may be identified also precludes the donor from providing specimens of 30 mL or more in future collections. This information is necessary for the MRO to determine whether to implement alternative methods of drug testing for the donor, as required under § 26.119(g)(3).

The agency added § 26.119(g) to prescribe the actions that the MRO must take based on the results of the evaluation, as follows:

Section 26.119(g)(1) requires the MRO to determine that the donor did not violate the FFD policy, if the physician concluded that a medical condition could account for the insufficient specimen and the MRO concurred with that conclusion. In this instance, the licensee or other entity does not impose sanctions on the donor because the donor had not violated the FFD policy by refusing to test.

Section 26.119(g)(2) requires the MRO to determine that the donor had refused to be tested by failing to provide a sufficient specimen, if the physician concluded that a medical condition could not account for the insufficient specimen. In this instance, the licensee or other entity imposes the sanction of a permanent denial of authorization for an attempt to subvert the testing process, as required under § 26.75(b).

Section 26.119(g)(3) requires the MRO to devise an alternative method of collecting specimens for drug testing, if the donor's medical condition, over the long-term, consistently prevents the donor from providing urine specimens of 30 mL or more. For example, the provision permits the MRO to direct the collection and testing of alternate specimens, including, but not limited to, hair, or other bodily fluids, if, in the MRO's professional judgment, the collection and analysis of these alternate specimens is scientifically defensible and forensically sound. The section grants flexibility to the MRO in exercising his or her professional judgment in determining an alternative method of conducting drug testing, rather than establishing detailed requirements that may not appropriately address the range of possible medical conditions that could arise.

Subpart F—Licensee Testing Facilities

In this subpart, the final rule replaces two terms used in the proposed rule in response to public comments. These language changes affect numerous sections within Subpart F. First, one public comment addressed a proposed provision in § 26.137(b) [Performance testing and quality control requirements for validity screening tests] that permitted licensee testing facilities to use validity screening tests approved by the U.S. Food and Drug Administration (FDA). The NRC has eliminated both the requirement and the use of the term ''device'' with respect to validity screening testing because the FDA is not responsible for approving validity screening devices. The final rule has replaced the term ''device'' in ''validity screening device'' with the term ''test'' throughout Subpart F. Second, several public comments addressed the use of the term ''non-negative'' to refer to drug and validity test results and requested that the NRC eliminate the term from the final rule and instead use a more familiar term such as ''positive'' test result. Throughout Subpart F, the NRC has replaced the term ''non-negative'' with a new term to address validity screening and initial validity testing results from a licensee testing facility that indicate that a specimen may be adulterated, substituted, dilute, or invalid. The new term used for these validity testing results is ''questionable validity.'' The NRC has added a definition for ''questionable validity'' to § 26.5 [Definitions]. Adding the term ''questionable validity'' addresses the commenters' concern and improves the clarity of the final rule to meet Goal 6 of this rulemaking. The NRC retained the use of ''positive'' to refer to results from initial testing for drugs that indicate the presence of a prohibited drug in the specimen.

Section 26.121 Purpose

The NRC added § 26.121 to provide an overview of the contents of the proposed subpart, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.123 Testing Facility Capabilities

Section 26.123 amends the second sentence of former Section 2.7(l)(2) in Appendix A to Part 26 as it related to the capabilities of licensee testing facilities. The final rule retains the former requirement for licensee testing facilities to be capable of performing initial tests for each drug and drug metabolite for which testing is conducted by the FFD program and adds a requirement for licensee testing facilities to have the capability to perform either validity screening tests, initial validity tests, or both. The agency moved the first sentence of former Section 2.7(l)(2), which established requirements for the capabilities of HHS-certified laboratories, to Subpart G [Laboratories Certified by the Department of Health and Human Services]. The NRC deleted the last sentence of the former paragraph, which permitted the testing of breath specimens for alcohol at the collection site, because the final rule addresses alcohol testing in Subpart E [Collecting Specimens for Testing]. The NRC made these changes to the former provision to meet Goal 6 of this rulemaking to improve organizational clarity in the final rule.

Section 26.125 Licensee Testing Facility Personnel

Section 26.125 amends former Section 2.6 in Appendix A to Part 26 [Licensee testing facility personnel], as follows:

Section 26.125(a) retains former Section 2.6(a) in Appendix A to Part 26. This provision requires each licensee testing facility to have one or more individuals who are responsible for the day-to-day operations of the facility and establishes requirements for those individuals' qualifications. The final rule makes minor changes in the former provision to improve consistency with amended language in the related portion of the HHS Guidelines.

Section 26.125(b) amends former Section 2.6(b) in Appendix A to Part 26. This provision required laboratory technicians and nontechnical staff to have the necessary training and skills for the tasks assigned to them. The final rule retains the former provision and adds another. The final rule requires laboratory technicians who perform urine specimen testing to demonstrate proficiency in operating the instruments and tests used at the licensee testing facility. The NRC added this proficiency requirement to ensure that technicians are capable of correctly using the instruments and tests that the licensee testing facility has selected for validity and drug testing. This change is necessary for several reasons. First, the final rule adds new requirements for licensee testing facilities to conduct validity testing, and the instruments and tests that the technicians will use are likely to differ from those previously used at licensee testing facilities. Therefore, additional training and proficiency testing is required to ensure that validity testing is conducted properly. Second, the final rule permits licensees and other entities to rely on drug test results from testing that was performed by another Part 26 program to a greater extent than the former rule. Therefore, it is necessary to ensure that all drug testing performed under Part 26, including tests performed at licensee testing facilities, meets minimum standards. The requirement for technicians to demonstrate proficiency, then, contributes to meeting this goal. Third, the experience of other Federal agencies has shown that requirements for technicians to demonstrate proficiency assist in any litigation that may occur with respect to urine test results.

With respect to the proposed rule and in response to a public comment that proficiency documentation requirements were missing from the proposed rule in several locations, the final rule adds a requirement for licensee testing facilities to document the proficiency of its technicians. Although proposed § 26.125(c) required licensee testing facility personnel files to include documentation of training and experience and the results of tests that establish employee competency for the position he or she holds, the final rule adds a requirement for documentation of proficiency in § 26.125(b) to further clarify that this documentation is required and

specifically applies to laboratory technicians who perform urine drug testing. The NRC made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.125(c) amends former Section 2.6(c) in Appendix A to Part 26. The provision establishes recordkeeping requirements for the personnel files of licensee testing facility staff. The final rule, with respect to the proposed rule, further clarifies the intent of the licensee testing facility personnel competency requirements by specifying that personnel must be proficient in conducting testing using the most recent instructions from instrument and test manufacturers. In addition, in response to comments received on the elimination of the former provision in Section 2.5(f) in Appendix A to Part 26 that required licensees and other entities to maintain color blindness testing records in files for licensee testing facility personnel, the final rule reinstates the requirement. The final rule retains the color blindness testing recordkeeping requirement because some validity screening and initial validity tests require laboratory testing facility personnel to visually evaluate the color of the assay to determine the test result. Retaining records of color blindness testing is necessary to demonstrate licensee testing facility personnel competency.

Section 26.127 Procedures

Section 26.127 combines, reorganizes, and amends requirements for procedures that were interspersed throughout Appendix A to Part 26, including requirements in former Sections 2.2 [General administration of testing] and 2.7 [Laboratory and testing facility analysis procedures]. These changes improve clarity in the organization of the final rule by grouping procedural requirements for licensee testing facilities in one section, consistent with Goal 6 of this rulemaking.

Section 26.127(a) makes minor editorial changes to the first sentence of former Section 2.2 in Appendix A to Part 26. The former provision required licensee testing facilities and HHS-certified laboratories to have detailed procedures for conducting testing. The final rule deletes the reference to blood samples in the former provision because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a). For organizational clarity, the final rule moves the reference to HHS-certified laboratories to § 26.157(a) in Subpart G. The final rule also deletes the former reference to procedures for specimen collections in this paragraph because procedural requirements for specimen collections are addressed in Subpart E.

Section 26.127(b) amends and combines portions of the requirements in the first sentence of former Section 2.4(d) and 2.7(a)(2) in Appendix A to Part 26 related to the content and implementation of specimen chain-of-custody procedures. The final rule retains the portions of the former provisions that required licensee testing facilities to develop, implement, and maintain written chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS-certified laboratory, and continuing until final disposition of the specimens. For organizational clarity, the NRC moved the former requirements related to HHS-certified laboratories to § 26.157(b) in Subpart G. The final rule also removes references to custody-and-control procedures for blood specimens because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a).

Section 26.127(c) retains the portions of former Section 2.7(o)(1) in Appendix A to Part 26 that addressed the required content of procedures for licensee testing facilities and amends the former requirements. The final rule retains the portions of the former provision that required licensee testing facilities to develop and maintain procedures to specify all of the elements of the testing process, including, but not limited to, the principles of each test and the preparation of reagents, standards, and controls. The final rule presents the required topics of the procedures in a list format in § 26.127(c)(1)–(c)(12) to clarify that each topic stands on its own and to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

Section 26.127(c) also amends former Section 2.7(o)(1) in Appendix A to Part 26 in several ways. First, the final rule eliminates the former requirement for the procedures to be maintained in a laboratory manual as unnecessarily restrictive. The final rule permits licensee testing facilities to use other means to maintain their procedures. Second, the agency has added a requirement for the development, implementation, and maintenance of written standard operating procedures for all laboratory instruments and validity screening tests, consistent with the addition of requirements to conduct validity testing throughout the final rule. Third, the final rule moves two portions of the former provision to other subparts of the rule that address related topics to improve clarity in the organization and language of the final rule, as follows: The agency relocated the last two sentences of former Section 2.7(o)(1) in Appendix A to Part 26, which addressed requirements for retaining copies of superceded procedures, to § 26.715(a) of Subpart N [Recordkeeping and Reporting Requirements], and the final rule moves procedural requirements for HHS-certified laboratories to § 26.157(b) in Subpart G.

Section 26.127(d) amends former Section 2.7(o)(3)(iii) in Appendix A to Part 26. This provision required procedures for the setup and normal operation of testing instruments, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. The final rule extends the former requirements to non-instrumented tests (such as some validity screening tests, if the licensee testing facility uses these tests), consistent with the addition of requirements to conduct validity testing throughout the final rule. The final rule also makes three organizational changes to the former provision. The final rule presents the required topics of the procedures in a list format in § 26.127(d)(1)–(d)(3) to clarify that each topic stands on its own. The NRC relocated the former requirement to maintain records of preventative maintenance to § 26.715(b)(10) in Subpart N. And, the NRC has moved the former requirements that applied to HHS-certified laboratories to § 26.157(d) in Subpart G. These changes improve clarity in the organization of the rule, consistent with Goal 6 of this rulemaking.

Section 26.127(e) reorganizes and amends former Section 2.7(o)(4) in Appendix A to Part 26. The former provision required corrective actions to be documented if systems are out of acceptable limits or errors are detected. The final rule extends the former requirement to validity screening tests if the licensee testing facility uses these tests, consistent with the addition of requirements to conduct validity testing throughout the final rule. The final rule, with respect to the proposed rule, also adds the term ''instrumented'' to clarify that a licensee testing facility must develop and implement procedures for remedial actions on testing facility equipment, instruments, and tests. The NRC has moved the requirements in the former paragraph that applied to HHS-

certified laboratories to § 26.157(e) in Subpart G for organizational clarity.

Section 26.129 Assuring Specimen Security, Chain of Custody, and Preservation

Section 26.129 has been added to group together in one section the requirements of the final rule that apply to licensee testing facilities with respect to the safeguarding of specimen identity, integrity, and security. The NRC made this organizational change because requirements that addressed these topics were dispersed throughout the former rule. Grouping them together in a single section makes them easier to locate within the final rule and meets Goal 6 of this rulemaking to improve clarity in the language and organization of the rule.

Section 26.129(a) retains the first four sentences of former Section 2.7(a)(1) in Appendix A to Part 26. The provision requires licensee testing facilities to be secure and accessible only to authorized personnel. The final rule moves the requirements in the former provision that applied to HHS-certified laboratories to § 26.159(a). The final rule moves the last sentence of the former paragraph, which established recordkeeping requirements, to § 26.715(b)(13) in Subpart N. The NRC made these changes for organizational clarity.

Section 26.129(b) amends former Section 2.7(b)(1) in Appendix A to Part 26. This provision established requirements for receiving specimens at the licensee testing facility and assuring their integrity and identity. For organizational clarity, the final rule moves the former requirements related to HHS-certified laboratories to § 26.159(b) in Subpart G. The final rule, with respect to the proposed rule, adds § 26.129(b)(1) and (b)(2) to improve the clarity of the organization of the rule. The NRC has also added several requirements to the former provision, as follows:

In § 26.129(b), the final rule retains the requirement for licensee testing facility personnel to inspect specimens received for testing to determine whether there is any evidence of tampering with the specimens and to ensure that the custody-and-control documents are correct. With respect to the proposed rule, the final rule adds a requirement for licensee testing facility personnel to attempt to resolve any discrepancies in the information on specimen bottles or on the accompanying custody-and-control forms to ensure the identity and integrity of specimens and prevent specimens from being unnecessarily rejected for testing by the HHS-certified laboratory (if the specimen must be subject to additional testing) when flaws can be corrected. For example, if the collector's signature is missing on the custody-and-control form, licensee testing facility personnel will work with collection site personnel to attempt to identify the collector and obtain a memorandum for the record from the collector if possible. This requirement reduces the potential burden on donors who may otherwise be required to submit additional specimens to replace those for which the chain of custody could not be confirmed. The final rule, with respect to the proposed rule, adds a provision that specifies the procedures to be followed by licensee testing facility personnel to correct custody-and-control form errors that are identified after the specimen collection process has been completed and the donor has departed from the collection site. This addition is based on a comment received on the proposed rule requesting the addition of these procedures. The requirements also improve the efficiency of FFD programs by avoiding the need to conduct additional specimen collections when discrepancies can be corrected. The additional provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, as well as Goal 1 of this rulemaking, to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.129(b)(1) adds requirements for licensee testing facility personnel to report to management any indications of specimen tampering within 8 hours of the discovery. This provision also requires licensee or other entity management personnel to initiate an investigation to determine whether tampering has occurred. Section 26.129(b)(i) requires management to take corrective actions if tampering is confirmed. The final rule adds these requirements because some licensees did not investigate or take corrective actions in response to indications of tampering with specimens under the former rule. The appropriate corrective actions that management personnel would take depend on the nature of the tampering identified as a result of the investigation. For example, if the investigation indicated that the tampering was an attempt to subvert the testing process and the persons involved were identified, management personnel would impose the sanctions in § 26.75(b) for a subversion attempt. This provision also requires management personnel to correct any systematic weaknesses in specimen custody-and-control procedures that may be identified in the investigation, such as inadequate safeguarding of specimen shipping containers.

Section 26.129(b)(1)(ii) adds a prohibition on testing of any specimen if the licensee or other entity has reason to believe that the specimen was subject to tampering or altered in a manner as to affect specimen identity and integrity. In this circumstance, the MRO will cancel testing of the specimen or any test results for the specimen, and require the licensee or other entity to retest the donor who submitted the original specimen. The final rule, with respect to the proposed rule, adds an exception for split specimen collections in response to a public comment that requested additional clarification of the proposed rule's requirements for cancelling tests. For a split specimen collection, if the tamper-evident seal remains intact on either Bottle A or Bottle B of the specimen and the bottle contains at least 15 mL of urine, the final rule requires the licensee testing facility to forward the intact specimen to the HHS-certified laboratory and prohibits any testing at the licensee testing facility. This new provision serves to eliminate unnecessary additional specimen collections, thereby meeting Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC added § 26.129(b)(2) in the final rule, with respect to the proposed rule, to include specific instances that would require the cancellation of the testing of a donor's urine specimen. This change has been made in response to a public comment that requested the NRC to add information in the final rule to describe the actions that must be taken if the integrity of a specimen is in question. Adding this information to the final rule meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, as well as Goal 1 to improve the consistency of NRC requirements with those of other Federal agencies. The provisions are modeled on similar requirements in the DOT's drug testing program.

Although the NRC is not aware of any instances when these circumstances have arisen in Part 26 programs, the experience of other Federal agencies indicates that specimen tampering is possible. Therefore, the requirements in § 26.129(b) are necessary to ensure that donors are not subject to sanctions for positive, adulterated, substituted, or invalid test results from a specimen that

may not have been theirs. These changes meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and ensure that the individuals are afforded accurate and consistent testing. These requirements are also consistent with the requirements of other Federal agencies.

Section 26.129(c) amends former Section 2.7(b)(2) in Appendix A to Part 26. This provision established requirements for chain-of-custody procedures for specimens and aliquots at licensee testing facilities. The final rule moves the requirements in the former paragraph that were related to HHS-certified laboratories to Subpart G to improve organizational clarity.

The section incorporates two additional changes to the former provision at the request of stakeholders at the public meetings discussed in Section I.D. The stakeholders requested that the NRC permit licensee testing facilities to use methods other than a custody-and-control form to maintain the chain of custody for aliquots of a specimen that are tested at the licensee testing facility. The NRC incorporated this change because methods other than a custody-and-control form, such as the use of bar coding, have been shown to be equally effective at tracking the chain of custody for an aliquot at licensee testing facilities. Adding this flexibility is consistent with Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

The stakeholders also requested that the section specify the conditions under which specimens and aliquots may be discarded because the former rule did not address discarding of negative specimens. Therefore, the final rule permits licensee testing facilities to discard specimens and aliquots as soon as practical after validity screening or initial validity tests have demonstrated that the specimen is valid and initial test results for drugs and drug metabolites are negative. The clarification codifies licensee practices. This permission has no impact on donors' rights under the final rule because donors are not at risk of management actions or sanctions as a result of negative test results and, therefore, do not need the licensee testing facility to retain the specimen for additional testing for review or litigation purposes. The change has been made to meet Goal 6 of this rulemaking to improve clarity in the language of the final rule.

Section 26.129(d) updates former Section 2.7(a)(2) in Appendix A to Part 26. This provision required licensee testing facility personnel to maintain and document the chain of custody for specimens and aliquots. The final rule incorporates the simpler language of the related provision from the HHS Guidelines while retaining the intent of the former provision. The final rule relocates the requirements in the former section that were related to HHS-certified laboratories to § 26.159(d) and (e) in Subpart G to improve organizational clarity.

Section 26.129(e) amends the first sentence of former Section 2.7(d) in Appendix A to Part 26 [Specimen processing]. That sentence required specimens that test as ''presumptive positive'' at the licensee testing facility to be shipped to the HHS-certified laboratory for further testing. The final rule replaces the term ''presumptive positive'' with terms to describe the specific test results, as appropriate (i.e., ''positive,'' ''questionable validity'') in order to address validity testing results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). For organizational clarity, the agency has moved the requirements in former Section 2.7(d) in Appendix A to Part 26 that related to quality control procedures for testing at licensee testing facilities and HHS-certified laboratories to § 26.137 [Quality assurance and quality control] and § 26.167 [Quality assurance and quality control] of the final rule, respectively.

Section 26.129(f) clarifies and revises former Section 2.7(c) in Appendix A to Part 26 [Short term refrigerated storage], as it related to refrigerating urine specimens to protect them from degradation. For organizational clarity, the final rule moves the former requirements that applied to HHS-certified laboratories to § 26.159(h) in Subpart G. The final rule restates portions of the former provision and adds a performance standard regarding ''appropriate and prudent actions'' to minimize specimen degradation. For the reasons discussed with respect to § 26.117(j), the final rule no longer requires all specimens to be refrigerated within 6 hours after collection, but adds a requirement that any specimen that has not been tested within 24 hours of receipt at the licensee testing facility must be refrigerated. The final rule continues to require the licensee or other entity to refrigerate any specimen (and the associated Bottle B for that specimen if the FFD program follows split specimen procedures) that yields a positive test result from initial drug testing at the licensee testing facility. The final rule also adds a requirement for refrigerating any specimen (and the associated Bottle B specimen if a split specimen collection is performed) that yields a questionable validity test result from validity screening or initial validity testing. Refrigerating these specimens is necessary because some adulterants have been shown to interfere with drug test results more rapidly if the specimen remains at room temperature.

The final rule also updates the terminology used in the former paragraph to be consistent with the new terminology adopted throughout the final rule for referring to split specimens. Therefore, in the final rule, the licensee testing facility continues to be responsible for protecting from degradation the primary specimen (Bottle A) and the specimen in Bottle B of a split specimen if the FFD program follows split specimen procedures. The rule also requires the licensee testing facility to refrigerate any specimen that yields a positive test result or a questionable validity test result. This includes the specimen in Bottle B associated with any aliquot that yields a positive or questionable validity test result at the licensee testing facility. The NRC made these changes in the terminology of the paragraph to improve clarity in the language of the final rule.

The final rule separates former Section 2.4(i) in Appendix A to Part 26 [Transportation to laboratory or testing facility] into two paragraphs, § 26.129(g) and (h), for organizational clarity and amends the former provision for the reasons previously discussed with respect to § 26.117(i) and (k). Section 26.129(g) and (h), which repeats the requirements for packaging and shipping specimens contained in § 26.117(i) and (k) of Subpart E, applies these requirements to packaging and shipping specimens from licensee testing facilities to HHS-certified laboratories. The basis for these requirements is discussed with respect to § 26.117(i) and (k).

Section 26.131 Cutoff Levels for Validity Screening and Initial Validity Tests

The NRC has added § 26.131 to establish cutoff levels for validity screening and initial validity tests that are conducted at licensee testing facilities. The procedures, substances, and cutoff levels for initial validity testing in this section incorporate related requirements from the HHS Guidelines (69 FR 19643; April 13, 2004). The validity screening test requirements have been adapted, in large part, from the HHS proposed

revision to the Guidelines that was also published in the **Federal Register** on April 13, 2004 (69 FR 19673).

In contrast to the requirements for initial validity testing in the HHS Guidelines, the final rule does not permit licensee testing facilities to evaluate the specific gravity of any specimens. To determine if a specimen is dilute or substituted, specific gravity testing is required. If the creatinine concentration of a specimen is less than 20 mg/dL, the final rule requires the licensee testing facility to forward the specimen to the HHS-certified laboratory to complete the testing, where the specimen's specific gravity will be measured. The final rule differs from the HHS Guidelines in this provision because the costs of the instruments (i.e., refractometers) that are required in the Guidelines for measuring specific gravity are high. Some licensee testing facilities are currently measuring the specific gravity of specimens. However, the cutoff levels established in the Guidelines require more sensitive measurement and licensee testing facilities would be required to purchase new equipment in order to test at the new HHS specific gravity cutoff levels. Therefore, the final rule requires licensee testing facilities to transfer all specimens with creatinine concentrations less than 20 mg/dL to an HHS-certified laboratory to complete the initial testing process and does not include cutoff levels for specific gravity or quality control requirements for measuring specific gravity.

Section 26.131(a) has been added to require licensee testing facilities to perform either validity screening tests, initial validity tests, or both. Consistent with related requirements for further testing of a specimen at an HHS-certified laboratory when initial drug testing at the licensee testing facility yields a positive test result, the final rule also requires licensee testing facilities to forward specimens that yield a questionable validity screening or initial validity test result to an HHS-certified laboratory for further testing. Further testing at an HHS-certified laboratory is necessary because licensee testing facilities do not have the sophisticated testing instruments required for conducting confirmatory testing that are required under the HHS Guidelines. In addition, further testing at an HHS-certified laboratory provides an independent check on test results from licensee testing facilities that is necessary to ensure that donors are afforded accurate and consistent testing under this part, consistent with Goal 7 of this rulemaking.

As discussed in Section IV.C, the primary distinction between validity screening tests and initial validity tests is that validity screening tests may be performed using non-instrumented devices, such as dipsticks, whereas initial validity tests generally rely on more complex instrumented testing technologies. The final rule permits licensee testing facilities to perform validity screening tests before performing initial validity tests but does not require them to do so because validity screening tests are unnecessary if the licensee testing facility performs initial validity testing. Licensees and other entities may choose to conduct validity screening tests, followed by initial validity testing of any specimens that are identified to be of questionable validity as a result of validity screening, potentially to reduce the number of donor specimens that must be forwarded to the HHS-certified laboratory. In addition, the rule permits licensee testing facilities to choose whether to conduct validity screening tests or initial validity testing for each type of validity testing that is required under the rule. For example, a licensee or other entity may choose to use dipsticks (a validity screening test) to evaluate a specimen's creatinine concentration and only a pH meter (a method for conducting initial validity testing) without first performing a validity screening test for pH to evaluate the specimen's pH. The NRC is permitting flexibility in the means licensee testing facilities use to conduct specimen validity testing to meet Goal 3 of this rulemaking to enhance the efficiency and effectiveness of FFD programs.

Section 26.131(b) requires licensee testing facilities to test each urine specimen for creatinine concentration, pH, and the presence of one or more oxidizing adulterants, such as nitrite or bleach. Abnormal creatinine concentrations, abnormal pH values, or the possible presence of an oxidizing adulterant indicate that a donor may have altered the specimen (e.g., adulterated the specimen or substituted another substance in place of the donor's urine) in an attempt to subvert the testing process. The final rule permits licensees and other entities to choose the oxidizing adulterant(s) for which testing will be conducted. The requirements in this paragraph are consistent with the related requirements in the HHS Guidelines.

Because validity testing is complex and the methods for testing are relatively new, the second sentence of § 26.131(b) prohibits an FFD program from establishing more stringent cutoff levels for validity screening and initial validity testing than the cutoff levels established in this provision. This prohibition is necessary to decrease the risk of obtaining false adulterated, substituted, or invalid test results and ensures that donors are not subject to sanctions on the basis of inaccurate test results.

Section 26.131(b)(1)–(b)(8) specifies the criteria for determining whether the licensee testing facility must forward a specimen to an HHS-certified laboratory for further validity testing. These criteria are incorporated from the HHS Guidelines. With respect to the proposed rule, the agency modified the requirements in the final rule in response to public comments received on the proposed specimen pH and nitrite levels. Specifically, the commenters identified that the proposed rule did not include pH and nitrite levels that would permit the licensee testing facility to detect a specimen that meets the criteria for an invalid test result in the HHS Guidelines. Therefore, § 26.131(b)(2) in the final rule establishes a pH level of less than 4.5, rather than a pH level of less than 3.0 in the proposed rule, as one criterion for determining that a specimen requires additional validity testing. The NRC also revised the nitrite concentration from equal to or greater than 500 micrograms (mcg) per mL in proposed § 26.131(b)(3) to equal to or greater than 200 mcg/mL in the final rule. These changes to the pH and nitrite criteria in the final rule are consistent with the current HHS Guidelines and meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. By ensuring detection of specimens that may be invalid, these changes also meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.133 Cutoff Levels for Drugs and Drug Metabolites

Section 26.133 replaces former Section 2.7(e)(1) in Appendix A to Part 26. That section established cutoff levels for initial testing for drugs and drug metabolites. Section 26.133 replaces and amends some cutoff levels for initial tests for drugs and drug metabolites in former Section 2.7(e)(1) in Appendix A to Part 26 to be consistent with the HHS cutoff levels for the same substances.

The NRC has decreased the initial test cutoff level for marijuana metabolites from 100 nanograms (ng) per milliliter (mL) to 50 ng/mL. Current immunoassay techniques can now reliably detect the presence of marijuana metabolites at

this cutoff level. As discussed in Section IV.B, this change strengthens the effectiveness of FFD programs by increasing the likelihood of detecting marijuana use.

The final rule increases the initial test cutoff level for opiate metabolites from 300 ng/mL in the former rule to 2,000 ng/mL. The change in the cutoff level for opiate metabolites substantially reduces the number of positive opiate test results that are reported to MROs by HHS-certified laboratories that MROs ultimately verify as negative.

The final rule retains the permission in the former rule for licensees and other entities to establish more stringent cutoff levels for initial drug tests, subject to the requirements specified in § 26.31(d)(3)(iii), for the reasons discussed with respect to that paragraph.

The final rule eliminates the former requirement for licensees and other entities to report drug test results for both the cutoff levels in the former rule and any more stringent cutoff levels they applied. The NRC in the former rule required FFD programs to report test results for the cutoff levels specified in this part, when the licensee was applying more stringent cutoff levels, because it provided means for the NRC to monitor licensees' implementation of the permission to use more stringent cutoff levels. The final rule eliminates this requirement because § 26.31(d)(3)(iii)(C) requires a qualified forensic toxicologist to certify the scientific and technical validity of the licensee's or other entity's testing process at any lower cutoff levels. Therefore, the reporting requirement is no longer needed to ensure licensee testing facility performance in this area. Eliminating this requirement meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.135 Split Specimens

The NRC has added § 26.135 to reorganize and amend the requirements contained in former Section 2.7(j) in Appendix A to Part 26 that related to licensee testing facility handling of split specimens. The requirements in this section apply only to FFD programs that follow split specimen collection procedures. The NRC has divided the former provision into separate paragraphs in this section to indicate that each requirement stands on its own. This change has been made to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the final rule.

Section 26.135(a) amends the second, third, and fourth sentences of former Section 2.7(j) in Appendix A to Part 26. The final rule revises the terminology used in these sentences (e.g., ''Bottle A'' rather than ''primary specimen,'' ''Bottle B'' rather than ''split specimen,'' ''positive or of questionable validity'' rather than ''presumptive positive'') to be consistent with terminology used in other parts of the regulation without amending the meaning of the sentences. The final rule deletes the requirement in the third sentence of former Section 2.7(j) to seal the split specimen prior to placing it in secure storage because Bottles A and B have already been sealed at the collection site, as required under § 26.113(b)(3). The final rule adds a requirement to forward the Bottle A specimen to an HHS-certified laboratory if the licensee testing facility obtains a questionable validity test result. This requirement is consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). With respect to the proposed rule, the final rule adds a requirement that Bottle B specimens must remain in secure storage under the requirements in § 26.159(i) if the licensee testing facility retains Bottle B specimens rather than sending the specimens to the HHS-certified laboratory with Bottle A specimens.

Section 26.135(b) amends the requirements in former Section 2.7(j) in Appendix A to Part 26 related to donor requests for testing of the specimen in Bottle B. The final rule adds adulterated or substituted validity test results as a basis for a donor request for testing the specimen in Bottle B consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). The final rule, with respect to the proposed rule, imposes a requirement on the MRO to ensure that Bottle B is forwarded to a second HHS-certified laboratory that did not test the specimen in Bottle A, at the request of the donor, and to follow the procedures specified in § 26.165(b). In addition, the NRC eliminated the procedures for donor requests for testing the specimen in Bottle B that were included in this provision in the proposed rule because they were incomplete and partially redundant with the related provision in § 26.165(b). The NRC made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The final rule eliminates the requirement in the fourth sentence of former Section 2.7(j) in Appendix A to Part 26 that required the licensee testing facility or HHS-certified laboratory to forward the split specimen to another HHS-certified laboratory for testing on the same day of the donor request. The final rule, with respect to the proposed rule, references the provisions in § 26.165(b) pertaining to the time period (1 business day) within which licensee testing facilities must forward a specimen to a second HHS-certified laboratory following the donor request. This change responds to stakeholder feedback provided during the public meetings discussed in Section IV.D. The stakeholders reported that implementing the former same-day requirement was often difficult for a number of reasons, including, for example, communication delays among donors, MROs, and FFD program personnel, particularly on weekends and holidays, and the time required to identify a second laboratory with the appropriate capability to test the split specimen, depending on the nature of the non-negative test result. The final rule alleviates some of these logistical difficulties (e.g., logistical problems associated with weekends and holidays) while continuing to provide the donor with timely test results. Therefore, the NRC made this change to meet Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.135(c) amends former Section 2.7(c) in Appendix A to Part 26 that applied to storing specimens at licensee testing facilities. The NRC has amended some of the terminology used in the former provision for consistency with the terminology changes made throughout the rule. For example, the provision replaces the term ''split specimen'' with the term ''Bottle B.'' In addition, the final rule imposes the requirements for long-term frozen storage of split specimens in former Section 2.7(h) in Appendix A to Part 26 on licensees and other entities who choose to retain Bottle B of a split specimen at the licensee testing facility rather than forwarding it with Bottle A to the HHS-certified laboratory when additional testing at the HHS-certified laboratory is required. The final rule requires licensees and other entities to ensure that Bottle B of any specimen that the MRO has confirmed to be positive, adulterated, substituted, or invalid is retained in long-term frozen storage for at least 1 year. The final rule, with respect to the proposed rule, includes a requirement that licensee testing facilities who retain Bottle B specimens must ensure that proper specimen storage conditions (i.e., frozen storage) are maintained during extended power outages. This change is based on comments received on the proposed

rule noting the oversight. The final rule is consistent with former Section 2.7(c) in Appendix A to Part 26, which required licensee testing facilities to have emergency power equipment available in case of a prolonged power failure. The final rule extends the former requirement to apply to Bottle B of any specimen that has yielded adulterated, substituted, or invalid validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). The final rule moves the portions of former Section 2.7(h) in Appendix A to Part 26 that applied to HHS-certified laboratories to § 26.159(i) in subpart G to improve the organizational clarity of the final rule.

Section 26.137 Quality Assurance and Quality Control

The NRC has added § 26.137 to amend former Section 2.8 in Appendix A to Part 26 [Quality assurance and quality control] . This section adds quality control requirements for performing validity screening tests, initial validity tests, and initial tests for drugs and drug metabolites at the licensee testing facility, for the reasons discussed with respect to each paragraph. The final rule incorporates the related requirements from the HHS Guidelines to meet, in part, Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. The NRC has relocated the portions of former Section 2.8 in Appendix A to Part 26 that established requirements for HHS-certified laboratories to § 26.167 in Subpart G of the final rule for organizational clarity. The agency has made many changes in this section with respect to the proposed rule in response to detailed technical comments the NRC received on the proposed rule. The performance testing and quality control requirements in the final rule are consistent, in large part, with those required for initial testing at the HHS-certified laboratories.

Section § 26.137(a) [Quality assurance program] amends former Section 2.8(a) in Appendix A to Part 26, which required licensee testing facilities and HHS-certified laboratories to have a quality assurance program for all aspects of the testing process. The NRC moved the former requirements related to HHS-certified laboratories to § 26.167(a) in Subpart G to improve organizational clarity. The final rule extends the former requirements for licensee testing facilities to have a quality assurance program and procedures for drug testing to validity testing at the licensee testing facility, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed § 26.31(d)(3)(i).

Section 26.137(b) [Performance testing and quality control requirements for validity screening tests] establishes new requirements for performance testing and quality control of validity screening testing at the licensee testing facility. This section permits licensee testing facilities to use validity screening tests to determine whether a specimen is valid or must be subject to further validity testing. However, any specific validity screening test that a licensee testing facility chooses to use (e.g., a validity screening test for creatinine concentration, a validity screening test for pH, a validity screening test for oxidizing adulterants) must meet the stringent performance testing requirements in this section. The requirements in this section are based on requirements that were proposed by HHS in a Notice of Proposed Revisions to the Mandatory Guidelines dated April 13, 2004 (69 FR 19673). However, in response to detailed public comments on the proposed rule and further technical analyses, the NRC has revised several of the proposed HHS requirements that were incorporated in this section in the proposed rule, as discussed with respect to each provision the NRC has changed.

Section 26.137(b)(1) permits licensee testing facilities to use validity screening tests to determine whether a specimen is valid or must be subject to further validity testing. However, under § 26.137(b)(1)(i) and (ii), the NRC requires licensee testing facilities to use only validity screening tests that either have been placed on the SAMHSA list of point-of-collection testing devices that are certified for use in the Federal Workplace Drug Testing Program as published in the **Federal Register**, or that meet the performance testing criteria set forth in § 26.137(b)(1)(ii) for the reasons discussed with respect to that provision. With respect to the proposed rule, § 26.137(b)(1) in the final rule includes a new provision to address an unintentional omission in the proposed rule. Specifically, the NRC has added a requirement that licensee testing facilities must use an HHS-certified laboratory that has the capabilities to confirm the presence of any adulterant for which the licensee testing facility conducts validity screening tests. The inclusion of this provision is necessary because, as proposed, a licensee testing facility could have used a validity screening test that identified an adulterant that the HHS-certified laboratory could not identify because the laboratory did not also test for the adulterant in their validity testing panel. If this was the case, a specimen with a questionable validity result from a licensee testing facility would be tested by the HHS-certified laboratory and the specimen would receive a negative or invalid validity test result, creating conflicting results. The final rule resolves this inconsistency.

In addition, the final rule eliminates the term, ''non-instrumented devices,'' that was used in proposed § 26.137(b)(1). By eliminating the specific reference to non-instrumented tests and by revising the definition of ''validity screening test'' in § 26.5, the NRC is permitting licensee testing facilities to use instrumented tests, in addition to non-instrumented tests, to perform validity screening testing. The NRC made this change in response to a public comment. The commenter suggested that the proposed requirement that limited licensee testing facilities to using only non-instrumented devices to perform validity screening tests was unduly restrictive. Specifically, the commenter stated that instrumented tests could successfully meet the performance testing requirements (e.g., pH testing) for some validity screening tests described in proposed § 26.137(b)(1). The inclusion of instrumented tests for validity screening testing meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

In § 26.137(b)(1)(i) of the final rule, the NRC permits licensee testing facilities to use validity screening tests that are identified, by lot number, on the SAMHSA list of point-of-collection tests approved for use in the Federal Workplace Drug Testing Program, as published in the **Federal Register**. The NRC is aware that SAMHSA has yet to publish a list of approved point-of-collection tests but added this permission so that licensee testing facilities may rely on that list when it is available. With respect to the proposed rule, the final rule has removed the requirement that validity screening tests must be cleared by the FDA in response to a public comment. The NRC eliminated the proposed requirement because, as the commenter pointed out, the FDA is not responsible for clearing specimen validity point-of-collection tests. The final rule also clarifies the proposed provision by adding the requirement that licensee testing facilities may only use validity screening tests from ''lots'' (i.e., batches or groups of tests that are manufactured

from the same original materials) that are identified on the SAMHSA list when it is available. The NRC added this clarification because SAMHSA approval will apply to all validity screening tests from the same lot but may not apply to other lots of the test that do not meet SAMHSA's criteria for approval.

Because SAMHSA has yet to publish a list of approved validity screening tests, the NRC has added § 26.137(b)(1)(ii) to permit licensee testing facilities to use validity screening tests that meet the stringent performance testing requirements established in this section. Adding these requirements to the final rule permits licensee testing facilities to conduct the required performance testing and begin using any validity screening tests that meet the criteria before SAMHSA's list is published. The NRC is aware that the performance testing requirements in § 26.137(b)(1)(ii) are stringent and that few, if any, validity screening devices are yet available that meet them. However, because individuals may be subject to a temporary administrative withdrawal of authorization on the basis of a positive initial drug test result for marijuana or cocaine from a specimen that yields negative test results from validity screening (see proposed § 26.75(i)), it is critical that any validity screening tests used in Part 26 programs provide accurate results. The proposed performance testing requirements are necessary to protect donors from inaccurate results and ensure that specimens of questionable validity are detected.

The final rule eliminates the proposed provision in § 26.137(b)(1)(ii)(A) that required a licensee testing facility or HHS-certified laboratory to conduct performance testing of 100 validity screening devices from all currently available manufactured lots of the device to ensure that the devices met the performance testing criteria in proposed § 26.137(b)(1)(ii)(C) before the licensee testing facility began using the validity screening test. The NRC eliminated proposed § 26.137(b)(1)(ii)(A) to address public comments received suggesting that licensee testing facilities and HHS-certified laboratories may not have the experience or expertise to conduct performance testing of validity screening devices. The commenters suggested that the NRC should instead consider requiring the manufacturer of the validity screening tests to perform and document validation studies of the validity screening tests as well as conduct tests of performance testing samples that licensee testing facilities submit to the manufacturer. The NRC agrees with the commenters and has revised the proposed rule to require manufacturers to perform and document validation studies in § 26.137(b)(1)(ii)(D) of the final rule. The final rule also requires licensees and others entities that intend to use validity screening tests to submit performance testing samples to the validity screening test manufacturer in § 26.137(b)(1)(ii)(E) of the final rule. This change ensures that the evaluation of a validity screening test is conducted by an individual(s) endorsed by the manufacturer. If an individual with limited training were used to conduct the tests, the manufacturer may have a reason to question the test results obtained by the licensee testing facility or the HHS-certified laboratory. The NRC believes that the validity screening test manufacturer is best qualified to demonstrate the effectiveness of each test because the manufacturer is the entity with the greatest knowledge of correct testing procedures.

Another public comment received on proposed § 26.137(b)(1)(ii)(A) stated that the requirement to test 100 validity screening devices was overly burdensome. The NRC agrees with the commenter, has revised the requirement, and relocated the amended provision to § 26.137(b)(1)(ii)(E). The new § 26.137(b)(1)(ii)(E) requires a licensee or other entity to submit three consecutive sets (at least 6 samples in each set) of performance testing samples to the validity screening test manufacturer for performance testing before the licensee testing facility begins using a validity screening to test donor specimens. Therefore, the final rule requires the licensee or other entity to submit a minium of 18 samples for each validity screening test to be used by a licensee or other entity. If a licensee or other entity chooses to use validity screening tests to conduct all of the validity testing required by this subpart (e.g., creatinine, pH, and oxidizing adulterants), the total minimum number of performance test samples that a licensee testing facility must submit to meet the minimum performance testing requirements in the final rule is 72 samples (18 samples for a creatinine test divided into three sets, 18 samples for pH testing at levels equal to or less than 4.5 divided into three sets, 18 samples for pH testing at levels equal to or greater than 9 divided into three sets, and 18 samples for an oxidant test divided into three sets). If a licensee or other entity chooses to use a validity screening test for only one of the types of validity testing required in this subpart, the total number of performance test samples that the licensee testing facility must submit is less. For example, if a licensee or other entity chooses to use a validity screening test only for determining creatinine concentration, the total number of performance samples that the licensee testing facility must submit for testing is 18 samples divided into three sets. The NRC believes that the revised performance testing sample requirements reduce the burden on licensees and other entities imposed by these performance testing requirements while ensuring that the validity screening tests provide accurate and consistent test results.

The agency has also relocated and revised the requirements in proposed § 26.137(b)(1)(ii)(B) and (b)(1)(ii)(C). These proposed provisions established requirements for the formulation of performance testing samples and criteria for licensees and other entities to apply when evaluating performance testing results, respectively. The final rule combines these requirements in § 26.137(b)(1)(ii)(E) and presents them in the rule in the sequence in which licensees and other entities would implement them for organizational clarity. The NRC has also made other changes to the provisions in proposed § 26.137(b)(1)(ii) to address a public comment that stated that the performance testing standards in the proposed rule were unduly prescriptive and should instead be performance based. The NRC agrees with the commenter and has further revised the performance testing provisions in proposed § 26.137(b) as is subsequently discussed with respect to each provision in the final rule.

Section 26.137(b)(1)(ii)(A) of the final rule specifies that a validity screening test that a licensee testing facility intends to use to conduct creatinine testing must be able to detect whether a specimen's creatinine concentration is less than 20 mg/dL. This provision replaces the portions of proposed § 26.137(b)(1)(ii)(B) and (b)(4) that established the required creatinine measurement capabilities of validity screening devices. The NRC revised the provision in response to a public comment received on proposed § 26.137(b)(4) that stated that tests currently available that could be used for validity screening testing for creatinine cannot distinguish creatinine concentrations in the proposed ranges of 5–20 and 1–5 mg/dL. The commenter noted that current validity screening tests, at best, can detect creatinine concentration at a cutoff of 20 mg/dL. Because the rule does not require licensee testing facilities to determine

whether a specimen meets the criteria for substitution or dilution, which depend on the results of specific gravity testing in addition to lower creatinine concentrations, the NRC agrees with the commenter that the proposed creatinine testing to lower concentrations is unnecessary. A validity screening test that can detect creatinine concentration at a cutoff of 20 mg/dL is adequate for a licensee testing facility to determine that a specimen is of questionable validity and requires further testing at an HHS-certified laboratory. This revision avoids imposing an unnecessary burden on licensee testing facilities while ensuring that the validity screening test will support the creatinine concentration cutoff at 20 mg/dL established in § 26.131(b)(1).

Section 26.137(b)(1)(ii)(B) of the final rule specifies that a validity screening test that a licensee testing facility intends to use to conduct pH testing must be able to identify specimens with pH of less than 4.5 and pH equal to or greater than 9. This provision replaces the portions of proposed § 26.137(b)(1)(ii)(B) and (b)(4) that established the required pH measurement capabilities of validity screening devices. Proposed § 26.137(b)(1)(ii)(B) and (b)(4) would have required pH validity screening tests to be capable of detecting pH in the ranges of 1–3 and 10–12. However, the NRC received two comments noting that the proposed pH ranges would not permit the licensee testing facility to detect a specimen that meets the criteria for an invalid test result in the HHS Guidelines (i.e., pH less than 4.5 or equal or greater than 9). Therefore, this change addresses the issue raised by the commenter and ensures that the validity screening test will support the pH cutoffs established in § 26.131(b)(2) as revised in the final rule.

Section 26.137(b)(1)(ii)(C) of the final rule specifies the required performance capabilities for a validity screening test that a licensee testing facility intends to use to conduct testing for oxidizing adulterants. This provision replaces the portions of proposed § 26.137(b)(1)(ii)(B) and (b)(4) that established the required oxidizing adulterant measurement capabilities of validity screening devices. Proposed § 26.137(b)(1)(ii)(B) and (b)(4) would have required oxidizing adulterant validity screening tests to be capable of detecting nitrite in the ranges of 250 mcg/mL to 400 mcg/mL and from 650 mcg/mL to 800 mcg/mL. However, one commenter on the proposed rule noted that the proposed nitrite concentrations for performance testing samples ranging from 250 mcg/mL to 400 mcg/mL and from 650 mcg/mL to 800 mcg/mL would not identify specimens that meet the invalid specimen testing criteria in the HHS Guidelines (i.e., nitrite concentration equal to or greater than 200 mcg/mL). The NRC agrees with the commenter and has revised the oxidant measurement requirements for validity screening tests to detect nitrite concentration at a cutoff of 200 mcg/mL in § 26.137(b)(1)(ii)(C) of the final rule. For completeness, the final rule also includes performance testing criteria for additional oxidant tests (i.e., chromium, halogen) that a licensee testing facility could perform to meet the requirements for testing for oxidizing adulterants in § 26.131(b). Therefore, these changes improve the clarity of the performance testing requirements in this section and the consistency of the final rule with the HHS Guidelines.

At the suggestion of a commenter, the NRC has added § 26.137(b)(1)(ii)(D) to the final rule. This provision requires the manufacturer of a validity screening test to conduct and document validation studies demonstrating the performance characteristics of the validity screening test around the cutoff levels established in this subpart. The commenter suggested that the majority of the burden of demonstrating the performance capabilities of validity screening tests should rest with the manufacturer rather than with licensees and other entities or HHS-certified laboratories, as required by several provisions of the proposed rule. The NRC agrees with the commenter and believes that the manufacturer of each validity screening test is the most appropriate entity to demonstrate the performance characteristics of the validity screening tests before a licensee or other entity begins using a test in an FFD program. The NRC believes it is necessary to establish requirements similar to those that exist for other types of testing performed by licensee testing facilities and HHS-certified laboratories. Both the former and final rules require licensee testing facilities and HHS-certified laboratories to validate their analytical methods before conducting drug testing of donor specimens. The requirement for manufacturers to validate their validity screening tests before providing them to licensee testing facilities is essentially parallel to these requirements for licensee testing facilities and HHS-certified laboratories. The NRC believes the validation requirement is necessary to ensure that the manufacturer has verified the performance characteristics of the validity screening test before shipment to suppliers and use by licensee testing facilities.

As discussed with respect to proposed § 26.137(b)(1)(ii)(A), the NRC has revised the performance testing requirements in proposed § 26.137(b)(1)(ii)(A)–(b)(1)(ii)(C). In addition to the changes to performance testing requirements previously discussed, the final rule revises the portion of proposed § 26.137(b)(1)(ii)(C) that established the percentage of total performance test samples that validity screening tests must correctly identify when licensees and other entities submit performance testing samples to the manufacturer. In § 26.137(b)(1)(ii)(E), the NRC has increased this required percentage from 80 percent in the proposed rule to 90 percent in the final rule. The more rigorous criterion for validity screening tests increases consistency among the rule's criteria for licensee testing facility drug testing performance and criteria in the HHS Guidelines for HHS-certified laboratory drug and validity testing performance. The NRC has made this revision in the final rule to ensure that validity screening tests perform accurately and reliably and that each FFD program effectively evaluates the validity of urine specimens.

Section 26.137(b)(1)(iii) revises proposed § 26.137(b)(1)(iii) to further reduce the performance testing burden on licensees and other entities who use validity screening tests. The proposed rule would have required licensees and other entities to ensure the continued effectiveness of any validity screening tests it is using, after they have been placed in service, by conducting or requesting the HHS-certified laboratory to conduct performance testing of 50 devices on a nominal annual frequency. Consistent with other changes to the performance testing requirements in § 26.137(b), the final rule requires the validity screening tests' manufacturers to conduct this followup performance testing rather than licensee testing facilities or HHS-certified laboratories as proposed. In addition, the final rule eliminates the specific requirement for testing of 50 devices annually and replaces it with a performance-based standard in response to a public comment suggesting that the specificity in the proposed provision was unnecessarily burdensome. The final rule does not specify the number of performance testing samples to be tested by the manufacturer using validity screening tests from the lot in use by the licensee testing facility. The final rule instead requires the manufacturer to test performance testing samples that are formulated around the cutoff levels for

validity testing in this subpart. The NRC believes this standard is adequate to determine whether validity screening tests in each lot are continuing to provide accurate and consistent test results and avoids imposing unnecessarily restrictive requirements.

The NRC has eliminated proposed § 26.137(b)(1)(iv) from the final rule. That provision required licensees and other entities to ensure that the manufacturer of a validity screening test that is used by the licensee testing facility informs the licensee or other entity of any changes to the device that may require additional performance and to conduct additional performance testing if recommended by the MRO or HHS-certified laboratory. This provision is no longer necessary because the revised performance testing requirements in the final rule are focused on each lot of validity screening tests the licensee testing facility intends to use. Because manufacturers cannot make changes to a validity screening test after a lot of the tests has been produced, information about changes to the tests in that lot and additional performance testing are not required.

Section 26.137(b)(2) establishes quality control requirements that licensee testing facility personnel must implement at the beginning of any 8-hour period when validity screening tests will be performed and while conducting validity screening testing. With respect to the proposed rule, the NRC has revised the quality control requirements that were in § 26.137(b)(2) in the proposed rule and relocated them to § 26.137(b)(2)(i). The agency made this change because the final rule adds a new § 26.137(b)(2)(ii) and it is necessary to group the related requirements together for organizational clarity in the final rule.

In response to a public comment, the agency has revised § 26.137(b)(2) in the final rule to require that the licensee testing facility personnel who will be or are performing validity screening testing must implement the quality control requirements in this section. The commenter reasoned that because some validity screening tests have visually read endpoints, the test result must be interpreted by the tester. Therefore, it is necessary to verify that each tester is able to interpret the quality control samples correctly before conducting tests on donor specimens and during the testing process. The NRC agrees with this comment and made the appropriate change in the final rule.

Section 26.137(b)(2)(i) revises portions of proposed § 26.137(b)(2) and requires that the quality control samples to be tested before beginning to test donor specimens in any 8-hour period must consist of one sample that is certified as negative and one that is formulated to appropriately challenge each type of validity screening test to be conducted (e.g., certified to contain an oxidizing adulterant, to have creatinine below 20 ng/mL). For example, the final rule requires that if a licensee testing facility is using a validity screening test to determine the nitrite concentration of a specimen, licensee testing facility personnel must use a certified quality control sample containing nitrite. This requirement is necessary to verify that the validity screening tests to be used are functioning properly and that licensee testing facility personnel are able to conduct the tests appropriately, as discussed with respect to § 26.137(b)(2). The final rule replaces the term ''non-negative'' in the proposed rule, which was used to describe the quality control samples that licensees and other entities must use, with a requirement that the quality control samples must be formulated to challenge each validity screening test around the cutoffs for initial validity testing specified in this subpart. The NRC made this change to improve the clarity in the language of the rule, as discussed with respect to § 26.5.

The final rule, with respect to the proposed rule, adds a provision to require validity screening tests to be challenged by licensee testing facility personnel after screening every 10 donor specimens in § 26.137(b)(2)(ii). Specifically, this provision requires the licensee testing facility to test at least 1 quality control sample after testing every 10 donor specimens during an 8-hour testing period and requires the quality control sample to be formulated to challenge the validity screening test(s) in use around the cutoffs specified in Subpart F. The NRC has added this provision to enhance the consistency of quality control procedures for conducting validity screening testing with quality control procedures for conducting initial validity and drug testing at licensee testing facilities. As discussed with respect to § 26.137(d) and (e), the NRC requires licensee testing facilities to test calibrators, controls, and blind quality control samples during each analytical run of initial validity and drug testing conducted at the licensee testing facility (See § 26.5 for a discussion of the term, ''analytical run'') to monitor the accuracy of testing. However, because it may not be possible to conduct validity screening tests in batches (i.e., the tester may have to insert a dipstick into an aliquot of each donor's specimen manually), it is impractical to impose similar requirements for calibrators, controls and blind quality control testing each time a single validity screening test is performed. Therefore, the NRC added this provision to ensure, without imposing unrealistic requirements, that validity screening tests continue to perform reliably during any 8-hour period in which the validity screening tests are used and to increase consistency among quality control requirements for validity screening and initial validity and drug testing in this section.

The NRC has moved the requirements in proposed § 26.137(b)(2) that addressed the steps that licensee testing facilities must take if a validity screening tests fails to perform correctly when testing quality control samples. For organizational clarity, the NRC relocated the proposed provisions to § 26.137(f) in the final rule because § 26.137(f) establishes requirements related to the topic of the proposed provisions, errors in testing.

Section 26.137(b)(3) requires licensee testing facility personnel to submit 1 out of every 10 donor specimens that yield negative results using validity screening tests to an HHS-certified laboratory. This requirement is necessary to detect false negative test results from validity screening tests. A false negative test result in this instance is a result from a validity screening test indicating that the specimen is valid when, in fact, validity testing at the HHS-certified laboratory identifies the specimen as adulterated, substituted, or invalid. Assessing the validity screening test's rate of false negative test results is necessary because false negative results from a validity screening test could mean that some attempts to subvert the testing process may not be detected. For example, if an individual had adulterated his or her specimen and it was not detected because of a faulty device, the licensee or other entity would have no reason to terminate the individual's authorization. As a result, an individual who has demonstrated that he or she is not trustworthy and reliable would be permitted to perform duties under this part and may pose a risk to public health and safety and the common defense and security.

With respect to the proposed rule, the NRC has moved the requirements in proposed § 26.137(b)(3) that addressed the steps that licensee testing facilities must take if the HHS-certified laboratory's results indicate that the validity screening test provided a false negative result. For organizational clarity, the NRC relocated the proposed provisions to § 26.137(f) in the final rule

because § 26.137(f) establishes requirements related to the topic of the proposed provisions, errors in testing.

The NRC notifications required in § 26.137(b)(2)and (b)(3) are necessary because false negative results from a validity screening test indicate the laboratory testing process may not be successfully detecting donor attempts to subvert the testing process through specimen adulteration or substitution. For example, if an individual had adulterated his or her specimen and it was not detected because of a faulty test, the licensee or other entity would have no reason to terminate the individual's authorization. As a result, an individual who has demonstrated that he or she is not trustworthy and reliable would be permitted to perform duties under this part and may pose a risk to public health and safety and the common defense and security. The NRC will use the information to ensure that HHS is notified of the test failure as well as inform other licensees and entities who may also be using the test of the false negative results to prevent additional testing errors. Therefore, the notifications are necessary to protect donors from inaccurate test results, to ensure that specimens of questionable validity are detected, and to ensure that any problems with a test are detected and corrected as soon as possible.

In response to public comments, the NRC has eliminated proposed § 26.137(b)(4) that required validity screening tests to be capable of measuring a specimen's creatinine concentration to 1 decimal place. Specificity below 20 mg/dL is unnecessary because NRC is not requiring licensee testing facilities to conduct the tests for specific gravity that are necessary for reporting substituted, dilute, or invalid validity test results, as discussed with respect to § 26.137(b)(1)(ii)(A). This change reflects the current capabilities of validity screening tests and supports the intent of the NRC that licensee testing facilities need only be able to identify whether a specimen has a creatinine concentration of less than 20 mg/dL and therefore requires additional testing at an HHS-certified laboratory.

The NRC has added a new § 26.137(b)(4) in the final rule to establish requirements for storing validity screening tests and requires licensee testing facilities to maintain the tests consistent with the manufacturer's storage specifications. Storing the tests as required by the manufacturer's instructions is necessary to ensure that the tests continue to function optimally. This requirement is consistent with the quality control requirements for ASDs in § 26.91(d) and meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has deleted proposed § 26.137(b)(5) and (b)(6) from the final rule and replaced these provisions with the performance testing requirements in § 26.137(b)(1)(ii) for the reasons discussed with respect to that section.

The NRC added § 26.137(c) [Validity screening test results] to specify the actions that the licensee testing facility must take if a donor's specimen yields questionable results from validity screening testing. If a specimen has a questionable validity screening test result, the final rule requires instrumented initial validity testing either at the licensee testing facility or the HHS-certified laboratory. This provision is consistent with the rule's requirements for transferring to the HHS-certified laboratory specimens with initial positive drug test results from testing at a licensee testing facility. Further testing of a specimen of questionable validity is necessary to protect donors from inaccurate test results, as well as provide assurance that specimens of questionable validity are detected using the more sophisticated technologies required for instrumented initial validity testing in the HHS Guidelines and the final rule. The final rule, with respect to the proposed rule, eliminates the term ''non-negative'' from the heading of the provision for the reasons discussed with respect to § 26.5 related to the elimination of this term throughout the final rule.

The agency added § 26.137(d) [Quality control requirements for performing initial validity tests] to specify the required methods for performing initial validity tests at a licensee testing facility that are necessary to ensure that initial validity testing at the licensee testing facility provides accurate results. The requirements in this paragraph incorporate the related requirements in the HHS Guidelines as revised on April 13, 2004 (69 FR 19644). The paragraph has been added to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.137(d)(1) requires licensee testing facilities to measure creatinine concentration to 1 decimal place and establishes requirements for the controls to be used in initial tests for creatinine concentration.

Section 26.137(d)(2) establishes quality control requirements for performing initial pH tests. Sections 26.137(d)(2)(i)–(d)(2)(v) specify the required calibrators and controls for initial pH testing, based on the type of testing instrument used and whether a pH validity screening test has been performed.

Section 26.137(d)(3) establishes quality control requirements for performing initial tests for oxidizing adulterants, including nitrite, and § 26.137(d)(4) establishes quality control requirements for performing initial tests for ''other'' adulterants at the licensee testing facility.

Section 26.137(d)(5) requires that one of the quality control samples included in each analytical run must appear to be a donor specimen to laboratory analysts. The final rule retains the related requirement in the last paragraph of Section 2.8(c)(3) in Appendix A to Part 26 and amends the provision to be consistent with the same requirement in the HHS Guidelines. With respect to the proposed rule, the NRC relocated this requirement from proposed § 26.137(e)(7) to § 26.137(d)(5) in the final rule to clarify that the requirement to test one blind quality control sample in each analytical run applies to initial validity test runs as well as to initial drug testing if the licensee testing facility does not conduct initial validity and drug testing concurrently. However, if a licensee testing facility conducts initial validity and drug testing of specimens concurrently, the NRC intends that the licensee testing facility would include only one blind performance test sample in the analytical run to meet this requirement as well as the same requirement in § 26.137(e)(6)(v) for drug testing runs. The NRC made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization of the rule.

The NRC also added § 26.137(d)(6) in the final rule to require licensee testing facilities to send 1 out of 10 specimens that test negative on initial validity tests to an HHS-certified laboratory for initial and, if necessary, confirmatory validity testing. The NRC added this requirement in response to public comments noting inconsistencies in the proposed rule's quality control requirements for validity screening, initial validity testing, and initial drug testing, and for the reasons discussed with respect to the addition of a similar requirement applicable to validity screening testing in § 26.137(b)(3). Adding this provision ensures that licensee testing facilities can assess their rates of false negative initial validity test results and therefore meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.137(e) [Quality control requirements for initial drug tests]

amends and combines portions of former Section 2.7(d), 2.7(e)(1), and 2.8(b) in Appendix A to Part 26. The former provisions established quality control requirements for performing initial tests for drugs and drug metabolites at licensee testing facilities. The final rule groups together in one paragraph the requirements that were dispersed throughout the former rule to meet Goal 6 of this rulemaking to improve clarity in the organization of the final rule.

Section 26.137(e)(1) amends the first sentence of former Section 2.7(e)(1) in Appendix A to Part 26 but retains the intent of the former provision as it applies to licensee testing facilities. This provision retains the former requirement that licensee testing facilities may use only immunoassay tests that meet the requirements of the Food and Drug Administration for commercial distribution. The NRC has moved the requirements in the former provision related to initial drug testing at HHS-certified laboratories to § 26.167(d)(1) of Subpart G of the final rule to improve organizational clarity in the rule.

In addition, § 26.137(e)(1) prohibits licensee testing facilities from relying on drug test results from any tests they may use to perform validity screening tests. The NRC added this prohibition because several non-instrumented devices are available that combine tests for the presence of drugs and drug metabolites in a urine specimen with tests for other attributes of a urine specimen, such as creatinine concentration. The final rule permits licensee testing facilities to use such combination tests as validity screening tests if the tests meet the requirements of § 26.137(b)(1). However, the drug testing capabilities of these tests are not yet sufficiently accurate and sensitive to be used in Part 26 programs, in which licensees and other entities are permitted to administratively withdraw an individual's authorization on the basis of positive initial drug test results for marijuana and cocaine metabolites. The NRC may consider accepting the use of initial drug test results from non-instrumented tests in a future rulemaking, when HHS publishes a final revision to the Mandatory Guidelines that establishes requirements for their use in Federal workplace drug testing programs. At this time, however, the final rule retains the former prohibition on using such tests for drug testing at licensee testing facilities.

The NRC added § 26.137(e)(2) to require licensee testing facilities to either discard specimens that yield negative results from initial tests at the licensee testing facility or pool them and use these specimens as quality control specimens, if the specimens are certified as negative and valid by an HHS-certified laboratory. This provision incorporates the related provision from the HHS Guidelines to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. With respect to the proposed rule, the final rule adds a sentence prohibiting licensee testing facilities from retaining any information linking donors to specimens pooled for use in the internal quality control program. The agency added this prohibition in response to a public comment requesting this addition. This change meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.137(e)(3) permits licensee testing facilities to conduct multiple tests of a single specimen for the same drug or drug class. The NRC has revised § 26.137(e)(3) in the final rule, with respect to the proposed rule, to include a more precise description of when multiple initial drug tests on a specimen (also know as rescreening) are permitted. The NRC added this information in the final rule in response to a comment received on the proposed provision requesting the addition. The requirements in the provision are consistent with a similar provision in the HHS Guidelines and, therefore, meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.137(e)(4) amends the first sentence of former Section 2.8(b) in Appendix A to Part 26. The former sentence stated that licensee testing facilities are not required to assess their false positive rates in drug testing. The final rule retains the intent of the former requirement, but the NRC has updated the terminology in the provision to use the new terms that are used throughout the final rule, e.g., ''initial'' rather than ''screening,'' as discussed with respect to § 26.5.

Section 26.137(e)(5) amends the second sentence of former Section 2.8(b) in Appendix A to Part 26. This provision required licensee testing facilities to submit specimens that yield negative results from initial testing to the HHS-certified laboratory as a quality control check on the licensee testing facility's drug testing process. The paragraph retains the intent of the former provision but makes several changes to the specific requirements.

The paragraph uses the term ''analytical run'' rather than the former term ''test run'' to reflect changes in testing technologies that some licensee testing facilities have adopted since the former rule was published. Requirements for blind performance and other quality control testing in the former rule were based on the assumption that specimens would be tested in batches. However, many licensee testing facilities now conduct continuous testing, and no longer test specimens in batches. Therefore, the final rule uses the term, ''analytical run,'' to refer to both batch and continuous processing, as defined in § 26.5. This change has been made to meet Goal 6 of this rulemaking to improve clarity in the language of the final rule.

The former rule did not establish a number or percentage of negative specimens that licensee testing facilities were required to submit to the HHS-certified laboratory for performance testing, which raised implementation questions from licensees who have wanted to know how many specimens must be submitted. Therefore, to clarify the former requirement to ''submit a sampling of specimens,'' the final rule requires licensee testing facilities to forward at least one specimen that yields negative drug test results from each analytical run to the HHS-certified laboratory for performance testing. The final rule also establishes five percent of the specimens tested in each analytical run as the percentage of negative specimens that the licensee testing facility must submit to the HHS-certified laboratory for testing, except if five percent of an analytical run is a number less than one specimen. In the latter case, the licensee testing facility submits at least one negative specimen from the analytical run. This requirement ensures the ongoing evaluation of the accuracy of the licensee testing facility's initial drug testing without imposing a large performance testing burden.

The NRC has moved the last sentence of the former paragraph, which addressed performance testing of breath analysis equipment for alcohol testing, to § 26.91(e) in Subpart E because that subpart of the final rule addresses quality control requirements for alcohol testing. The NRC made this change to meet Goal 6 of this rulemaking to improve clarity in the organization of the final rule.

Section 26.137(e)(6) amends the requirements of former Section 2.8(c) in Appendix A to Part 26 and applies them to licensee testing facilities. The NRC is applying requirements for quality

controls to initial drug testing at licensee testing facilities to provide greater assurance that initial drug tests performed by these facilities provide accurate results. The increased performance testing requirements in the final rule are necessary because the final rule permits licensees and other entities to rely on test results from other Part 26 programs to a greater extent that the former rule. Therefore, it is necessary to ensure that any tests performed at licensee testing facilities meet minimum standards. This change meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The final rule, with respect to the proposed rule, moves the provision in proposed § 26.137(e)(7) to § 26.137(e)(6) in the final rule to improve organizational clarity. The NRC made this change to address a public comment received on the proposed rule that noted that because the second sentence in proposed § 26.137(e)(7) discussed a quality control sample requirement, the provision would be more appropriately located in § 26.137(e)(6) which describes the quality control sample requirements for each analytical run.

Section 26.137(e)(6) establishes requirements for the number of quality control samples to be included in each analytical run at the licensee testing facility. The final rule requires that a minimum of 10 percent of the specimens in each analytical run must be quality control samples. For example, if an analytical run consists of 50 donor specimens, an additional 5 quality control samples would be included in the analytical run for a total of 55 specimens tested in the run. The licensee testing facility will not send the quality control samples to the HHS-certified laboratory for confirmatory testing, but use them for internal quality control purposes only. The requirements in this paragraph incorporate the related requirements in the HHS Guidelines and meet Goal 1 of this rulemaking, which is to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The final rule also requires licensee testing facilities to ensure that quality control samples that are positive for each drug and metabolite for which the FFD program conducts testing are included in at least one analytical run in each quarter of the calendar year. The NRC added this provision at the request of comments received addressing inconsistences within the proposed rule. The proposed rule required quality control samples for each type of validity test, but failed to specify the required distribution of quality control samples among the drugs and metabolites for which the FFD program tests. This provision clarifies the former rule and increases the internal consistency of this subpart. Additionally, this provision provides for enhanced monitoring of the effectiveness of the licensee testing facilities' drug testing procedures to meet Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

The NRC has added § 26.137(e)(6)(i)–(e)(6)(iii) to describe the required characteristics of the quality control samples that the licensee testing facility must include in each analytical run of specimen testing. These provisions require each analytical run to include at least one negative quality control sample as well as quality control samples targeted at 25 percent above the cutoff and at 25 percent below the cutoff level for each drug and drug metabolite for which testing is conducted. The final rule, with respect to the proposed rule, revises the requirement that a quality control sample must be targeted at 75 percent of the cutoff level and instead, the final rule requires the calibrator to be targeted at 25 percent below the cutoff level. This change was made to improve the clarity of the language of the final rule without changing the intent of the provision. These requirements are consistent with the current HHS Guidelines for processing quality control samples during initial drug testing.

With respect to the proposed rule, the final rule has added § 26.137(e)(6)(iv) and § 26.137(e)(6)(v) to further enhance quality control requirements for initial drug testing at licensee testing facilities. In response to a public comment, the NRC added § 26.137(e)(6)(iv) to require that each analytical run has a sufficient number of calibrators to ensure linearity of the assay. This additional provision is consistent with the related requirement in the HHS Guidelines. Section 26.137(e)(6)(v) requires that one sample must appear to be a donor sample to the laboratory analysts. This requirement was previously embedded in § 26.137(e)(7) of the proposed rule, and the NRC moved the requirement to § 26.137(e)(6)(v) of the final rule in response to a comment received that noted this move would enhance organizational clarity in the rule. The NRC agrees with the commenter.

Section 26.137(e)(7) extends to licensee testing facilities the requirement in the third sentence of the last paragraph of former Section 2.8(c) in Appendix A to Part 26. That provision required HHS-certified laboratories to implement procedures to ensure that carryover does not contaminate the testing of a donor's specimen and to document the procedures. The final rule extends this requirement to licensee testing facilities because it is a standard forensic practice that is necessary to ensure the integrity of the testing process.

The NRC has added § 26.137(f) [Errors in testing] to require licensees and other entities who maintain testing facilities to investigate any errors or unsatisfactory performance of the testing process, identify the cause(s) of the adverse conditions, and correct them. The final rule requires the licensee or other entity to document the investigation and any corrective actions taken. The provision requires licensees and other entities to investigate any testing errors or unsatisfactory performance identified throughout the testing process or during the review process that are required under § 26.91 [Review process for fitness-for-duty policy violations]. The NRC intended, in the original rule, that testing or process errors discovered in any part of the program, including through the review process, be investigated as an unsatisfactory performance of a test. This provision clarifies that intent. Thorough investigation and reporting of such test results will continue to assist the NRC, the licensees, HHS, and the HHS-certified laboratories in preventing future occurrences.

The NRC has reorganized the requirements in proposed § 26.137(f) into a list format in § 26.137(f)(1)–(f)(5) in the final rule to improve the organizational clarity of the rule and added new requirements to this section for the reasons discussed with respect to each provision.

Section 26.137(f)(1) requires, whenever possible, that the investigation of testing or processing errors must determine relevant facts and identify the root cause(s) of the error. Section 26.137(f)(2) requires the licensee testing facility to take action to correct the cause of any error or unsatisfactory performance within the licensee testing facility's control.

The NRC has added § 26.137(f)(3) to the final rule, with respect to the proposed rule, to address instances when testing of a quality control sample at a licensee testing facility yields a false negative test result. This provision requires the licensee testing facility to forward all donor specimens from the analytical run in which the error is detected to the HHS-certified laboratory for additional testing. This requirement is necessary to ensure that licensees and other entities do not permit individuals who may have altered a specimen or

used prohibited drugs to be granted or maintain authorization to have the types of access or perform the duties that require them to be subject to the rule. Additional testing at the HHS-certified laboratory of the donor specimens included in the analytical run during which the error is identified ensures that public health and safety and the common defense and security are not placed at risk because initial validity or drug test results from the licensee testing facility failed to identify an individual who has attempted to subvert the testing process or engaged in substance abuse. In addition, testing of these specimens at the HHS-certified laboratory may also provide the licensee testing facility with additional information regarding the cause(s) and extent of condition that resulted in the error. The NRC added this requirement to the final rule to enhance consistency of the rule's requirements for addressing errors in testing at licensee testing facilities with those required for addressing errors in testing at HHS-certified laboratories and in response to public comments received on the proposed rule noting the inconsistencies. This requirement is consistent with standard forensic practices and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section § 26.137(f)(3) also requires the licensee testing facility to implement corrective actions before resuming testing of donor specimens. For example, if testing of a certified-positive quality control sample at the licensee testing facility yields false negative test results for opiates, this provision requires the licensee testing facility to stop testing donor specimens for opiates until the cause(s) of the false negative test are identified and corrected. Similarly, if a quality control sample that has been certified to contain an adulterant at a concentration above the cutoff levels established in Subpart F for validity screening or initial validity testing yields a false negative test result, this provision requires the licensee testing facility to stop testing for that adulterant until the cause(s) of the false negative test result are identified and corrected. This requirement is necessary to prevent additional errors in testing that could permit individuals who may have altered a specimen or used prohibited drugs to be granted or maintain authorization to have the types of access or perform the duties that require them to be subject to the rule. The NRC added this requirement to the final rule to enhance consistency of the rule's requirements for addressing errors in testing at licensee testing facilities with those required for addressing errors in testing at HHS-certified laboratories and in response to public comments received on the proposed rule mentioning the inconsistencies. This requirement is consistent with standard forensic practices and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The NRC has added § 26.137(f)(4) to address instances where testing conducted at an HHS-certified laboratory identifies a specimen that yielded a false negative test result from the licensee testing facility. To evaluate whether tests at a licensee testing facility may be providing false negative test results, § 26.137(b)(3), (d)(6), and (e)(5) require the licensee testing facility to submit some donor specimens that yield negative test results to an HHS-certified laboratory for additional testing. If, after confirmatory testing by the HHS-certified laboratory, a donor specimen yields positive, substituted, adulterated, or invalid results, § 26.137(f)(4) mandates that the licensee testing facility must take corrective action(s) before resuming testing for the drug(s), drug metabolite(s), adulterant(s), or other specimen characteristics (i.e., creatinine, pH) associated with the donor specimen(s) that yielded the false negative result(s). Additionally, § 26.137(f)(4) permits the licensee or other entity to re-collect and test specimens from any donor whose test results from initial testing at the licensee testing facility may have been inaccurate. The NRC added this provision to the final rule for the same reasons discussed with respect to § 26.137(f)(3).

Section 26.137(f)(5) requires the licensee or other entity to document the investigation and any corrective actions taken for consistency with Criterion XVI in Appendix B to 10 CFR Part 50.

Section 26.137(g) [Accuracy] retains former Section 2.7(o)(3)(i) in Appendix A to Part 26 as it applied to licensee testing facilities. This provision requires checking the instruments used in testing for accuracy. The final rule moves the former requirement as it relates to HHS-certified laboratories to § 26.167(h) in Subpart G for organizational clarity.

Section 26.137(h) [Calibrators and controls] updates former Section 2.7(o)(2) in Appendix A to Part 26, which established requirements for the standards and quality control samples used for performance testing. At the time the original paragraph was written, most laboratories prepared their own standards and controls. In the ensuing years, the number and variety of sources for materials used in performance testing have increased. This provision updates the former requirements to refer to several of the alternatives, including, but not limited to, pure drug reference materials, stock standard solutions from other laboratories, and standard solutions obtained from commercial manufacturers. The requirements in this paragraph incorporate the related requirements in the HHS Guidelines and meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.139 Reporting Initial Validity and Drug Test Results

The NRC has added § 26.139 to combine requirements related to the reporting and management of test results from the licensee testing facility that were interspersed throughout former Appendix A to Part 26. The agency made this change to meet Goal 6 of this rulemaking to improve clarity in the organization of the final rule, by grouping related requirements together in a single section.

Section 26.139(a) amends former Section 2.7(g)(2) in Appendix A to Part 26. That provision established requirements for the manner in which HHS-certified laboratories and licensee testing facilities must report test results to licensee management. The final rule amends the former provision by moving the former requirements that were related to reporting test results from HHS-certified laboratories to § 26.169(b) of Subpart G for organizational clarity. The final rule also deletes the former reference to ''special processing'' and replaces it with reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). The NRC made these changes to improve clarity in the language and organization of the rule consistent with Goal 6 of this rulemaking.

With respect to the proposed rule, the final rule eliminates use of the term ''non-negative'' in § 26.139(a) for the reasons discussed with respect to § 26.5 for eliminating this term throughout the proposed rule. Eliminating the term ''non-negative'' and replacing it with terms to describe specific results of drug and validity testing (e.g., ''positive,'' ''adulterated''), necessitates splitting the last sentence of proposed § 26.139(a) into two sentences for clarity. Therefore, the final rule prohibits licensee testing facilities from reporting to licensee or

other entity management any positive drug test results from initial drug testing at the licensee testing facility, except as permitted under § 26.75(h). The final rule also prohibits licensee testing facilities from reporting to licensee or other entity management any validity screening and initial validity test results that indicate a specimen is of questionable validity and any positive initial drug test results from specimens that are of questionable validity. The NRC made these changes to improve clarity in the language of the rule, consistent with Goal 6 of this rulemaking.

Section 26.139(b) amends the last sentence of former § 26.24(d)(1), which specified the individuals to whom results of initial tests from the licensee testing facility may be released. The NRC added the MRO's staff to the list of individuals who are permitted to have access to the results of initial tests performed at the licensee testing facility consistent with the addition of this job role to the final rule. Individuals who are serving as MRO staff members require access to initial test results from a licensee's testing facility in the course of performing their administrative duties for the MRO. Additionally, with respect to the proposed rule, the final rule permits an SAE to access initial test results when appropriate consistent with the addition of this job role to the final rule. Omitting the SAE from this provision was an unintended oversight in the proposed rule which the NRC has corrected in the final rule.

Section 26.139(c) amends former Section 2.7(o)(5) in Appendix A to Part 26. The NRC has moved the requirements in the former paragraph that addressed the availability of personnel to testify in proceedings related to drug test results from an HHS-certified laboratory to § 26.153(f)(2) of Subpart G for organizational clarity. The final rule moves the former requirement for licensee testing facility personnel to be available to testify at any proceedings with respect to breath analysis test results to § 26.85(d) [Personnel available to testify at proceedings] because the collection site and not the licensee testing facility is typically responsible for quality control of alcohol testing equipment. The agency made these changes for organizational clarity in the rule, consistent with Goal 6 of this rulemaking.

Section 26.139(d) amends the portions of former Section 2.7(g)(6) in Appendix A to Part 26 that applied to the summary report that licensee testing facilities must provide to FFD program management. The NRC has replaced the former requirement for the licensee testing facility to prepare a monthly report of test results with a requirement for the licensee testing facility to summarize the data annually in the FFD program performance report required under § 26.717(b) of the final rule. Experience implementing the former requirement for a monthly statistical summary has indicated that the monthly summary has not been as useful to licensees for ongoing monitoring of testing program effectiveness as other mechanisms that licensees have developed. Therefore, the final rule replaces the monthly reporting requirement in former Section 2.7(g)(6) in Appendix A to Part 26 with a requirement in § 26.139(f) of the final rule for FFD program management to monitor the ongoing effectiveness of the licensee testing facility testing program. This change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. The NRC has moved the requirements in the former paragraph that addressed summary reports from HHS-certified laboratories to § 26.169(k) of Subpart G for organizational clarity. With respect to the proposed rule, the agency changed the cross-reference to FFD program performance reporting requirements in § 26.217(b) in the proposed rule to § 26.717(b) in the final rule to reflect the changes the NRC has made in the organization of the final rule.

Section 26.139(e) amends former Section 2.7(g)(7) in Appendix A to Part 26. That provision required licensee testing facilities and HHS-certified laboratories to report test results for both the cutoff levels specified in Part 26 and any more stringent cutoff levels used by the FFD program. The NRC has relocated the former requirement related to HHS-certified laboratories to § 26.169(c) of Subpart G for organizational clarity. The final rule requires licensees and other entities who operate testing facilities, and have adopted more stringent cutoff levels for initial tests for drugs and drug metabolites than those specified in § 26.133 [Cutoff levels for drugs and drug metabolites], to conduct tests and report test results based only on their more stringent cutoff levels. The basis for the former requirement to conduct tests and report test results for the cutoff levels specified in this part, when the licensee is using more stringent cutoff levels, was a method by which the NRC monitored licensee implementation of the permission to use more stringent cutoff levels. The final rule eliminates this requirement, because § 26.31(d)(3)(iii)(C) requires a qualified forensic toxicologist to certify the scientific and technical suitability of the licensee's or other entity's testing process at any lower cutoff levels. Therefore, the testing and reporting requirements in the former rule are no longer needed to monitor licensee testing facility performance in this area. The final rule continues to require licensee testing facilities to report test results (and the cutoff levels used) from testing for additional drugs and drug metabolites, beyond those specified in § 26.31(b)(1).

Section 26.139(f) has been added to require FFD program management to monitor the ongoing effectiveness of the licensee testing facility testing program. The final rule provides examples of the types of information and possible program performance indicators that licensees and other entities may use for program monitoring. The final rule also requires FFD program management to make adjustments to the testing program in response to information gained from the ongoing monitoring. These requirements replace the monthly summary report required under former Section 2.7(g)(7) in Appendix A to Part 26 to strengthen FFD programs by ensuring that licensees monitor licensee testing facility performance on an ongoing basis and correct any weaknesses as they are identified. The paragraph is also consistent with the NRC's performance-based approach to regulation. This change meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs, as discussed in Section IV.B.

Subpart G—Laboratories Certified by the Department of Health and Human Services

Section 26.151 Purpose

The NRC has added § 26.151 to introduce the purpose of the subpart, which is to establish requirements for the HHS-certified laboratories that licensees and other entities must use for testing urine specimens for validity and the presence of drugs and drug metabolites. Adding this paragraph meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. The majority of the requirements in this subpart are based on the former requirements in Appendix A to Part 26, as they relate to HHS-certified laboratories. However, the rule substantially updates the former requirements to be consistent with the HHS Guidelines.

Section 26.153 Using Certified Laboratories for Testing Urine Specimens

The NRC added § 26.153 to group into one section requirements related to the use of HHS-certified laboratories by licensees and other entities who are subject to the rule.

Section 26.153(a) combines and updates former requirements for licensees and other entities to use HHS-certified laboratories for initial and confirmatory drug testing of urine specimens. The paragraph relocates and combines former § 26.24(f) and former Sections 1.1(3) and 4.1(a) in Appendix A to Part 26. These provisions required licensees and other entities to use HHS-certified laboratories for drug testing. The NRC made this change to eliminate redundancies in the former rule and improve organizational clarity. The paragraph updates the former citations for the HHS Guidelines because the guidelines have been amended several times since the former rule was published. In addition, the provision provides current contact information for obtaining information about the certification status of HHS-certified laboratories because the contact information has changed since the former rule was published. The paragraph also adds a requirement for licensees and other entities to use HHS-certified laboratories for initial and confirmatory validity testing, consistent with the addition of urine specimen validity testing requirements to the rule, as discussed with respect to § 26.31(d)(3)(i). The rule also updates the cross-reference to former § 26.24(d), which permitted licensee testing facilities to conduct initial drug tests, to reference the related provision in the final rule, § 26.31(d)(3)(ii).

Section 26.153(b) amends the first sentence of former Section 2.7(l)(2) in Appendix A to Part 26. The former provision required HHS-certified laboratories to have the capability, at the same laboratory premises, of performing initial and confirmatory tests for any drug and drug metabolite for which service is offered and confirmatory testing of blood for alcohol concentrations. The former requirement for HHS-certified laboratories to be capable of conducting confirmatory alcohol testing of blood has been deleted for the reasons discussed with respect to § 26.83(a). The paragraph adds a requirement for HHS-certified laboratories to have the capability to perform both initial validity and confirmatory validity tests at the same premises for consistency with the addition of requirements to perform validity testing to the rule, as discussed with respect to § 26.31(d)(3)(i). The second sentence of former Section 2.7(l)(2) in Appendix A to Part 26, which established requirements for the capabilities of licensee testing facilities, has been moved to § 26.123 of Subpart F [Licensee Testing Facilities] for organizational clarity. The agency deleted the last sentence of the former paragraph, which permitted the testing of breath specimens for alcohol at the collection site, because the rule addresses alcohol testing in Subpart E [Collecting Specimens for Testing]. These organizational changes to the former paragraph have been made to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.153(c) amends the first sentence of former Section 2.7(k) in Appendix A to Part 26. The former provision prohibited HHS-certified laboratories from subcontracting unless authorized by the licensee. The rule extends this restriction to subcontracting for specimen validity testing for consistency with the addition of requirements to perform validity testing to the rule, as discussed with respect to § 26.31(d)(3)(i). The second sentence of former Section 2.7(k) has been deleted from the paragraph for several reasons: First, the requirement to have the capability to test for marijuana, cocaine, opiates, phencyclidine, and amphetamines has been deleted because it is redundant with § 26.31(d)(1). The requirement to be capable of testing whole blood has been deleted because the rule no longer permits donors to request confirmatory alcohol testing of blood for the reasons discussed with respect to § 26.83(a). Finally, the requirement for laboratories to be capable of using gas chromatography/mass spectrometry (GC/MS) has been eliminated because HHS-certified laboratories would be permitted to use other methods of confirmatory testing, consistent with related revisions to the HHS Guidelines.

Section 26.153(d) amends former Section 4.1(b) in Appendix A to Part 26, which required licensees and C/Vs to use only HHS-certified laboratories who agree to follow the same rigorous testing, quality control, and chain-of-custody procedures when testing for more stringent cutoff levels, additional drugs to those for which testing required under Part 26, and blood. The final rule eliminates reference to testing for blood in this provision because the rule no longer permits donors to request confirmatory alcohol testing of blood for the reasons discussed with respect to § 26.83(a).

Section 26.153(e) amends the third sentence of former Section 2.7(m) in Appendix A to Part 26. That sentence required licensees to conduct an inspection and evaluation of a laboratory's drug testing operations before using the laboratory's services. Some licensees have incorrectly interpreted the former regulation as requiring licensee employees to perform the pre-award inspection and evaluation. In many cases, however, appropriately qualified licensee employees may not be available to perform the inspection and evaluation, and the use of contracted experts may be necessary to achieve the NRC's intent. The paragraph revises the former requirement to indicate that licensees and other entities are responsible ''to ensure'' that the inspection and evaluation is performed, in order to clearly indicate that the use of expert contractors is acceptable. In addition, the rule clarifies that the pre-award inspection and evaluation must be performed by qualified individuals.

Section 26.153(e) also permits a licensee or other entity to begin using the services of another HHS-certified laboratory immediately, without a pre-award evaluation and inspection, in the event that the licensee's or other entity's primary laboratory loses its certification. To be considered acceptable, the rule requires that the replacement laboratory must be in use by another Part 26 program. The rule adds this provision to ensure that testing can continue, in the event that the HHS-certified laboratory on whom a licensee or other entity relies loses its certification, as some licensees have experienced. Related requirements for auditing the replacement laboratory are specified in § 26.41(g)(5).

The agency added § 26.153(f) to require that licensees' and other entities' contracts with HHS-certified laboratories must require the laboratories to implement the applicable requirements of this part. Because the NRC does not regulate HHS-certified laboratories, this revision would ensure that the agency has a legal basis for requiring HHS-certified laboratories to comply with this part when conducting testing for licensees and other entities.

Section 26.153(f)(1) retains the requirement in former Section 2.7(l)(1) in Appendix A to Part 26. The former requirement stated that HHS-certified laboratories must comply with applicable State licensor requirements. The final rule replaces the term ''HHS-certified laboratories'' with the term ''laboratory facilities'' to clarify that State requirements apply to laboratory facilities rather than to the HHS-

certified laboratory as a corporate entity. The clarification is necessary because some HHS-certified laboratories are operated by large national corporations with facilities in several different States, and only the facilities in a specific State are required to meet the requirements of that State. The NRC made this change for clarity in the language of the rule as well as consistency with the HHS Guidelines.

Section 26.153(f)(2) amends former Section 2.7(o)(5) in Appendix A to Part 26. The former regulation required HHS-certified laboratories to make available qualified personnel to testify in proceedings based on urinalysis results reported by the laboratory. The NRC moved the reference to licensee testing facilities to § 26.139(c) in Subpart F for organizational clarity. The requirement for qualified personnel to be available to testify in proceedings related to breath analysis results has been moved to § 26.85(d) in Subpart E for organizational clarity and because responsibility for testifying with respect to breath analysis results resides with the licensee's or other entity's collection site personnel.

Section 26.153(f)(3) updates former Section 3.1 in Appendix A to Part 26, which required HHS-certified laboratories to protect donors' records. The former requirement for licensee testing facilities to protect donors' records has been subsumed within the second sentence of § 26.37(a) for organizational clarity. The cross-reference to former § 26.29 has been updated to reference § 26.39 in the final rule.

Section 26.153(f)(4) updates former Section 3.2 in Appendix A to Part 26. Specifically, the rule adds a reference to Sec. 503 of Pub. L. 100–71 to document the basis for this requirement. The paragraph adds a requirement for a donor to have access to records relating to his or her validity test results for consistency with the addition of validity testing requirements to the rule, as discussed with respect to § 26.31(d)(3)(i). The paragraph deletes the former reference to records related to alcohol test results because the final rule will no longer require HHS-certified laboratories to be capable of testing blood specimens for alcohol, as discussed with respect to § 26.83(a). With respect to the proposed rule, the NRC has added a phrase to the provision to clarify that a donor's designated representative is also permitted to have access to records relating to the donor's validity test results. The NRC made this change in response to a public comment requesting the clarification.

The NRC added § 26.153(f)(5) to clarify that HHS-certified laboratories must avoid relationships with a licensee's or other entity's MRO(s) that may be construed as a potential conflict of interest. The final rule, with respect to the proposed rule, adds a reference to provisions added in the final rule at § 26.183(b) to specify specific conflict of interest relationships. The NRC added the provisions in § 26.183(b) in response to a comment on the proposed rule requesting the NRC to consider using the examples of MRO conflict of interest relationships specified in DOT's drug and alcohol testing regulations. The paragraph responds to the experiences of other Federal agencies regarding apparent conflicts of interest involving laboratories and MROs. Although the NRC is not aware of any situations of this type in Part 26 programs, the integrity of the MRO function is sufficiently important that incorporating this requirement is warranted to prevent potential conflict of interest concerns. The paragraph is consistent with the related provision in the HHS Guidelines.

Section 26.153(f)(6) amends the requirements in the first two sentences of former Section 2.7(m) in Appendix A to Part 26, which required HHS-certified laboratories to permit the NRC, licensees, and other entities to conduct inspections at any time, including unannounced inspections. The rule deletes, for organizational clarity, the existing references to collection site services and licensee testing facilities, which are covered under Subpart F. The paragraph also deletes reference to confirmatory testing of blood specimens for alcohol because HHS-certified laboratories are no longer testing blood specimens for alcohol, as discussed with respect to § 26.83(a).

A new § 26.153(g) requires licensees and other entities to provide a memorandum for the record to the HHS-certified laboratories that they use to document why the licensee or other entity is using a non-Federal custody-and-control form. Under the HHS Guidelines, laboratories may reject any specimen that is submitted for testing with a non-Federal custody-and-control form unless the licensee or other entity provides a memorandum for the record. The paragraph is necessary to prevent licensee and other entity specimens from being rejected.

Section 26.155 Laboratory Personnel

Section 26.155 updates former Section 2.5 in Appendix A to Part 26 to be consistent with revisions to the HHS Guidelines.

Section 26.155(a) [Day-to-day management of the HHS-certified laboratory] amends former Section 2.5(a)(1) in Appendix A to Part 26, which required the HHS-certified laboratory to have a qualified individual to assume responsibility for day-to-day management of the HHS-certified laboratory. Specifically, the paragraph replaces the term ''qualified individual'' with the term ''responsible person'' for consistency with terminology that other Federal agencies use to refer to this job role. The final rule retains the majority of Section 2.5(a)(2) in Appendix A to Part 26 and establishes qualification requirements for the responsible person. The provisions in § 26.155(a)(1)(i)–(a)(1)(iv) retain former Section 2.5(a)(2)(i)–(a)(2)(iv) in Appendix A to Part 26, with minor grammatical changes that are consistent with similar changes to the related provisions in the HHS Guidelines.

Section 26.155(a)(2) and (a)(3) establishes minimum day-to-day management responsibilities of the responsible person and retains former Section 2.5(a)(4) and (a)(5) in Appendix A to Part 26.

Section 26.155(a)(4) retains former Section 2.5(a)(5) in Appendix A to Part 26, which relates to the responsible person's responsibility to maintain the HHS-certified laboratory procedures in a manual. With respect to the proposed rule, the final rule includes a provision that HHS-certified laboratories' procedures be maintained in a manual of standard operating procedures. The proposed rule eliminated the former requirement in Section 2.5(a)(5) to provide flexibility to HHS-certified laboratories in how laboratory operating procedures were maintained. However, based on a comment received on the proposed rule, the NRC has reinstituted the former requirement that laboratory procedures be maintained in a manual to improve consistency with the HHS Guidelines, meeting Goal 1 of this rulemaking. The paragraph retains the former requirements in the second and third sentences of Section 2.5(a)(5) in Appendix A to Part 26, and requires the responsible person to review, sign, and date the procedures when they are first placed in use, changed, or a new individual assumes responsibility for management of the laboratory. The responsible person must also maintain copies of the procedures. The final rule updates the former cross-reference to Section 2.7(o) in Appendix A to Part 26 to reference § 26.157, consistent with the organizational changes made to the rule.

Section 26.155(a)(5) and (a)(6) retains former Section 2.5(a)(6) and (a)(7) in

Appendix A to Part 26. These provisions define the responsible person's responsibilities with respect to maintaining a quality assurance program and taking remedial actions to maintain satisfactory laboratory operations.

Section 26.155(b) [Certifying scientist] amends former Section 2.5(b) in Appendix A to Part 26 to be consistent with changes made to the related requirement in the HHS Guidelines. Consistent with the HHS Guidelines, the rule provides more detailed requirements with respect to the individual who certifies test results at the HHS-certified laboratory before they are transmitted to the licensee or other entity's MRO.

In § 26.155(b)(1), a new job title, ''certifying scientist,'' replaces the term ''qualified individual(s)'' in the first sentence of former Section 2.5(b) in Appendix A to Part 26 for consistency with a related change in the HHS Guidelines. The final rule, with respect to the proposed rule, replaces the phrase ''attest the validity of'' with ''certify'' test results, as this is a more accurate description of the responsibilities of a certifying scientist. The NRC made this change in response to a comment received on the proposed rule. Section 26.155(b)(2) specifies the required qualifications of individuals who serve as certifying scientists. Section 26.155(b)(3) permits laboratories to use more than one certifying scientist with differing responsibilities.

Section 26.155(c) [Day-to-day operations and supervision of analysts] retains former Section 2.5(c) in Appendix A to Part 26. The rule makes minor language changes to the former paragraph to increase the consistency of the language in this provision with that of the related provision in the HHS Guidelines.

Section 26.155(d) [Other personnel] and (e) [Training] retains former Section 2.5(d) and (e) in Appendix A to Part 26, respectively.

Section 26.155(f) [Files] updates former Section 2.5(f) in Appendix A to Part 26. The revisions are consistent with related requirements in the HHS Guidelines.

Section 26.157 Procedures

Section 26.157 reorganizes and amends requirements for HHS-certified laboratories' procedures. The requirements for procedures were interspersed throughout former Appendix A to Part 26, including requirements contained in former Sections 2.2 and 2.7 in Appendix A to Part 26. The NRC has combined procedural requirements for the laboratories into a single section to improve organizational clarity in the rule.

In § 26.157(a), the agency has made minor editorial changes to the first sentence of former Section 2.2 in Appendix A to Part 26, but retains the former requirement for HHS-certified laboratories to have detailed procedures for conducting testing. The rule deletes the former reference to blood samples because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a). Reference to licensee testing facilities has been moved to § 26.127(a) in Subpart F for organizational clarity. The rule also deletes reference to procedures for specimen collections, because the NRC relocated procedural requirements for specimen collections to Subpart E in the final rule.

Section 26.157(b) combines and amends portions of the requirements in the first sentence of former Sections 2.4(d) and 2.7(a)(2) in Appendix A to Part 26 related to the content and implementation of specimen chain-of-custody procedures. The regulation retains the portions of the former paragraphs that required HHS-certified laboratories to develop, implement, and maintain written chain-of-custody procedures to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to another HHS-certified laboratory, and continuing until final disposition of the specimens. The former requirements related to licensee testing facilities have been moved to § 26.127(b) in Subpart F for organizational clarity. The rule also removes references to custody-and-control procedures for blood specimens because donors no longer have the option to request blood testing for alcohol, as discussed with respect to § 26.83(a).

The NRC has amended the portions of former Section 2.7(o)(1) in Appendix A to Part 26 that address the required content of procedures for HHS-certified laboratories. Section 26.157(c) retains the portions of the former provision that required laboratories to develop and maintain written procedures to specify all of the elements of the testing process, including, but not limited to, the principles of each test and the preparation of reagents, standards, and controls. The paragraph presents the required topics of the procedures in a list format in § 26.157(c)(1) through (c)(12) to clarify that each topic stands on its own. For organizational clarity, two portions of the former provision have been moved to other subparts of the rule that address related topics. The NRC relocated requirements for licensee testing facility procedures to § 26.127(c) in Subpart F. In addition, the rule moves the last two sentences of former Section 2.7(o)(1), which specify records retention requirements, to § 26.715(b)(4) of Subpart N [Recordkeeping and Reporting Requirements].

Section 26.157(d) amends former Section 2.7(o)(3)(iii) in Appendix A to Part 26. The final (and former) provision requires procedures for the setup and normal operation of testing instruments; a schedule for checking critical operating characteristics for all instruments; tolerance limits for acceptable function checks; and instructions for major troubleshooting and repair. The rule makes three changes to the former provision for organizational clarity. The paragraph presents the required topics of the procedures in a list format in § 26.157(d)(1)–(d)(3) to clarify that each topic stands on its own. The former requirement to maintain records of preventative maintenance has been relocated to § 26.715(b)(10) in Subpart N. And, the rule moves the former requirements that apply to licensee testing facilities to § 26.127(d) in Subpart F.

Section 26.157(e) amends former Section 2.7(o)(4) in Appendix A to Part 26, but continues to require documented corrective actions if systems are out of acceptable limits or errors are detected. The requirements in the former paragraph that apply to licensee testing facilities have been moved to § 26.127(e) in Subpart F for organizational clarity.

Section 26.159 Assuring Specimen Security, Chain of Custody, and Preservation

The NRC added § 26.159 to present in one section the requirements of the rule that apply to HHS-certified laboratories with respect to the safeguarding of specimen identity, integrity, and security. This organizational change consolidates requirements that were dispersed throughout the former rule.

Section 26.159(a) amends former Section 2.7(a)(1) in Appendix A to Part 26. This provision retains the first three sentences of former Section 2.7(a)(1) in Appendix A to Part 26, which required HHS-certified laboratories to be secure and accessible only to authorized personnel. For organizational clarity, the NRC moved the requirements that apply to licensee testing facilities to § 26.129(a) in Subpart F. The last sentence of the former paragraph, which establishes recordkeeping requirements, has been moved to § 26.715(b)(13) in Subpart N. In addition, the NRC has

revised the last sentence of the former paragraph to increase clarity in the requirement and expands the list of persons who are authorized to have access to the laboratory to include representatives of the Secretary of HHS and emergency responders. This change increases the consistency of Part 26 with the related provision in the HHS Guidelines.

Section 26.159(b) amends former Section 2.7(b)(1) in Appendix A to Part 26. That provision established requirements for receiving specimens at the HHS-certified laboratory and assuring their integrity and identity. The final rule makes several organizational changes to the former rule by dividing the provision into paragraphs § 26.159(b)(1) and (b)(2) for increased organizational clarity.

Section 26.159(b)(1) retains the former requirement for the HHS-certified laboratory to report evidence of tampering to licensees' or other entities' management within 24 hours of discovery, as well as the requirement for the laboratory to document any evidence of tampering on the specimen's custody-and-control form. The rule moves the former requirements related to licensee testing facilities to § 26.129(b) in Subpart F for organizational clarity. With respect to the proposed rule, the final rule adds several requirements to the provision.

The NRC has renumbered as § 26.159(b)(1)(i), but retained without change, the portion of proposed § 26.159(b)(1) that required licensee or other entity management personnel to ensure that an investigation is initiated if any indications of specimen tampering are identified, and take corrective actions if tampering is confirmed. The appropriate corrective actions will depend on the nature of the tampering identified as a result of the investigation. For example, if the investigation indicates that the tampering was an attempt to subvert the testing process and the persons involved are identified, the rule requires licensee and other entity management personnel to impose the sanctions in § 26.75(b) for a subversion attempt.

Section 26.159(b)(1)(ii) requires the licensee and other entity to collect another specimen as soon as possible, if the licensee or other entity has reason to question the integrity and identity of a specimen. With respect to the proposed rule, the final rule eliminates the need to collect another specimen if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. If this circumstance arises and the licensee testing facility has retained the specimen in Bottle B and it is intact, the rule requires the licensee testing facility to forward the intact specimen for testing to the HHS-certified laboratory. The NRC added this provision to the final rule in response to public comments on the related provision in the proposed rule. The commenters requested the NRC to include this provision from DOT's procedures. The NRC agreed with the commenters' suggestion because eliminating the recollection when an intact specimen is available reduces the burden on donors that a recollection would impose.

The final rule, with respect to the proposed rule, establishes a new section, § 26.159(b)(2) to specify the exclusive grounds requiring an MRO to cancel a test. The NRC added this section in response to public comments received on the proposed rule that requested this clarification. Section 26.159(b)(2)(i) requires the MRO to cancel a test if the custody and control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity. Section 26.159(b)(2)(ii) requires the MRO to cancel a test if the identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form. Section 26.159(b)(2)(iii) requires the MRO to cancel a test if a specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist. Section 26.159(b)(2)(iv) requires the MRO to cancel a test if the specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist. Section 26.159(b)(2)(v) requires the MRO to cancel a test if the provisions of § 26.165(f)(2) apply. The NRC incorporated these requirements from the related DOT procedures.

Section 26.159(c) updates and combines former Section 2.7(b)(2) in Appendix A to Part 26 with portions of former Sections 2.7(n) and 3.1 in Appendix A to Part 26. These regulations in the former rule established requirements for chain-of-custody procedures for specimens and aliquots at licensee testing facilities and HHS-certified laboratories. For organizational clarity, the NRC has relocated the requirements in the former paragraphs that are related to licensee testing facilities to § 26.129(c) in Subpart F. The final rule retains the requirements in former Sections 2.7(n) and 3.1 in Appendix A to Part 26, which require the laboratory to maintain the original specimen and custody-and-control form in secure storage at the HHS-certified laboratory. The NRC made these changes to reduce redundancies and improve the organizational clarity of the rule.

Section 26.159(d) and (e) updates the portions of former Section 2.7(a)(2) in Appendix A to Part 26 that established requirements for HHS-certified laboratory personnel to maintain and document the chain of custody for specimens and aliquots, by replacing the former paragraph with two related provisions from the HHS Guidelines. Paragraph (d) in this section requires the laboratory's internal custody-and-control form to allow for identification of the donor, documentation of the testing process and transfers of custody of the specimen. The agency added the phrase, ''within the laboratory,'' to paragraph (e) of this section to clarify that the requirement to document each instance of handling and transfer of specimens applies to internal laboratory activities and does not apply to transfers involving couriers. For organizational clarity, the rule relocates the requirements in the former paragraph that are related to licensee testing facilities to § 26.129(d) and (e) in Subpart F.

Section 26.159(f) and (g) separates former Section 2.4(i) in Appendix A to Part 26 into two paragraphs, for the reasons discussed with respect to the similar provisions of § 26.117(i) and (k) and § 26.129(g) and (h). The paragraphs repeat the requirements for packaging and shipping positive, adulterated, substituted, or invalid specimens that have been presented in § 26.117(i) and (k) of Subpart E and § 26.129(g) and (h) in Subpart F, but apply them to packaging and shipping specimens from one HHS-certified laboratory to another. The bases for these requirements are discussed with respect to § 26.117(i) and (k). With respect to the proposed rule, the final rule clarifies § 26.159(f) to ensure that a copy of the custody-and-control form, rather than the original custody-and-control form, is included with an aliquot of a single specimen or Bottle B of a split specimen that is transferred to a second HHS-certified laboratory for testing. The NRC made this change in response to a public comment on this provision that noted the proposed provision was inconsistent with the related requirement in the HHS Guidelines.

Section 26.159(h) replaces former Section 2.7(c) in Appendix A to Part 26. The former provision established requirements for refrigerating urine

specimens at the HHS-certified laboratory and licensee testing facility to protect them from degradation. The rule replaces the former paragraph with the simplified language of the related provision in the HHS Guidelines. The NRC moved the requirements related to short-term refrigerated storage at licensee testing facilities to § 26.129(f) in Subpart F for organizational clarity. The final rule, with respect to the proposed rule, adds the Fahrenheit temperature level that is equivalent to the Celsius temperature level included in the proposed rule to improve the clarity of the final rule.

In § 26.159(i), the NRC amends former Section 2.7(h) in Appendix A to Part 26. The former requirement established requirements for long-term frozen storage of positive urine specimens at HHS-certified laboratories and licensee testing facilities. For organizational clarity, the NRC moved the requirements related to long-term storage of specimens by licensee testing facilities to § 26.135(c) in Subpart F. The rule adds requirements for storing specimens that yield adulterated, substituted, or invalid test results from specimen validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). The NRC has eliminated the reference to ''administrative or disciplinary proceedings'' in the first sentence of the former paragraph because there are other circumstances in which it may be necessary to have a specimen available for retesting, including, but not limited to, retesting an aliquot of an invalid specimen at a second HHS-certified laboratory under § 26.161(g). The rule also updates the terminology used in the former paragraph by adding a reference to ''Bottle B'' of a split specimen. As discussed with respect to § 26.5 [Definitions], these changes in terminology are intended to improve clarity in the language of the rule.

The NRC added § 26.159(j) to incorporate related changes to the HHS Guidelines. The final rule permits the HHS-certified laboratory to discard negative specimens. This paragraph also permits laboratories to pool specimens that are certified to be negative for drugs and drug metabolites and valid, as well as use them as quality control samples, as permitted under the HHS Guidelines. With respect to the proposed rule, the final rule prohibits the laboratory from retaining any information linking donors to specimens that are pooled for use in the laboratory's internal quality control program. The NRC added this prohibition in response to a public comment received on the proposed rule. This addition meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Section 26.161 Cutoff Levels for Validity Testing

A new § 26.161 establishes maximum cutoff levels and methods for conducting specimen validity testing at HHS-certified laboratories, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). The rule incorporates these requirements from the HHS Guidelines as revised on April 13, 2004, (69 FR 19644) to meet, in part, Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. This section prohibits licensee and other entities from using more stringent validity test cutoff levels to ensure consistency among licensees and other entities and reduce the likelihood of false adulterated, substituted, or invalid test results, and ensure that donors are not subject to sanctions on the basis of inaccurate test results. The prohibition supports Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC added § 26.161(a) to specify that HHS-certified laboratories must conduct initial and, if necessary, confirmatory validity testing using two different aliquots of a urine specimen. This provision incorporates the related provision from the HHS Guidelines. With respect to the proposed rule, the final rule revises the provision to clarify that confirmatory testing of a second aliquot is required if initial validity test results indicate that the specimen may be adulterated, substitute, dilute, or invalid. The final rule also adds a requirement that licensees and other entities must ensure that the HHS-certified laboratory is capable of conducting, and conducts, confirmatory testing for at least one oxidizing adulterant and any other adulterants for which the licensee's or other entity's FFD program conducts testing. The agency made these changes in response to public comments and to improve clarity in the language of the rule.

The agency added § 26.161(b) to establish requirements and cutoff levels for initial validity tests to be performed at HHS-certified laboratories. With respect to the proposed rule, the final rule renumbers these paragraphs to improve the organization and clarity of the rule. Section 26.161(b)(1) through (b)(5) establishes requirements for initial validity tests that HHS-certified laboratories must conduct on a primary specimen. The primary specimen is either a single specimen submitted by an FFD program that does not follow split specimen procedures, or the specimen contained in Bottle A of a split specimen. For initial validity tests of each specimen, HHS-certified laboratories will determine the creatinine concentration of each specimen under § 26.161(b)(1). If the creatinine concentration is less than 20 mg/dL, the laboratory will determine the specimen's specific gravity under § 26.161(b)(2). Section 26.161(b)(3) requires the laboratory to determine each specimen's pH. Section 26.161(b)(4) requires the laboratory to test the specimen for the presence of oxidizing adulterants, and § 26.161(b)(5) requires additional validity testing, depending on the characteristics of the specimen.

With respect to the proposed rule, the final rule deletes proposed § 26.161(b)(2). The proposed paragraph specified the results from initial validity testing that would indicate the need for the HHS-certified laboratory to conduct confirmatory validity testing. The NRC deleted this paragraph in the final rule because the criteria it contained repeated the criteria embedded in § 26.161(c)–(f). In addition, the HHS Guidelines do not include these criteria separately. Therefore, this revision increases the consistency of Part 26 with the related provisions in the HHS Guidelines.

The final rule adds § 26.161(c) to establish criteria for HHS-certified laboratories to apply in determining whether to report to a licensee's or other entity's MRO that a specimen is adulterated. Section 26.161(c)(1) through (c)(8) specifies results from initial and confirmatory validity testing that indicate that a specimen is adulterated. The paragraphs also specify the appropriate testing devices and instruments to be used for initial and confirmatory validity tests. In general, the paragraphs require the HHS-certified laboratory to report to the MRO that a urine specimen is adulterated if it meets any one of the following criteria: (1) It is confirmed to contain a substance that should not be present at all in normal human urine; (2) it is confirmed to contain a substance which, although it could be present in normal human urine, is found to be at a concentration that appears to be inconsistent with human physiology; or (3) it presents an acid/base balance (pH) that appears to be inconsistent with human life. The paragraphs address several substances

that some donors have used to try to defeat drug tests through ''in vitro'' contamination (i.e., adding the substance to a urine specimen). These adulterants include substances that create a urine pH inconsistent with human life, oxidizing adulterants, chromium (VI), halogens, glutaraldehyde, pyridine, and surfactants. These substances, when either placed into an already voided urine specimen or used in place of a urine specimen, generally either attempt to defeat the chemistry of the test or destroy a drug that is present. The NRC recognizes that this list will be updated and/or modified as new substances and formulas are introduced, and methods to detect them have been developed and implemented by HHS-certified laboratories. Section 26.161(c)(8) recognizes that new adulterants will be found and, therefore, requires HHS-certified laboratories to use appropriate testing methods when conducting initial and confirmatory testing for new adulterants for which cutoff levels and criteria have not yet been established.

Section 26.161(d) and (e) establishes cutoff levels and criteria for a determination by the laboratory that a specimen has been substituted or is dilute, respectively. In § 26.161(d), the HHS-certified laboratory will report to the MRO that a specimen is substituted if it contains less than 2 mg/dL of creatinine and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200. These low creatinine concentrations combined with the highly skewed specific gravity values indicate that the specimen is not human urine. In § 26.161(e), the HHS-certified laboratory is required to report to the MRO that a specimen is dilute if the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specimen specific gravity is greater than 1.0010 but less than 1.0030.

The NRC added § 26.161(f)(1) through (f)(12) to establish the criteria that HHS-certified laboratories apply when determining that a specimen is invalid. In 1998, HHS established criteria for what were termed ''unsuitable'' specimens (Program Document 35, September 28, 1998). An unsuitable specimen was defined as one that contained an interfering substance but the laboratory could not determine the nature of the substance with scientific certainty. In these circumstances, the laboratory could not achieve a ''valid'' test result. The HHS recognized that in some cases, an interfering substance could be a legitimately ingested medication (some non-steroidal anti-inflammatory drugs have been known to interfere with the chemistry of some of the initial tests). However, it was also recognized that many of these problem specimens actually contained an adulterant that the laboratory could not specifically identify with ''scientific certainty'' which is the requirement for reporting a specimen as adulterated. Therefore, the HHS adopted the term ''invalid specimen'' to mean that the laboratory has determined that valid test results cannot be obtained from a specimen or an unknown substance interfered with the confirmatory test. The rule adopts the term ''invalid specimen'' with the same meaning.

The rule adds § 26.161(g) to address circumstances in which an HHS-certified laboratory suspects that a specimen is adulterated but cannot identify the adulterant. The paragraph permits the laboratory to transfer the specimen to a second HHS-certified laboratory for additional testing, if the first HHS-certified laboratory cannot identify a possible adulterant in the specimen using their standard testing technologies and the licensee's or other entity's MRO concurs with the additional testing. Personnel at the first HHS-certified laboratory will consult with the licensee's or other entity's MRO to determine whether to transfer the specimen to a second laboratory for additional testing.

The agency added § 26.161(h) to prohibit licensees and other entities from requiring an HHS-certified laboratory to apply validity testing cutoff levels and criteria that are more stringent than those specified in this proposed section. Because validity testing is complex and the methods for testing are relatively new, the rule does not permit an FFD program to establish more stringent cutoff levels for validity testing. The prohibition is necessary to decrease the risk of obtaining false adulterated, substituted, or invalid test results and ensure that donors are not subject to sanctions on the basis of inaccurate test results.

Section 26.163 Cutoff Levels for Drugs and Drug Metabolites

Section 26.163 groups together in one section, for organizational clarity, the requirements for conducting initial and confirmatory tests for drugs and drug metabolites at HHS-certified laboratories. The section also updates requirements related to cutoff levels for drugs and drug metabolites in the former rule to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.163(a) [Initial drug testing] amends former Section 2.7(e) in Appendix A to Part 26. When determining whether to report to the MRO that a specimen is positive for drug(s) or drug metabolite(s), § 26.163(a)(1) requires HHS-certified laboratories to apply the same cutoff levels that licensee testing facilities are required to use in § 26.133, except if the FFD program specifies more stringent cutoff levels or the specimen is dilute, as discussed further in § 26.163(a)(2). The paragraph reiterates the former permission for licensees and other entities to establish lower cutoff levels. In addition, § 26.163(a)(1) decreases the initial test cutoff level for marijuana metabolites from 100 nanograms (ng) per milliliter (mL) to 50 ng/mL and increases the initial test cutoff level for opiate metabolites from 300 ng/mL to 2,000 ng/mL for the reasons discussed with respect to § 26.133. The changes are consistent with the HHS cutoff levels for the same substances.

A new § 26.163(a)(2) establishes requirements and criteria for the initial drug testing of any specimen that confirmatory validity testing indicates is dilute. Although there are many legitimate reasons that a donor may provide a urine specimen that is dilute, dilution is also a method used to subvert the testing process. Dilution of a specimen decreases the concentration of any drugs or drug metabolites in the specimen. Dilution may decrease the concentration sufficiently that applying the cutoff levels specified in this part, or a licensee's or other entity's more stringent cutoff levels, would provide false negative drug test results. Therefore, the rule adds special testing procedures and criteria for determining which dilute specimens must be subject to confirmatory drug testing. With respect to the proposed rule, the NRC has eliminated the optional provision for FFD programs to test specimens with initial validity test results that indicate a specimen is dilute using FDA approved kits for the lowest concentration levels marketed for the technologies being used to conduct initial testing of specimens for drug or drug metabolites. This change is based on a comment received on the proposed provision. Instead, the NRC is adopting the procedure proposed by the commenter. That is, for dilute specimens, the final rule permits an FFD program to request the HHS-certified laboratory to conduct confirmatory testing of dilute specimens at the confirmatory assay's LOD for a drug or drug class, if the response to the initial drug test for any drug class for

which testing is performed is within 50 percent of the cutoff calibrator level. The NRC agrees that the commenter's approach is consistent with the intent of the proposed provision, while reducing the burden on HHS-certified laboratories imposed by the proposed requirements. This special processing of dilute specimens increases the likelihood that any drugs and drug metabolites in the specimen will be detected. Therefore, this requirement meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs, by increasing the likelihood that testing of dilute specimens will reveal drug use if the donor had engaged in substance abuse.

As discussed with respect to § 26.133, the final rule eliminates the requirement in the last sentence of former Section 2.7(e)(1) of Appendix A to Part 26 for HHS-certified laboratories to report drug test results for both the cutoff levels in the rule and any more stringent cutoff levels that the licensee or other entity may establish. The basis for the former requirement to report test results for the cutoff levels specified in this part, when the licensee is using more stringent cutoff levels, was a means by which the NRC monitored implementation of the permission to use more stringent cutoff levels. The rule eliminates this requirement, because § 26.31(d)(3)(iii)(C) requires a qualified forensic toxicologist to certify the scientific and technical validity of any testing at lower cutoff levels. Therefore, the former reporting requirement is no longer needed to ensure laboratory performance in this area. Eliminating this requirement meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

The rule also eliminates former Section 2.7(e)(2) in Appendix A to Part 26. The former provision stated that the list of substances and cutoff levels contained in Appendix A to Part 26 were subject to change by the NRC. At the time the former rule was published, the NRC expected to be able to amend the list of substances and cutoff levels in the former rule without additional rulemaking. However, the NRC has determined that rulemaking is required to make such changes. Therefore, the rule deletes this paragraph because it is unnecessary.

The final rule replaces former Section 2.7(f) in Appendix A to Part 26 with § 26.163(b) [Confirmatory drug testing]. The former provision established cutoff levels and requirements related to confirmatory testing for drugs and drug metabolites at the HHS-certified laboratory. The rule also makes a number of changes to the former paragraph.

The agency has moved former Section 2.7(f)(1) in Appendix A to Part 26 to § 26.169(b)(1) of the final rule. Former Section 2.7(f)(1) required the HHS-certified laboratory to report to the MRO that test results are negative for any specimens that yield negative test results when they are subjected to confirmatory testing. The NRC moved this requirement to § 26.169(b)(1) for organizational clarity because § 26.169 addresses the topic of reporting test results by the HHS-certified laboratory to the MRO.

The NRC has also eliminated the requirement in former Section 2.7(f)(1) in Appendix A to Part 26 that the laboratory must conduct confirmatory testing using both the maximum cutoff values established in Part 26 as well as any more stringent cutoff levels adopted by the licensee's or other entity's FFD program. The former requirement to conduct testing for the cutoff levels specified in this part, when the licensee is using more stringent cutoff levels, was a means by which the NRC monitored implementation of the permission to use more stringent cutoff levels. The rule eliminates this requirement, because § 26.31(d)(3)(iii)(C) requires a qualified forensic toxicologist to certify the scientific and technical validity of any testing at lower cutoff levels. Therefore, the requirement to test at both cutoff levels is no longer needed to assure laboratory performance in this area.

For organizational clarity, the NRC has moved the first sentence of former Section 2.7(f)(2) in Appendix A to Part 26 that required the laboratory to use GC/MS techniques for confirmatory testing to § 26.167(e)(1) in the final rule. Section 26.167(e)(1) addresses quality control requirements for conducting confirmatory drug tests.

The rule eliminates former Section 2.7(f)(3) in Appendix A to Part 26. The former provision required HHS-certified laboratories to use GC analysis of blood specimens in testing for alcohol. The final rule also eliminates the confirmatory alcohol cutoff level in former Section 2.7(f)(1) in Appendix A to Part 26. The NRC eliminated these provisions because the rule no longer permits donors to request confirmatory testing of a blood specimen for alcohol, as discussed with respect to § 26.83(a).

In addition, the rule eliminates former Section 2.7(f)(4) in Appendix A to Part 26 for the same reasons discussed with respect to former Section 2.7(e)(2) in Appendix A to Part 26.

Section 26.163(b)(1) amends several of the cutoff levels in former Section 2.7(f)(1) in Appendix A to Part 26 that the HHS-certified laboratory uses to determine that a confirmatory drug test result is positive. The rule increases the confirmatory test cutoff levels for morphine and codeine to 2,000 ng/mL. This change in the cutoff level for opiate metabolites substantially reduces the number of positive opiate test results that are reported to MROs by HHS-certified laboratories that MROs ultimately verify as negative and is consistent with the opiate cutoff levels contained in the HHS Guidelines.

Section 26.163(b)(1) also amends two of the testing procedures in former Section 2.7(f) in Appendix A to Part 26. The rule amends former Section 2.7(f)(5) in Appendix A to Part 26, which required the laboratory to test for 6-acetylmorphine (6–AM) if a specimen tests positive for opiates on the initial drug test. The rule requires the HHS-certified laboratory to test for 6–AM, if test results for morphine are at or above the 2,000 ng/mL opiate cutoff levels, and establishes a cutoff level of 10 ng/mL for determining that a specimen is positive for 6–AM. In addition, § 26.163(b)(1) adds a requirement that a specimen must also contain amphetamine at a concentration equal to or greater than 200 ng/mL in order for the HHS-certified laboratory to report to the MRO that the specimen has yielded a positive test result for methamphetamine. These changes are consistent with the related provisions in the HHS Guidelines.

Section 26.163(b)(1) updates the terminology used in former Section 2.7(f)(1) in Appendix A to Part 26. As discussed with respect to § 26.5, the final rule replaces the term ''presumptive positive'' with the phrase ''positive on an initial drug test'' to increase clarity in the language of the rule.

A new § 26.163(b)(2) amends the second sentence of former Section 2.7(f)(2) in Appendix A to Part 26. The former sentence required the HHS-certified laboratory to document drug and drug metabolite concentrations that exceed the linear region of the standard curve in the laboratory record. The rule replaces the former sentence with a paragraph that incorporates the related provision from the HHS Guidelines. The HHS Guidelines permit the laboratory to dilute an aliquot of the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range. This change has been made to meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.165 Testing Split Specimens and Retesting Single Specimens

Section 26.165 reorganizes and amends the requirements formerly found in § 26.24(f), and Section 2.7(i) and (j) in Appendix A to Part 26 that related to testing split specimens and retesting specimens at HHS-certified laboratories. For organizational clarity, the final rule groups the requirements together in a single section to make them easier to locate in the rule. The section also adds several new requirements.

Section 26.165(a) [Testing split specimens] combines and amends former § 26.24(f) and Section 2.7(j) in Appendix A to Part 26. Those provisions established requirements for HHS-certified laboratories when testing split specimens. The final rule uses the terms ''Bottle A'' and ''Bottle B'' to refer to the primary and split specimens, respectively, for consistency with the updated terminology used throughout the rule. The rule also requires specimen validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i).

Section 26.165(a)(1) retains the portions of former Section 2.7(j) in Appendix A to Part 26 that required the HHS-certified laboratory to analyze the primary specimen of a split specimen. The former requirements related to licensee testing facilities in this section have been moved to § 26.135 in Subpart F for organizational clarity. This paragraph retains the former requirement that the primary specimen (Bottle A) must be subject to initial testing by the HHS-certified laboratory, and confirmatory testing, if the results of initial testing indicate that the specimen is positive. The final rule adds a requirement for HHS-certified laboratories also to conduct initial and, if necessary, confirmatory validity testing of the specimen in Bottle A of a split specimen.

Section 26.165(a)(2) retains the portion of the second sentence of former § 26.24(f) that required the HHS-certified laboratory to perform initial and confirmatory tests, if required, on the primary specimen in Bottle A, even if a licensee testing facility conducted initial testing on an aliquot of the specimen. The NRC moved the former requirement to this section for organizational clarity. With respect to the proposed rule, the final rule replaces the term ''non-negative'' in the proposed rule with the more specific terms ''positive'' and ''of questionable validity'' to refer to the results of testing at the licensee testing facility. The agency made this change to improve the clarity of the rule's language.

Section 26.165(a)(3) retains the authorization in the second sentence of former Section 2.7(j) in Appendix A to Part 26 for licensee testing facilities to retain custody of the split specimen in Bottle B or forward it with Bottle A to the HHS-certified laboratory for storage until testing of Bottle A is completed. The final rule also retains the former authorization for the specimens in Bottle A and Bottle B to be discarded if test results from the HHS-certified laboratory are negative. With respect to the proposed rule, the final rule makes minor editorial changes to this provision to increase the clarity of the language. In addition, the final rule adds cross-references to § 26.135(a) and (c). These provisions contain requirements for storing Bottle B of a split specimen at a licensee testing facility, if the licensee testing facility chooses to retain Bottle B rather than forwarding it with Bottle A to the HHS-certified laboratory. The NRC made these changes to improve clarity in the language of the rule and in response to a public comment requesting the clarifications.

The NRC added § 26.165(b) [Donor request to MRO for a retest of a single specimen or testing Bottle B of a split specimen] to permit donors to request retesting of an aliquot from a single specimen, if the FFD program does not follow split specimen procedures, and testing of Bottle B if the program follows split specimen procedures. This paragraph assures that donors who are subject to a program that does not follow split specimen procedures have the right to request additional testing. With respect to the proposed rule, the final rule combines and reorganizes the provisions in proposed § 26.165(b) pertaining to a donor's request for retesting a single specimen with those in proposed § 26.165(c) pertaining to a donor's request for testing of Bottle B of a split specimen. The agency made these changes in response to a public comment. The commenter noted that the separate paragraphs in the proposed rule contained redundant requirements and that separating the requirements into two paragraphs was inconsistent with the related provisions in the HHS Guidelines. Therefore, the NRC also changed the title of this section from ''Donor request to MRO for a retest of a single specimen'' in the proposed rule to ''Donor request to MRO for a retest of a single specimen or testing of Bottle B of a split specimen'' in the final rule.

Section 26.165(b)(1) assures that donors may request through the MRO additional testing of an aliquot from a single specimen or testing of Bottle B by a second HHS-certified laboratory. This permission is consistent with related provisions in the HHS Guidelines and amends the requirements in former Section 2.7(j) in Appendix A to Part 26 that pertained to donor requests to test the specimen in Bottle B. The final rule permits donors to request retesting of an aliquot of a single specimen by a second HHS-certified laboratory to protect donors' rights to retesting under FFD programs that do not follow split specimen procedures. The rule adds confirmed adulterated and substituted validity test results as bases for a donor request for testing the specimen in Bottle B or retesting an aliquot of a single specimen, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). However, in order to have sufficient urine to support retesting, the paragraph applies only if the donor had originally submitted a specimen of 30 mL or more in a single specimen, or a specimen in Bottle A. Specimens that the HHS-certified laboratory determines to be invalid are not eligible for retesting because of the risk of damage to laboratory equipment that some invalid specimens may pose and because retesting the specimen would not provide useful information. The procedures for requesting and conducting the retest of a single specimen are consistent with those for requesting and conducting tests on the specimen in Bottle B of a split specimen in the final rule.

Section 26.165(b)(2) adds a requirement for the MRO to inform the donor that he or she may, within 3 business days of notification by the MRO of a confirmed positive, adulterated, or substituted test result, request a retest of an aliquot of a single specimen or, as appropriate, Bottle B of a split specimen. The NRC also added a requirement that the donor must request retesting an aliquot of a single specimen or testing the Bottle B specimen within 3 business days after notification by the MRO that a single specimen or the specimen in Bottle A of a split specimen has yielded positive, adulterated, or substituted test results. Since 1994, the HHS Guidelines have allowed up to 72 hours for a donor to make this request, so this change increases the consistency of Part 26 with the HHS Guidelines. This provision combines proposed § 26.165(a)(4) and (b)(1) into one paragraph for the reasons discussed with respect to § 26.165(b).

The final rule, with respect to the proposed rule, includes a new

requirement that the MRO must provide the donor with specific contact information and have the ability to verify the time the donor's call was received by the MRO's office if telephone notifications for retesting are the preferred method of the MRO's office. The NRC added this provision in response to a public comment received on the proposed rule that requested the addition to further protect donors' rights under the rule. The requirement is consistent with related requirements in the DOT's drug and alcohol testing procedures and, therefore, meets Goal 1 of the this rulemaking to enhance the consistency of Part 26 with the related regulations of other Federal agencies.

In § 26.165(b)(2) of the final rule, the NRC has modified the requirement in proposed § 26.165(a)(4) that a donor must inform the MRO in writing of his or her request to conduct testing of an aliquot of the single specimen or the specimen contained in Bottle B at a second HHS-certified laboratory. This change is based on public comments received on the proposed rule which stated that requiring a donor to make a written request for additional specimen testing would be unduly restrictive given that other Federal agencies permit the donor to make these requests verbally. The NRC agrees that a donor should be provided with as much flexibility as possible, while ensuring the request is made in a secure and accurate manner. Therefore, the final rule permits the donor to make his or her request for additional testing verbally to the MRO or in writing. This change meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal drug and alcohol testing programs.

Section 26.165(b)(3) combines into one paragraph the requirements that were contained in the last sentences of proposed § 26.165(a)(4) and (b)(1) for the reasons discussed with respect to § 26.165(b). The final rule requires permission from the donor for testing Bottle B of a split specimen or retesting an aliquot of a single specimen and prohibits the MRO, NRC, or any other entity from requiring additional tests of a donor's specimen without his or her permission. These limitations are consistent with the principle established in § 26.31(d)(6) that affirms the donor's right to retain control over his or her specimen. Therefore, adding this provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

In § 26.165(b)(4) of the final rule, with respect to the proposed rule, the NRC has added a new provision that permits a donor to present to the MRO evidence supporting the inability of the donor to make a timely request for retesting of a single specimen or the testing of the Bottle B specimen after the 3-business-day period permitted has elapsed. For example, a donor may have been severely ill when informed of a confirmed positive, adulterated, or substituted test result and was unable to contact the MRO to make the request because of hospitalization. On the basis of the information the donor presents, the MRO will make the sole determination whether the circumstances described unavoidably prevented the donor from making a timely request. If the MRO makes this determination, he or she will direct a retest of an aliquot of a single specimen or testing of Bottle B of a split specimen by a second HHS-certified laboratory, as if a timely request was made. The NRC added this provision in response to public comments on the proposed rule, and has incorporated the related requirement in the DOTs' procedures. The added provision protects donors' rights to fair and consistent testing procedures under the rule, consistent with Goal 7 of this rulemaking, and meets Goal 1 to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.165(b)(5) requires the MRO, in response to a donor's timely request for a retest of an aliquot of a single specimen or testing of Bottle B of a split specimen, to ensure that either the HHS-certified laboratory forwards an aliquot of a single specimen, or the HHS-certified laboratory or licensee testing facility forwards Bottle B of a split specimen, as appropriate, to a second HHS-certified laboratory that did not test the specimen in Bottle A. This paragraph amends the requirement in the fourth sentence of former Section 2.7(j) in Appendix A to Part 26, which required that the split specimen must be forwarded to another HHS-certified laboratory for testing on the same day of the donor request. The final rule requires the licensee testing facility or HHS-certified laboratory, as applicable, to forward Bottle B of a split specimen or the aliquot of a single specimen to a second laboratory as soon as reasonably practical and not more than 1 business day following the day of the donor's request. The NRC amended the former provision to respond to stakeholder comments during the public meetings discussed in Section I.D. The stakeholders indicated that implementing the ''same-day'' requirement for forwarding Bottle B in former Section 2.7(j) of Appendix A to Part 26 has often been difficult for a number of reasons. These reasons included communication delays among donors, MROs, the HHS-certified laboratory, and FFD program personnel, particularly on weekends, holidays, and the time required to identify a second HHS-certified laboratory with the appropriate capability to test the specimen, depending on the nature of the positive test result. The change alleviates some types of logistical problems associated with weekends and holidays while continuing to provide the donor with timely test results. This change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. The final rule renumbers proposed § 26.165(a)(5) as § 26.165(b)(5) for the reasons discussed with respect to § 26.165(b).

Section 26.165(b)(6) retains the last sentence of former Section 2.7(j) in Appendix A to Part 26. This provision requires the second HHS-certified laboratory to provide quantitative test results from Bottle B to the MRO, who provides them to the donor. The rule adopts the simpler language from the related provision in the HHS Guidelines, consistent with Goal 6 of this rulemaking to improve clarity in the language of the rule. This provision also extends the former requirement to apply to communicating results from retesting an aliquot of a single specimen, consistent with the explicit permission the NRC has added for a donor to request retesting of a single specimen if the FFD program does not follow split specimen procedures. With respect to the proposed rule, § 26.165(b)(6) combines the redundant requirements in proposed § 26.165(a)(6) and (c)(4) for the reasons discussed with respect to § 26.165(b).

Section 26.165(c) [Retesting a specimen for drugs] amends former Section 2.7(i) in Appendix A to Part 26, which specified that retesting of a specimen is not subject to cutoff requirements. This paragraph updates and expands the former requirements for retesting a single specimen or Bottle B of a split specimen for drugs and drug metabolites to be consistent with the related provisions in the HHS Guidelines, as follows:

The NRC added § 26.165(c)(1) to require the second HHS-certified laboratory to use the laboratory's confirmatory test for the drug or drug metabolite for which the specimen tested positive at the first laboratory. The second HHS-certified laboratory will not conduct initial tests, or tests for

other drugs or drug metabolites, consistent with the related requirements in the HHS Guidelines. With respect to the proposed rule, for completeness, the final rule adds a reference to conducting confirmatory tests on specimens that the first laboratory confirmed to be positive and dilute as a result of the special analysis permitted in § 26.169(a)(2). In addition, in response to a public comment, the final rule eliminates the reference to the second laboratory's ''standard'' confirmatory drug test in the proposed provision because HHS-certified laboratories do not have ''standard'' confirmatory drug tests. The NRC made this change to enhance clarity in the language of the rule.

Section 26.165(c)(2) amends former Section 2.7(i) in Appendix A to Part 26, which specified that retesting of a specimen is not subject to cutoff requirements. The paragraph retains the requirement for the second HHS-certified laboratory to provide data sufficient to confirm the presence of the drug(s) or drug metabolite(s) and adds permission to test the specimen at the assay's LOD. This addition ensures that the second laboratory's testing is as sensitive to the presence of the drug(s) or drug metabolite(s) as is scientifically and legally defensible.

The NRC has added § 26.165(c)(3) to require the second laboratory, if retesting fails to confirm the presence of the drug(s) or drug metabolite(s) identified by the first HHS-certified laboratory, to attempt to determine the reason why it could not reconfirm the drug test results from the first laboratory. The provision requires the second laboratory to conduct specimen validity testing if the second laboratory fails to reconfirm the first laboratory's findings, consistent with the related requirements in the HHS Guidelines.

Section 26.165(c)(4) retains the requirement in the last sentence of former Section 2.7(j) in Appendix A to Part 26 that requires the second laboratory to report the test results of testing a split specimen to the MRO. The rule extends this requirement to reporting results from retesting an aliquot of a single specimen, consistent with the explicit permission the rule adds in § 26.165(b) for a donor to request retesting of a single specimen if the FFD program does not follow split specimen procedures. The requirement is consistent with the related requirements in the HHS Guidelines.

The NRC added § 26.165(d) [Retesting a specimen for adulterants] to incorporate related requirements in the HHS Guidelines for performing retests for adulterants at a second HHS-certified laboratory. The final rule limits retesting for adulterants to conducting confirmatory testing only for the adulterant(s) identified by the first laboratory. This limitation is consistent with limitations on retesting specimens for drugs and drug metabolites in the related requirements of the HHS Guidelines. With respect to the proposed rule, the final rule, when discussing confirmatory validity testing in § 26.165(d), replaces the phrase ''appropriate confirmatory test'' with ''required confirmatory test'' in response to a comment received on the proposed rule. The commenter noted that the confirmatory testing requirements in § 26.161(d) are ''required'' rather than ''appropriate,'' and the NRC concurs. The agency made this change to enhance the consistency of the final rule with the HHS Guidelines and improve clarity in the language of the rule.

The NRC added § 26.165(e) [Retesting a specimen for substitution] to incorporate related requirements in the HHS Guidelines for performing retests on substituted specimens at a second HHS-certified laboratory. The rule limits retesting for specimen substitution to conducting confirmatory testing only for creatinine and specific gravity. This limitation is consistent with limitations on retesting specimens for drugs and drug metabolites and the related requirements in the HHS Guidelines. With respect to the proposed rule, the final rule eliminates the second sentence of the proposed provision in response to a public comment that noted it was inconsistent with the related provision in the HHS Guidelines.

Section 26.165(f) [Management actions and sanctions] has been added to specify the management actions that licensees and other entities must take when a donor requests a retest of a single specimen or testing of Bottle B of a split specimen. The NRC added this paragraph to establish the requirements for management actions and sanctions when an individual has had a confirmed positive, adulterated, or substituted test result and requests a retest of a single specimen or Bottle B of a split specimen. This section responds to stakeholder comments at the public meetings discussed in Section I.D. The stakeholders noted that the former rule did not address required management actions when an individual has had a confirmed positive test result and requests a retest of a single specimen or Bottle B of a split specimen. Therefore, the NRC added this section to establish such requirements.

The agency added § 26.165(f)(1) to address circumstances in which the MRO has confirmed a positive, adulterated, or substituted test result from the first HHS-certified laboratory that tested the specimen as a violation of the licensee's or other entity's FFD policy and the donor requests a retest of a single specimen or testing of the specimen in Bottle B. This provision requires the licensee or other entity to take the same actions in response to the confirmed positive, adulterated, or substituted test result(s) from the first HHS-certified laboratory, as explained in § 26.75(i), in response to a positive drug test result for marijuana or cocaine from initial testing at a licensee testing facility. That is, § 26.165(f)(1) requires the licensee or other entity to administratively withdraw the donor's authorization until the test results from the second HHS-certified laboratory have been reported to and reviewed by the MRO. If the test results from the second laboratory reconfirm any positive, adulterated, or substituted test results from the first HHS-certified laboratory, the rule requires the licensee or other entity to impose the appropriate sanctions that are specified in subpart D for any positive, adulterated, or substituted results that were confirmed by the second laboratory. If the test results from the second laboratory do not reconfirm the positive, adulterated, or substituted test results from the first laboratory, the rule (1) prohibits the licensee or other entity from imposing any sanctions on the individual; (2) requires the licensee or other entity to eliminate any records of the first confirmed positive, adulterated, or substituted results; and (3) requires the licensee or other entity to inform the donor, in writing, that the records have been expunged and that he or she need not disclose the temporary administrative action to any other licensee or entity. These requirements protect public health and safety and the common defense and security by ensuring that an individual whose fitness for duty is questionable does not perform any duties or have the types of access that require the individual to be subject to this part, while serving to protect the privacy rights of individuals who are subject to Part 26 and ensure that the individuals are afforded accurate and consistent testing.

The NRC added § 26.165(f)(2) to address the unlikely circumstances in which a donor requests retesting of a single specimen or testing Bottle B of a split specimen, but the testing cannot be performed because the single specimen or Bottle B is no longer available due to causes that are outside of the donor's control. These causes could include, but are not limited to, an insufficient

quantity of urine in the single specimen to permit retesting, either Bottle B or the aliquot of a single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been misplaced. This provision requires the MRO to cancel the original test result, prohibits the licensee or other entity from imposing any sanctions on the donor, and requires the licensee or other entity to ensure that any records are expunged that could link the donor to the original positive, adulterated, or substituted test result and the administrative action required under § 26.165(f)(1). The final rule, with respect to the proposed rule, adds the requirement that the MRO must direct the licensee or other entity to collect a second specimen under direct observation as soon as reasonably practical. The paragraph requires a second collection as soon as reasonably practical because other provisions of the regulation (see Subpart C) require negative test results in order for the licensee or other entity to grant or maintain the donor's authorization. The NRC made this change in response to public comments received on the proposed rule and to increase the consistency of Part 26 with the related requirements in the HHS Guidelines.

The last sentence of § 26.165(f)(2) requires the licensee or other entity to impose the appropriate sanctions, as specified in Subpart D, if the results of testing the specimen from a second collection are positive, adulterated, or substituted and confirmed by the MRO to be an FFD policy violation. However, the rule prohibits the licensee or other entity from considering the results of testing the original specimen when imposing sanctions because the donor was (inadvertently) denied his or her right to due process in this case.

The new requirements in § 26.165(f) are generally consistent with the related requirements in the HHS Guidelines. The differences from the HHS Guidelines' requirements in the rule are variations in the terminology used to adapt the language for the NRC's purposes and the addition of cross-references to other portions of the rule.

Section 26.167 Quality Assurance and Quality Control

Section 26.167 updates former Section 2.8 in Appendix A to Part 26 [Quality assurance and quality control], which established quality assurance and quality control requirements for drug testing at HHS-certified laboratories. This section provides more detailed requirements for the quality assurance and quality control programs of HHS-certified laboratories to improve consistency with related provisions in the HHS Guidelines, and adds new requirements for validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i).

Section 26.167(a) [Quality assurance program] amends and combines former Section 2.8(a) and the last two sentences of Section 2.8(d) in Appendix A to Part 26, which required HHS-certified laboratories and licensee testing facilities to have quality assurance programs. For increased clarity in the language of the rule, the rule replaces the term ''specimen acquisition'' with the term ''specimen accessioning'' in the first sentence of former Section 2.8(a), which is the more accurate term. The rule also adds a requirement for the quality assurance program to encompass the certification of calibrators and controls to ensure that calibrators and controls are accurate. This requirement is consistent with the related provision in the HHS Guidelines.

In addition, the rule moves to § 26.167(a) and amends the requirements in the last two sentences of former Section 2.8(d) in Appendix A to Part 26, which required that the linearity and precision of testing methods used must be periodically documented as well as the procedures to ensure that carryover does not contaminate a donor's specimen. The rule updates these requirements for consistency with the HHS Guidelines and requires that (1) the performance characteristics (e.g., accuracy, precision, LOD, limit of quantitation (LOQ), specificity) for each test must be validated and documented; (2) validation of procedures must document that carryover does not affect the donor's specimen results, and (3) the laboratory must periodically re-verify the analytical procedures. The NRC relocated the updated requirements to § 26.167(a) for organizational clarity because they are aspects of the laboratory's quality assurance program.

The NRC has moved the requirements in former Section 2.8(a) in Appendix A to Part 26 that applied to licensee testing facilities to § 26.137(a) [Quality assurance program] in Subpart F. Section 26.167(a) retains the second sentence of former Section 2.8(a). The NRC also relocated the quality control requirements for initial tests at licensee testing facilities in former Section 2.8(b) in Appendix A to Part 26 to § 26.137 in Subpart F. The NRC made these changes for organizational clarity in the rule.

Section 26.167(b) [Calibrators and controls required] retains the portions of former Section 2.8(c) and (d) in Appendix A to Part 26 that required HHS-certified laboratories to use appropriate calibrators and controls for initial and confirmatory drug testing. The rule adds a requirement to include appropriate calibrators and controls for initial and confirmatory validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). The NRC has added more detailed requirements for calibrators and controls to this section than were contained in the former section for consistency with the HHS Guidelines. The final rule presents these requirements in separate paragraphs that address each type of test to be performed by the HHS-certified laboratory for organizational clarity.

The NRC added § 26.167(c) [Quality control requirements for performing initial and confirmatory validity tests] to establish quality control requirements for performing initial and confirmatory validity tests at an HHS-certified laboratory. The quality control requirements for validity tests in this paragraph incorporate the related provisions of the HHS Guidelines.

The final rule adds § 26.167(c)(1) [Requirements for performing creatinine tests] to require HHS-certified laboratories to measure creatinine concentration to 1 decimal place on initial and confirmatory creatinine tests and to establish requirements for the quality control samples to be used in initial and confirmatory tests for creatinine concentration.

Section 26.167(c)(2) [Requirements for performing specific gravity tests] establishes the required characteristics of the refractometers that HHS-certified laboratories must use to measure specific gravity and the characteristics of the quality control samples to be used for initial and confirmatory tests for a specimen's specific gravity.

Section 26.167(c)(3) [Requirements for performing pH tests] establishes quality control requirements for performing initial and confirmatory pH tests. Section 26.167(c)(3)(ii) through (c)(3)(vi) specifies the required calibrators and controls for pH testing, based on the type of testing instrument used and whether the laboratory has performed a pH validity screening test. In response to a public comment on the proposed rule, the NRC relocated the requirements for calibrators and controls for an initial colorimetric pH test from § 26.167(c)(3)(ii) in the proposed rule to § 26.167(c)(3)(vi) in the final rule. The agency made this change to increase consistency between the organization of Part 26 and the

organization of the related requirements in the HHS Guidelines.

The NRC has added three additional paragraphs related to quality control of initial and confirmatory validity testing: § 26.167(c)(4) [Requirements for performing oxidizing adulterant tests], § 26.167(c)(5) [Requirements for performing nitrite tests], and § 26.167(c)(6) [Requirements for performing ''other'' adulterant tests]. These paragraphs establish quality control requirements for performing initial and confirmatory tests for oxidizing adulterants, among which nitrites are one example, and for ''other'' adulterants. The added paragraphs are consistent with the related requirements in the HHS Guidelines. With respect to the proposed rule, the agency made minor editorial changes to these provisions in response to public comments to improve the clarity of the requirements. For example, the NRC implemented one commenter's suggestion to add cross-references in § 26.167(c)(4)(i) and (c)(4)(ii) to the specific provisions in § 26.161 that establish the cutoff criteria for oxidizing adulterants to clarify the adulterant concentrations that calibrators must contain.

Section 26.167(d) [Quality control requirements for initial drug tests] amends and combines portions of former Sections 2.7(d) and (e)(1), and 2.8(c) in Appendix A to Part 26. The former sections established quality control requirements for performing initial tests for drugs and drug metabolites at HHS-certified laboratories. For organizational clarity, the final rule groups together these related requirements that were dispersed throughout the former rule. In addition, the NRC has amended a number of the former requirements, as follows:

Section 26.167(d)(1) updates the first sentence of former Section 2.7(e)(1) in Appendix A to Part 26 but retains the intent of the former provision as it applies to HHS-certified laboratories. This section requires laboratories to use only immunoassay tests that meet the requirements of the Food and Drug Administration for commercial distribution. The requirements in the former paragraph related to initial drug testing at licensee testing facilities have been moved to § 26.137(e)(1) of Subpart F to improve organizational clarity in the rule.

Section 26.167(d)(2) permits HHS-certified laboratories to conduct multiple tests of a single specimen for the same drug or drug class. The final rule, with respect to the proposed rule, includes an example to clarify this section in response to a public comment. The requirements and example in this paragraph are consistent with a similar provision in the HHS Guidelines.

Section 26.167(d)(3)(i)–(d)(3)(v) updates former Section 2.8(c) in Appendix A to Part 26. The former section required HHS-certified laboratories to include quality control samples in each analytical run of specimens for initial drug testing. Section 26.167(d)(3)(i)–(d)(3)(v) specifies the number and characteristics of the quality control samples to be included in each analytical run of specimens. With respect to the proposed rule, the final rule contains minor language clarifications. These requirements are identical to those contained in § 26.137(e)(6) and (e)(7) for initial drug tests at licensee testing facilities and have been added for consistency with the related provisions in the HHS Guidelines.

In addition, in response to a public comment on the organization of this section, the final rule, with respect to the proposed rule, moves proposed § 26.167(d)(3)(v) to § 26.167(d)(4) to improve organizational clarity. Section 26.167(d)(4) requires that 10 percent of the specimens in each analytical run must be quality control samples.

Proposed § 26.167(e) [Quality control requirements for performing confirmatory drug tests] updates and combines portions of former Sections 2.7(f)(2) and 2.8(d) in Appendix A to Part 26. The former sections addressed quality control requirements for performing confirmatory drug tests. In general, the changes the NRC has made to the former requirements are made for organizational clarity in the final rule and to incorporate the related provisions in the HHS Guidelines.

Section 26.167(e)(1) amends former Section 2.7(f)(2) in Appendix A to Part 26. The former provision required that confirmatory drug tests must be performed using GC/MS testing. The final rule permits HHS-certified laboratories to use other techniques for confirmatory drug testing that the HHS Guidelines approve for use in Federal workplace drug testing programs.

The NRC added § 26.167(e)(2) to update Section 2.8(d) in Appendix A to Part 26 by establishing a requirement for the percentage of quality control samples that HHS-certified laboratories must include in each analytical run for confirmatory testing. The former rule did not specify a percentage. The NRC added this requirement for consistency with the HHS Guidelines. With respect to the proposed rule, the final rule separates the first and second sentences of the proposed provision into separate paragraphs and renumbers the second sentence of proposed § 26.167(e)(2) as § 26.167(e)(3) for organizational clarity, in response to a public comment.

Section 26.167(e)(3)(i) through (e)(3)(iv) amends the requirements for quality control samples in former Section 2.8(d) in Appendix A to Part 26. The final rule, with respect to the proposed rule, makes minor language clarifications in this paragraph. Section 26.167(e)(3)(i) and (e)(3)(ii) retains the former requirements for laboratories to include blank samples and samples that contain known standards in each analytical run. The requirements adopt the simpler language from the related provisions in the HHS Guidelines to improve clarity in the language of the rule. For consistency with the related requirements in the HHS Guidelines, the paragraph provides more detailed requirements for ''positive controls with the drug or metabolite at or near the threshold'' than in former Section 2.8(d)(1) in Appendix A to Part 26. The rule requires, in § 26.167(e)(3)(iii), at least one control fortified with a drug or drug metabolite targeted at 25 percent above the cutoff and, in § 26.167(e)(3)(iv), at least one calibrator or control that is targeted at or below 40 percent of the cutoff.

The NRC moved the requirements in proposed § 26.167(f) [Blind performance testing] to a new section in the final rule, § 26.168 [Blind performance testing]. The agency made this change because licensees and other entities, rather than HHS-certified laboratories, are primarily responsible for implementing these requirements. Therefore, presenting requirements for licensees' and other entities' blind performance testing of HHS-certified laboratories in a separate section makes them easier to locate in the final rule and meets Goal 6 to improve clarity in the organization of the rule.

With respect to the proposed rule, the final rule renumbers proposed § 26.167(g) [Errors in testing] as § 26.167(f). This section amends former Section 2.8(e)(4) through (e)(6) in Appendix A to Part 26, and imposes requirements on licensees, other entities, and HHS-certified laboratories related to unsatisfactory performance, including false positive and false negative test results from the HHS-certified laboratory. This paragraph requires the licensee or other entity to ensure that the HHS-certified laboratory investigates any conditions that may adversely reflect on the testing process. Notably, the rule no longer requires the licensee to perform the investigation, but rather to ''ensure'' that the

laboratory completes an investigation. The NRC made this change because licensees and other entities do not typically retain personnel with the expertise required to investigate the complex technologies and processes involved in testing at HHS-certified laboratories. The agency has moved the requirements for reporting and documentation of the investigation, which formerly appeared in Section 2.8(e)(4) in Appendix A to Part 26, to §§ 26.715(b)(8) and 26.719(c) in Subpart N of the final rule for organizational clarity.

Section 26.167(f)(1) explicitly states the requirements that were implied in former Section 2.8(e)(4) in Appendix A to Part 26 that the investigation must identify the root cause(s) of any unsatisfactory performance and the HHS-certified laboratory must take corrective actions. The rule expands these requirements to include the licensee or other entity, as well as the HHS-certified laboratory, depending on the causes identified and the extent to which the causes are within each entity's control. The NRC revised the former requirement to recognize that some testing errors are not attributable to the HHS-certified laboratory.

Section 26.167(f)(2) amends former Section 2.8(e)(5) in Appendix A to Part 26. This provision required the licensee to notify the NRC if a false positive error occurred on a blind performance test sample and the error was determined to be administrative. The final rule requires the licensee or other entity, and the HHS-certified laboratory, to take corrective actions for any false positive errors in blind performance testing, in response to the findings of the investigation that would be required in this section. The rule continues to authorize licensees and other entities to require the laboratory to review and re-analyze previously tested specimens, if the investigation indicates that the error could have been systematic. The rule also deletes reference to administrative errors, which appeared in former Section 2.8(e)(5), so that any type of errors falls under the requirements of the paragraph. The NRC moved the reporting requirement in former Section 2.8(e)(5) to § 26.719(c)(2) in Subpart N for organizational clarity.

Section 26.167(f)(3) amends former Section 2.8(e)(6) in Appendix A to Part 26. This section addressed false positive errors resulting from technical or methodological errors by the laboratory. The rule incorporates reference to validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as previously discussed with respect to § 26.31(d)(3)(i). The rule deletes the last sentence of the former paragraph because it addressed the responsibilities of the HHS and is not relevant to the NRC or the licensees and other entities who are subject to Part 26. The paragraph retains the other provisions of former Section 2.8(e)(6), but adopts the simpler language of the related provision in the HHS Guidelines for increased clarity in the language of the rule. With respect to the proposed rule, the final rule replaces the term ''certifying scientist'' in the third sentence of the proposed provision with the accurate term ''responsible person'' in response to a public comment which noted the use of the incorrect term in the proposed rule.

Section 26.167(g) [Accuracy] retains former Section 2.7(o)(3)(i) in Appendix A to Part 26 with minor editorial revisions. The agency relocated the former paragraph to § 26.167(g) because it relates to quality control of the HHS-certified laboratory's drug testing processes. The NRC made this change to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.167(h) [Calibrators and controls] updates former Section 2.7(o)(2) in Appendix A to Part 26. At the time the original paragraph was written, most laboratories prepared their own standards and controls. In the ensuing years, the number and variety of sources for materials used in performance testing has increased. The final rule updates former requirements to refer to several of the alternatives, including, but not limited to pure drug reference materials, stock standard solutions from other laboratories, and standard solutions obtained from commercial manufacturers. The requirements in this paragraph incorporate the related requirements in the HHS Guidelines and meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. The labeling requirements in the second sentence of former Section 2.7(o)(2) have been retained without change.

Section 26.168 Blind Performance Testing

Section 26.168 updates and expands former Section 2.8(e) in Appendix A to Part 26 [Licensee blind performance test procedures]. The former paragraph established requirements for licensees and other entities to conduct blind performance testing of HHS-certified laboratories. With respect to the proposed rule, the final rule has moved the requirements in proposed § 26.167(f) to this new section because presenting them in a separate section makes them easier to locate in the final rule. The final rule also provides more detailed requirements for the formulation of blind performance test samples that licensees and other entities use to obtain HHS-certified laboratory performance data and revises the number, composition, and percentages of blind samples that licensees and other entities must submit to the HHS-certified laboratories. The NRC made these changes in response to detailed public comments that addressed these issues.

The NRC added § 26.168(a) to require licensees and other entities to submit blind performance test samples to the HHS-certified laboratories with whom they contract for drug testing services. To improve clarity in the language of the rule, the NRC added this provision to make explicit the same requirement that was implied in former Section 2.8(e) of Appendix A to Part 26.

Section 26.168(a)(1) amends the portion of former Section 2.8(e)(2) in Appendix A to Part 26 that established the percentages and numbers of blind performance test samples that licensees and other entities must submit to the HHS-certified laboratory during the first 90 days of any initial contract with the HHS-certified laboratory. The final rule decreases the percentage of blind performance test samples that licensees and other entities must submit to the HHS-certified laboratory during the initial 90-day period of any contract (not including rewritten or renewed contracts). Specifically, the rule reduces the percentage from 50 percent to 20 percent of the total number of specimens submitted in the 90-day period, up to a maximum of 100 blind samples, rather than a maximum of 500 samples as specified in the former rule. This decrease in the blind performance testing rate increases the consistency of Part 26 with related provisions in the HHS Guidelines. In addition, since the NRC published the former rule, the number and size of Federal agencies who conduct drug testing has substantially increased. These agencies are also required to submit blind performance test samples under the HHS Guidelines. As a result, especially with respect to the issue of correctly identifying negative specimens, the burden on Part 26 programs to conduct performance tests of the HHS-certified laboratories can be reduced without affecting the likelihood that errors in testing will be detected.

The regulation also adds a requirement for licensees and other entities to submit a minimum of 30 blind performance test samples in the

initial 90-day period. The agency has established this minimum to address Part 26 programs who submit only a small number of specimens to HHS-certified laboratories for testing each quarter. For example, for a very small program, 20 percent of the number of specimens submitted in the initial 90-day period could be less than one blind performance test sample. Establishing a minimum number of samples will provide assurance that the HHS-certified laboratories used by these Part 26 programs are providing accurate test results.

Section 26.168(a)(2) amends the portion of former Section 2.8(e)(2) in Appendix A to Part 26 that addressed ongoing blind performance testing after the first 90 days of an initial contract with an HHS-certified laboratory. The rule decreases the rate at which licensees and other entities must submit blind performance test samples to an HHS-certified laboratory in each quarter after the initial 90-day period from 10 percent in the former rule to one percent, or a total of 10 samples, whichever is greater. The rule also decreases the maximum number of samples to be submitted per quarter from 250 to 100 samples. The rationale for these changes is the same as discussed with respect to § 26.168(a)(1).

The NRC added § 26.168(a)(3) to require licensees and other entities to submit blind performance test samples to the HHS-certified laboratory at a frequency that is similar to the frequency for other specimens. This change enhances the consistency of Part 26 with the HHS Guidelines.

Section 26.168(b) amends and expands former Section 2.8(e)(3) in Appendix A to Part 26, which required that 80 percent of the blind samples submitted by the licensee or other entity each quarter to the HHS-certified laboratory must be ''blank'' (i.e., certified to contain no drugs or drug metabolites). With respect to the proposed rule, the NRC has substantially changed the requirements in proposed § 26.167(f)(3) in response to extensive comments on the proposed blind performance test sample provisions. In the final rule, § 26.168(b) now requires that approximately 60 percent of all blind performance test samples that licensees and other entities send to the HHS-certified laboratory must be positive for one or more of the drugs for which the licensee or other entity tests, and that all drugs for which the licensee or other entity tests must be submitted to the HHS certified laboratory at least once a quarter except as indicated in § 26.168(b)(1) and (2). The requirement that approximately 60 percent of all blind samples submitted to HHS-certified laboratories must be positive for one or more drugs per sample will ensure that all licensees, including those who will only send the minimum number of blind samples required under this rule, will submit several samples for each drug being tested. This change will permit licensees and other entities to better monitor and make more informed decisions regarding their HHS-laboratories' performance. Under the previous ''80 percent negative'' rule, licensees who submitted only the 40 minimum blind samples required would nominally receive two results per year on three drugs (which were chosen by the licensee or other entity). This requirement provided licensees with scant information to determine independently, as required by rule, whether the HHS-certified laboratory was meeting the licensee or other entity contract provisions with the HHS-certified laboratory. Under the revised section, assuming a reasonable distribution, even those licensees and other entities who submit only the minimum 40 required blind samples a year will receive results from marijuana blind performance test samples at least 8 times a year, from cocaine text samples at least 7 times a year, from amphetamines and opiate test samples at least 3 times a year, and from PCP test samples at least 2 times a year. The NRC's increased emphasis on testing for marijuana and cocaine and the reduction in testing for PCP in § 26.168(b)(1) and (2) reflect the fact that among all FFD programs, marijuana and cocaine have resulted in the largest number of confirmed positive drug tests and PCP the least number of confirmed positive drug tests, as reported in the NRC's ''Summary of FFD Performance Reports'', from 1990 through 2005. Therefore, the NRC has made these changes to meet Goal 3 of this rulemaking to enhance the effectiveness and efficiency of the rule.

Section 26.168(c) limits the submission of positive blind performance test samples to the HHS-certified laboratory to samples containing only those drugs for which the licensee or other entity tests and requires that the blind samples sent to HHS-certified laboratories must be formulated according to the requirements established in § 26.168(g)(2). This provision updates former Section 2.8(e)(3) in Appendix A to Part 26, which also limited performance testing to only those drugs included in the licensee's panel. With respect to the proposed rule, the final rule replaces the proposed requirement for positive samples to be spiked to between 60 and 80 percent of the initial cutoff levels used by the licensee or other entity with a cross-reference to the more detailed requirements for positive blind performance test samples in § 26.168(g)(2), as discussed with respect to that section.

The NRC has added § 26.168(d) to require licensees and other entities to submit approximately 10 percent of all blind performance test samples as false negative challenge samples to the HHS-certified laboratory according to the requirements established in § 26.168(g)(3). The NRC has added this provision in response to public comments on proposed § 26.167(f) that blind samples containing drugs or drug metabolites at a concentration 20 percent above the cutoff levels would frequently yield false negative test results and, therefore, unfairly challenge HHS-certified laboratories. False negatives occur when drug levels that are positive but close to the initial drug test cutoff level may actually be reported as negative. Assuming that an initial negative drug test has an error rate of one percent (one percent false negatives) and all HHS-certified laboratories perform equally, then over time, for every 100 people who have recently used drugs and been tested by licensees and other entities, one person will not be identified as having a positive test result for one or more drugs on the basis of the initial test alone. Recent research [Cone et al., 2003] strongly suggests that the issue of false negatives may be significantly greater than previously understood. The NRC recognizes that false negatives will occur within its drug testing guidelines, but intends to minimize them as much as is reasonably possible within scientific constraints and practical limitations of resources. Therefore, the NRC has established the requirements for the characteristics of false negative challenge samples under the final rule to present a fair test to HHS-certified laboratories because they are targeted at specimens clearly above the range of laboratory controls yet below the standard cutoff levels.

Section 26.168(e) requires licensees and other entities to submit approximately 20 percent of all blind samples as adulterated, diluted, or substituted and formulated according to the requirements established in § 26.168(g)(4)–(g)(6). The NRC added this provision for consistency with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to proposed § 26.31(d)(3)(i). This

performance testing is necessary to challenge the accuracy of the HHS-certified laboratories' specimen validity testing. With respect to the proposed rule at proposed § 26.167(f)(3), the final rule increases the proportion of blind samples that licensees and other entities must submit to challenge the laboratories' specimen validity testing. The NRC made this change in response to public comments on the proposed rule and the NRC's concern that validity test results are accurate. The requirements elaborated in this section protect public health and safety and the common defense and security by increasing the effectiveness of FFD programs (Goal 3 of this rulemaking) in ensuring that an individual whose fitness for duty is questionable does not perform duties or have the types of access that require the individual to be subject to this part.

The final rule substantially decreases the percentage of negative blind performance test samples that licensees were required to submit to HHS-certified laboratories in former Section 2.8(e)(3) of Appendix A, as retained in proposed § 26.168(f). The former and proposed provision required 80 percent of blind samples to be negative. The final rule revises this percentage to 10 percent. The NRC made this change in response to public comments on the proposed rule and because the NRC believes that carryover effects (i.e., a positive sample contaminates a negative sample because of improper laboratory equipment cleaning), while a concern during the early years of drug testing, are not an issue in current HHS-certified laboratories based on current specimen testing practices. The agency also believes that it is more appropriate to challenge the drug and validity testing capabilities of HHS-certified laboratories and therefore, is increasing the percentage of positive, adulterated, substituted, dilute, and invalid specimens submitted as blind performance test samples in each quarter of testing. With regard to the issue of correctly identifying negative specimens (i.e., ensuring that laboratories do not report false positive test results), the NRC is confidant that the 10 percent negative sample requirement in the final rule will provide adequate oversight regarding false positive test results due to carryover and other related issues. Another reason that the NRC is decreasing the required percentage of negative samples in the final rule is that the number and size of Federal agencies who conduct drug testing has substantially increased since Part 26 was first promulgated. Also, these agencies are required to submit negative blind performance test samples at a rate of 80 percent under the HHS Guidelines. Therefore, the previous need for Part 26 programs to so extensively challenge the HHS-certified laboratories' false positive rates is reduced.

The NRC has added formulation standards for the blind performance test samples that licensees and other entities must use in § 26.168(g). The final rule revises proposed § 26.167(f)(5)(i) in response to detailed public comments on the scientific and technical suitability of the proposed standards in achieving the NRC's objective of ensuring that the performance testing required under this rule ensures that test results from HHS-certified laboratories are accurate.

The agency added § 26.168(g)(1) to require that negative blind performance test samples may not contain a measurable amount of a target drug or analyte, and must be confirmed by immunoassay and confirmatory testing. Section 26.168(g)(2) requires that positive blind performance test samples must contain drug or analyte concentrations between 150 and 200 percent of the initial cutoff levels and be certified by immunoassay and confirmatory testing to contain one or more drug(s) or drug metabolites. Section 26.168(g)(3) requires that false negative challenge samples must contain target drug or analyte concentrations between 130 and 155 percent of the initial cutoff values. Section 26.168(g)(4) requires that an adulterated blind performance test sample must have a pH of less than or equal to 2, or greater than or equal to 12, or nitrite or other oxidant concentration equal to or greater than 500 mcg/mL) using either a nitrite colorimetric test or a general oxidant colorimetric test. Section 26.168(g)(5) requires that a dilute blind performance test sample must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030. Section 26.168(g)(6) requires that a substituted blind performance test sample must contain less than 2 mg/dL of creatinine and the specific gravity must be less than or equal to 1.0010, or equal to or greater than 1.0200.

The NRC has made these changes in § 26.168(b)–(g) to increase the ability of licensees and other entities to independently monitor the ability of their HHS-certified laboratories to consistently identify positive, adulterated, dilute, and substituted specimens and hold false negatives to a minimum. The NRC recognizes that these issues are routinely scrutinized and evaluated by the HHS Laboratory Certification Program (LCP), but is mindful that the LCP challenges are not blind to the HHS-certified laboratories. Because of its over-arching interest in making the Part 26 drug testing program as rigorous as possible, as evidenced by the detail of Subparts F and G, the NRC believes that a more aggressive licensee and other entity blind challenge to the HHS-certified laboratories in these area adds an important independent dimension to ensuring licensee and other entity confidence in the overall drug testing program.

Section 26.168(h) has been added to establish additional detailed requirements for the blind performance test samples that licensees and other entities must submit to the HHS-certified laboratories and to ensure the consistency and effectiveness of the blind performance testing process. Section 26.168(h)(1) requires the supplier of the blind samples to certify that all blind specimen batches are confirmed by an HHS-certified laboratory prior to being put into service and to remove blind specimen batches from service after they have been open for 6 months. Section 26.168(h)(2) requires the supplier to provide an expiration date for each sample. Section 26.168(h)(3) requires the supplier to monitor each open batch on a bi-monthly (i.e., every two months) basis to ensure that the remaining batch does not fall below the criteria in this section. These requirements are based on related provisions in the HHS Guidelines and DOT's procedures for drug and alcohol testing. The NRC added these requirements in response to a public comment on the proposed rule requesting the NRC to clarify the requirements in proposed § 26.167(f)(5).

The NRC added § 26.168(i) to provide specific requirements for ensuring that blind performance test samples are indistinguishable to laboratory personnel from a donor's specimen in response to a public comment on proposed § 26.167(f)(5). These requirements are based on the related DOT procedures.

Section 26.168(i)(1) requires the licensee or other entity to ship blind performance test samples to the HHS-certified laboratory in the same way donors' specimens are sent to the laboratory. This provision provides greater assurance than the former rule that personnel at the HHS-certified laboratories will not be aware that the specimen they are handling is a blind performance test sample. The NRC

added this provision to increase the effectiveness of blind performance testing under the rule.

Section 26.168(i)(2) specifies the information that must be entered on the custody-and-control form accompanying the blind performance test sample. This information is necessary to ensure that the MRO is aware that the specimen is a blind performance test sample.

Section 26.168(i)(3) requires licensees and other entities to submit split samples where applicable. This provision is necessary to ensure that the FFD program submits blind performance test samples that appear to be normal specimens that the laboratory may receive from a donor.

Section 26.169 Reporting Results

This section contains requirements for HHS-certified laboratories' reporting of test results to the licensee's or other entity's MRO. The final rule in § 26.169 updates former Section 2.7(g) in Appendix A to Part 26. The rule updates the former requirements for consistency with the HHS Guidelines. In addition, the rule adds requirements for reporting the results of validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). With respect to the proposed rule, the NRC has made several organizational changes to improve clarity by presenting the provisions in the order that is more consistent with the order in which HHS-certified laboratories, licensees, and other entities will implement them, consistent with Goal 6 of this rulemaking.

Section 26.169(a) amends former Section 2.7(g)(1) in Appendix A to Part 26, which established a time-limit on the HHS-certified laboratory's reporting of test results to the MRO and requirements for the processing and content of the report. The NRC has retained the requirement for the laboratory to report results to the MRO within 5 business days of receiving the specimen at the laboratory. Under the final rule, the HHS-certified laboratory's ''certifying scientist,'' rather than the laboratory's ''responsible individual,'' certifies the test results. This change has been made for consistency with the updated term used to refer to this individual, as discussed with respect to § 26.155(b). The rule adds a reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed with respect to § 26.31(d)(3)(i). The final rule deletes the former prohibition on reporting test results for any specimen in a group of specimens sent to the laboratory by the licensee or other entity until the laboratory completes testing of all of the specimens in the group. The prohibition in the former rule was based on a concern for maintaining control of specimen identity. However, new technologies for identifying specimens and aliquots (such as bar codes on specimen labels matched to bar codes on aliquots and the associated custody-and-control forms) have reduced the likelihood that specimen identity may be lost, and, therefore, have substantially reduced the need for the requirement in the former rule.

Section 26.169(b) amends portions of former Section 2.7(f)(2) in Appendix A to Part 26 by eliminating the requirement for the HHS-certified laboratory to conduct tests for drugs and drug metabolites using both the cutoff levels specified in this part and any more stringent cutoff levels specified by the FFD program. If the FFD program specifies cutoff levels that are more stringent than those specified in this part, the final rule requires the laboratory only to conduct testing using those more stringent cutoff levels, and only to report results from those tests to the MRO. The NRC made this change for the reasons discussed with respect to § 26.31(d)(1)(i)(D). This provision was § 26.169(c) in the proposed rule.

Section 26.169(c) (§ 26.169(b) in the proposed rule) establishes requirements for the laboratory's reporting of validity test results. This provision amends former Section 2.7(g)(2) in Appendix A to Part 26, which established requirements for the manner in which HHS-certified laboratories and licensee testing facilities must report test results to licensee management. The NRC has moved the requirements in the former paragraph that are related to reporting test results from the licensee testing facility to § 26.139(a) of Subpart F for organizational clarity. The final rule deletes the former reference to ''special processing'' and replaces it with reference to validity test results, consistent with the addition of requirements to conduct validity testing throughout the final rule, as discussed with respect to § 26.31(d)(3)(i). In addition, the final rule makes minor changes in terminology, such as referring to a ''drug or drug metabolite,'' rather than a ''substance,'' for clarity in the rule language.

The NRC has renumbered proposed § 26.169(e) as § 26.169(c)(1) in the final rule. The NRC added this provision to require the HHS-certified laboratory to report all test results for a single specimen, if the laboratory obtains more than one positive, adulterated, substituted, or invalid test result from testing of the specimen. The regulation requires the laboratory to report any positive test results, as well as any adulterated, substituted, or invalid validity test results from the same specimen. This change is necessary because sanctions for the different test results differ under § 26.75. Reporting multiple test results for a single specimen is consistent with related requirements in the HHS Guidelines.

Section 26.169(c)(2) updates former Section 2.7(g)(3) in Appendix A to Part 26, which permitted the MRO routinely to obtain quantitative test results from the HHS-certified laboratory. This paragraph incorporates the first two sentences of proposed § 26.169(d). Specifically, the final rule revises the first sentence of former Section 2.7(g)(3) by stating that the HHS-certified laboratory shall provide quantitative test results for a positive confirmatory drug test result to the MRO on request. The paragraph clarifies the former requirement by stating that the MRO's request may be either a general request covering all such results or a specific case-by-case request. The changes to this paragraph are consistent with the related provisions in the HHS Guidelines. The final rule also moves the requirement that was contained in proposed § 26.169(g) to this paragraph for organizational clarity. Therefore, this provision of the final rule requires the HHS-certified laboratory to routinely report to the MRO, whether requested or not, quantitative values for confirmatory opiate test results for morphine or codeine that are equal to or greater than 15,000 ng/mL. The rule adds this requirement for consistency with the related provision in the HHS Guidelines and because the MRO is not required to perform an assessment for clinical signs of opiate abuse in this instance, as discussed with respect to § 26.185(j)(1). The reference to test results from blood specimens in former Section 2.7(g)(3) in Appendix A to Part 26 has been deleted for the reasons discussed with respect to § 26.83(a).

In response to public comments on the proposed rule, the NRC has added § 26.169(c)(3) to require the HHS-certified laboratory to report to the MRO numerical values supporting an adulterated or substituted test result. The final rule also adds instructions for the laboratory's report to the MRO if a specimen's numerical values for creatinine are below the LOD. The NRC added this provision for consistency with the HHS Guidelines.

Section 26.169(c)(4) requires the HHS-certified laboratory to contact the MRO after the HHS-certified laboratory has

determined that a specimen has an invalid result, but before reporting out the test result, to determine whether testing by a second HHS-certified laboratory would be useful. The rule permits the laboratory's contact with the MRO to occur using electronic means, such as telephone, fax, and e-mail. If no further testing is necessary, the final rule requires the laboratory to report the invalid result to the MRO. These reporting requirements have been added for consistency with the related provisions in the HHS Guidelines. This provision retains the portions of proposed § 26.169(d) that pertained to reporting invalid test results but the final rule presents them in a separate paragraph to improve organizational clarity.

Section 26.169(c)(5) establishes requirements for the HHS-certified laboratory in reporting drug, metabolite, or adulterant concentrations that exceed normal testing ranges. This provision updates the last sentence of former Section 2.7(f)(2) in Appendix A to Part 26 for consistency with the HHS Guidelines. This provision appeared in the proposed rule as the third sentence of proposed § 26.169(d).

Section 26.169(d) retains the portion of former Section 2.7(g)(3) in Appendix to Part 26 that prohibited the MRO from disclosing quantitative results to a licensee or other entity and extends it to MRO staff for clarity in the language of the rule. This provision requires the MRO to only report whether the specimen was positive (and for which analyte), adulterated, substituted, dilute, invalid, or negative, except as permitted under § 26.37(b). This provision appeared as the fourth and fifth sentences of proposed § 26.169(f).

Section 26.169(e), which was § 26.169(h) in the proposed rule, amends former Section 2.7(g)(4) in Appendix A to Part 26, which established requirements for the electronic transmission of test results from the HHS-certified laboratory to the MRO. Specifically, the rule clarifies that the licensee or other entity is responsible for assuring the security of data transmissions from the laboratory to the MRO, rather than only the HHS-certified laboratory, as specified in the former requirement. This change responds to stakeholder comments at the public meetings discussed in Section V. The stakeholders accurately noted that licensees and other entities are responsible to the NRC for ensuring the security of their HHS-certified laboratories' data storage and transmission systems through their contracts with and audits of the laboratories. This revision accurately characterizes these relationships without changing the intent of the former provision.

Section 26.169(f) updates former Section 2.7(g)(5) in Appendix A to Part 26, which established requirements for transmitting chain-of-custody documentation with test results to the MRO. The rule permits HHS-certified laboratories to use various means to transmit test results to the MRO, including transmittal of a computer-generated electronic report for negative test results. However, for positive, adulterated, substituted, or invalid test results, the rule requires the laboratory to transmit a legible image or copy of the completed custody-and-control form to the MRO. The change has been made for consistency with the related provision in the HHS Guidelines. This provision contains the requirements in § 26.169(i) of the proposed rule.

Section 26.169(g) further amends former Section 2.7(g)(5) in Appendix A to Part 26. The paragraph continues to require that the HHS-certified laboratory must retain the original custody-and-control form for any positive, adulterated, substituted, or invalid specimens. However, the paragraph assigns responsibility for certifying the test results to the laboratory's certifying scientist, rather than to ''the individual responsible for day-to-day management of the laboratory or the individual responsible for attesting to the validity of the test reports.'' The change has been made for consistency with the updated terminology used to refer to this individual in the HHS Guidelines, as discussed with respect to § 26.155(b). This provision was § 26.169(j) in the proposed rule.

Section 26.169(h) combines and amends former Section 2.7(g)(6) and (g)(7) in Appendix A to Part 26, which required the laboratory to submit a monthly statistical summary of drug test results to the licensee or other entity. The rule reduces the required frequency of the statistical summary report from monthly to annually in order to reduce the burden on licensees, other entities, and their laboratories. The requirement for annual reporting makes the reporting time consistent with the NRC's need for the information as it relates to the NRC's inspection schedule and the annual FFD program performance report that is required under § 26.717, for the reasons discussed with respect to that section. The rule also deletes the existing reference to blood specimens because the option for donors to request blood testing for alcohol has been eliminated from the rule, as discussed with respect to § 26.83(a). The rule also deletes the requirement to report drug test results at the cutoff levels specified in this part, if the FFD program uses more stringent cutoff levels, for the reasons discussed with respect to § 26.169(b). The rule adds a requirement to report initial and confirmatory test results for additional drugs (if the FFD program tests for additional drugs), as well as a requirement to report the number of specimens with confirmed positive 6–AM test results. (The rule includes testing for 6–AM, because the presence of 6–AM in a specimen uniquely identifies heroin use.) In addition, the rule adds requirements to report the results of validity testing. The NRC has made these changes to conform to other changes in the rule, as discussed with respect to §§ 26.717(b)(2), 26.185(j)(1), and 26.31(d)(3)(i). With respect to the proposed rule, the NRC has added requirements for the laboratory to report whether a specimen that has been reported as positive and dilute was subject to the special analyses permitted under § 26.163(a)(2) and the number of specimens reported as rejected for testing. The NRC added these reporting requirements in response to public comment noting that the NRC will require this information to maintain adequate oversight of FFD programs and for consistency with related provisions in the HHS Guidelines. This requirement appeared as proposed § 26.169(k) in the proposed rule.

Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness

Throughout this subpart, the final rule makes minor clarifications to the proposed rule because of public comment, to accommodate conforming changes, and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. For example, the final rule eliminates the term ''non-negative,'' which was used in proposed Subpart H in many places and replaces it with the terms ''positive, adulterated, substituted, dilute, or invalid,'' as appropriate, for the reasons discussed with respect to § 26.5 [Definitions]. Also, in § 26.185, the final rule adds the term ''confirmatory'' when referring to test results that have been reported to the MRO by the HHS-certified laboratory and deletes the ambiguous term ''referral'' when referring to a physician. The final rule also uses ''business days'' instead of only ''days'' to be consistent with other provisions in the rule.

The final rule also makes more substantive changes to the proposed rule in this subpart because of public comment or to improve clarity in the organization and language of the rule.

The substantive changes in this subpart can be found in §§ 26.183(b), (d), (d)(1), and (d)(2)(iv); 26.185(g), (g)(2), (g)(5), (h)(1), and (i)(1); 26.187(a) and (f); and 26.189(a) and (c). These changes are discussed in detail below. However, other than the changes mentioned above, the final rule adopts the provisions of this subpart as proposed, without change.

Section 26.181 Purpose

Section 26.181 of the final rule describes the purpose of Subpart H, which is to establish requirements for MRO reviews of positive, adulterated, substituted, dilute or invalid confirmatory drug test results and for making determinations of fitness. This section provides an overview of the contents of the subpart, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.183 Medical Review Officer

The NRC has added § 26.183 to the final rule to present requirements related to the qualifications, relationships, staff, and responsibilities of the MRO. Grouping these requirements together in a single section meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.183(a) [Qualifications] of the final rule combines and amends the requirements in former § 26.3 [Definitions] and Section 1.2 of Appendix A to Part 26, as well as portions of former Section 2.9(b) in Appendix A to Part 26. The provision reorganizes the former requirements to eliminate redundancies and group in one paragraph the related provisions in the former rule. These changes meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The provision amends portions of the former requirements related to MRO qualifications. It continues to provide that the MRO must be a licensed physician, but clarifies that the MRO may hold either a Doctor of Medicine or Doctor of Osteopathy degree for consistency with the related regulations of other Federal agencies. The provision adds a requirement that the MRO must be knowledgeable of Part 26 and the FFD policies and procedures of the licensees and other entities for whom the MRO provides services. The requirements of this part and the policies and procedures of various Part 26 FFD programs may differ from those of other workplace drug and alcohol testing programs for which an MRO provides services. This provision ensures that an MRO is able to perform his or her function appropriately under this part. In addition, the provision adds a requirement that within 2 years following the date on which this rule is published in the **Federal Register**, the MRO must pass an MRO certification examination. The requirement increases consistency in the performance of the MRO function among FFD programs because licensees and other entities are permitted to accept test results and the results of determinations of fitness conducted by other licensees and entities who are subject to the FFD rule. The 2-year implementation date provides MROs who are not currently certified with an opportunity to pass the required examination. With the exception of the first sentence of this provision that specifically relates to the MRO function under Part 26, these MRO qualification requirements are consistent with those of other Federal agencies.

Section 26.183(b) [Relationships] of the final rule establishes requirements related to the relationships that are permitted or prohibited between the MRO, the licensee or other entity, and HHS-certified laboratories. The first sentence of this provision retains the portion of the first sentence of former Section 2.9(b) in Appendix A to Part 26 that permitted the MRO to be an employee of a licensee or other entity, or a contractor. The NRC has added requirements to prohibit the MRO from being an employee or agent of, or have any financial interest in, a laboratory or a contracted operator of a licensee testing facility for whom the MRO reviews drug testing results for the licensee or other entity. The NRC has added this prohibition based upon the experiences of other Federal agencies and to be consistent with the related provision in the HHS Guidelines, consistent with Goal 1 of the rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

With respect to the proposed rule, the final rule adds the last sentence of § 26.183(b) and paragraphs (b)(1) through (b)(6) to provide some examples of relationships between laboratories and MROs that create conflicts of interest. The NRC has included these examples in response to a public comment requesting more clarification regarding such conflict-of-interest relationships. The basis for these examples is 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944; August 9, 2001). Adding these examples meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other Federal rules and guidelines and Goal 6 of the rulemaking to improve clarity in the rule language.

Section 26.183(c) [Responsibilities] of the final rule reorganizes and updates the requirements in former § 26.3, as well as former Sections 1.2, 2.4(j), 2.7(d), and 2.9(a) and (b) in Appendix A to Part 26 to specify the responsibilities of the MRO in Part 26 programs. This provision reorganizes the former provisions and combines them. In addition, the NRC has revised the terminology to be consistent with that used throughout the FFD rule. These changes meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.183(c) retains the requirement in former Section 2.9(a) in Appendix A to Part 26 for the MRO to review positive confirmatory drug test results from the HHS-certified laboratory. The provision also adds a requirement for the MRO to review adulterated, substituted, or invalid results from confirmatory validity testing, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). If a licensee's or other entity's FFD program elects to conduct the special analyses of dilute specimens permitted in § 26.163(a)(2), the MRO also is required to review those results. This provision also requires the MRO to identify evidence of subversion of the testing process, identify issues or problems associated with the collection and testing of specimens, and work with FFD program management to ensure the overall effectiveness of the FFD program. The final rule adds these responsibilities to clarify that the MRO carries programmatic responsibilities within a licensee's or other entity's FFD program, in addition to responsibility for reviewing drug and specimen validity test results. These additional responsibilities strengthen the effectiveness of FFD programs by ensuring that the MRO's expertise is brought to bear in the management of FFD programs. This provision also increases the consistency of the MROs' responsibilities under Part 26 with the responsibilities of MROs in the drug and alcohol testing programs of other Federal agencies. Therefore, the changes meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.183(c)(1) retains and updates the former definitions of the term ''Medical Review Officer'' contained in former § 26.3 and Sections 1.2 and 2.9(b) in Appendix A to Part 26. This provision continues to require the MRO to examine alternate medical explanations for any positive drug test results. It also adds a requirement to examine alternate medical explanations for adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute test results report by the HHS-certified laboratory. The provision also retains the former provision that the MRO may interview the donor and review the donor's medical history and any other relevant biomedical factors, and review all medical records that the donor may make available to the MRO. In addition to the responsible use of legally prescribed medication, this provision requires the MRO to consider a documented condition or disease state and the demonstrated physiology of the donor in determining whether a positive, adulterated, substituted, or invalid test result is an FFD policy violation. The provision requires the MRO to consider the latter factors because they may cause some adulterated, substituted, invalid, or dilute validity test results. These changes are necessary for consistency with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). The changes also increase the consistency of Part 26 with advances in other relevant Federal rules and guidelines, which is Goal 1 of this rulemaking.

Section 26.183(c)(2) retains the meaning of the last sentence of former Section 2.9(b) in Appendix A to Part 26, but adds minor editorial revisions for consistency with the terminology used throughout the rule. For example, the rule replaces the term ''split samples'' in the former rule with the term ''split specimens.'' The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.183(d) [MRO staff] to the final rule to establish requirements related to individuals who provide routine administrative support functions to MROs, whether the individuals are employees of the licensee or other entity, employees of the MRO, or employees of an organization with whom the licensee or other entity contracts for MRO services. This provision adds requirements related to MRO staff because these individuals have access to drug test results that are forwarded to an MRO from the HHS-certified laboratory, perform some administrative functions for MROs that permit them to view donors' private medical information, and often have contact with donors. The NRC is not aware of any instances when individuals who serve as MRO staff have compromised the confidentiality of donors' test results, medical information, or otherwise acted improperly in Part 26 programs. However, this provision adopts requirements related to the MRO staff function from the regulations of other Federal agencies who similarly permit MRO staff to provide administrative support to MROs to ensure that donors' medical information is handled with the highest concern for individual privacy. The requirement also ensures that information related to positive, adulterated, substituted, invalid, or dilute test results is not released to licensee or other entity management personnel unless the MRO has determined that a donor has violated the FFD policy. These changes meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines and Goal 7 to protect the privacy and due process rights of individuals who are subject to Part 26.

With respect to the proposed rule, the final rule adds another sentence to § 26.183(d) to clarify that employees of a licensee or other entity who serve MRO staff functions may also perform other duties for the licensee or other entity and need not be under the direction of the MRO while performing those other duties. The final rule also clarifies § 26.183(d)(1) to reflect this intent and specify that individuals who serve MRO staff functions need only to be under the direction of the MRO while performing those functions. The NRC has added these changes to specify NRC's intent in response to a public comment that requested clarification on this issue.

The NRC has added § 26.183(d)(1) [Direction of MRO staff activities] to require an MRO to be directly responsible for the administrative, technical, and professional activities of individuals who perform MRO staff duties. As discussed with respect to § 26.5, directing means the exercise of control over a work activity by an individual who is directly involved in the execution of the activity and either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity. The NRC does not intend to mandate that MROs must share the same physical space with all their staff members at all times. Direction of staff activities need not occur face-to-face on an all-day, every-day basis. Also, the definition of directing, specifically the phrase ''directly involved in the execution of the work activity,'' does not require the MRO to be on site when giving direction to individuals who are performing MRO staff functions. For example, the MRO must be directly involved in the work of onsite licensee MRO staff, even if that direct involvement occurs by telephone. Direction may also take place through using a variety of electronic communications.

However, this provision requires that the MRO's direction of staff must be meaningful. Meaningful direction involves personal oversight of staff members' work; providing input to their performance evaluation; line authority over the staff for decisions, direction, and control; and regular contact and oversight concerning drug testing program matters. This provision also requires that the MRO's direction and control of the staff members cannot be superseded by or delegated to anyone else with respect to the review of negative tests and other functions that staff members perform for the MRO. In addition, the provision requires that MROs must personally review a confirmed positive drug test result that is received from the HHS-certified laboratory, as well an adulterated, substituted, invalid, or dilute result. This requirement is consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i).

Section 26.183(d)(1)(i) requires that MRO staff duties must be independent from any other activity or interest of the licensee or other entity. The rule has added this requirement because, in contrast to other Federal agencies' regulations, Part 26 permits employees of licensees and other entities to perform MRO staff activities for MROs who work off site and are not physically present to supervise the staff. These circumstances may provide greater opportunities for inadvertent compromise of the independence of the MRO function than situations when the MRO and his or her staff are physically co-located, such as the inadvertent release of positive, adulterated, substituted, or invalid test results before the MRO has discussed the results with the donor. Therefore, the NRC believes that the requirement is necessary to protect the integrity of the MRO function and donors' privacy, consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including

due process) of individuals who are subject to Part 26.

The NRC has added § 26.183(d)(ii) to the final rule to further specify the MRO's responsibilities for directing MRO staff. These responsibilities include, but are not limited to, ensuring that the procedures that must be followed by MRO staff meet the regulations of this part and HHS and professional standards of practice. The MRO must also ensure that personal information about the donor is maintained confidentially with the highest regard for individual privacy. These requirements meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC has also added § 26.183(d)(1)(iii) to prohibit the MRO from delegating his or her responsibilities for directing MRO staff activities to any individual or entity, other than another MRO. Although the NRC is unaware of any instances when the MRO function has been compromised by MRO staff in Part 26 programs, the experience of other Federal agencies has indicated that clear limits on who may direct MRO staff activities are advisable to maintain the independence and integrity of the MRO function. Therefore, § 26.183(d)(1)(iii) establishes these clear limits and is consistent with Goal 3 of this rulemaking to improve the effectiveness of the FFD program.

The NRC has added § 26.183(d)(2) [MRO staff responsibilities] to specify the duties that MRO staff may and may not perform. The provisions are also based on the experience of other Federal agencies, which has indicated that clear limits on MRO staff duties are necessary to protect donor confidentiality and the integrity of the MRO process. Therefore, this addition is consistent with Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines. Section 26.183(d)(2)(i) permits MRO staff to receive results from the HHS-certified laboratory and to review and report negative test results to the licensee's or other entity's designated reviewing official under the MRO's direction. Section 26.183(d)(2)(ii) permits MRO staff to review the custody-and-control forms for specimens that the laboratory reports as positive, adulterated, substituted, invalid, or dilute, and to correct errors. However, the MRO is required to review and approve the corrections. Section 26.183(d)(2)(iii) prohibits staff from conducting interviews with donors to discuss positive, adulterated, substituted, invalid, or dilute test results. The provision also prohibits MRO staff from requesting or reviewing medical information from donors related to any positive, adulterated, substituted, dilute, or invalid test results.

Section 26.183(d)(2)(iv) prohibits MRO staff from reporting or discussing positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory with any individuals other than the MRO and other MRO staff. The provisions are necessary to protect donor confidentiality and the integrity of the MRO review process, consistent with Goal 7 of this rulemaking to protect privacy and other rights (including due process) of individuals who are subject to Part 26. At the same time, the provision permits licensees and other entities to realize the cost efficiencies associated with the MRO delegating some tasks to staff, consistent with Goal 3 of this rulemaking to increase the effectiveness and efficiency of Part 26 programs. With respect to the proposed rule, the NRC has clarified this provision to specify that the MRO staff may not report or discuss positive, adulterated, substituted, dilute, or invalid test results received from the HHS-certified laboratory with any individuals other than the MRO and other MRO staff before those results have been reviewed and confirmed by the MRO. The final rule also adds limitations on with whom the MRO staff can discuss confirmed positive, adulterated, substituted or invalid test results, as well as limitations on discussion of quantitative test results and any personal medical information. The NRC believes that only the MRO is qualified to answer questions from FFD program personnel about the basis for his or her decisions and the proper interpretation of test results from the HHS lab. These changes are consistent with Goal 6 of this rulemaking to improve clarity in the language of the rule.

Section 26.185 Determining a Fitness-for-Duty Policy Violation

Section 26.185 of the final rule contains requirements related to the MRO's determination that a positive, adulterated, substituted, invalid, or dilute test result constitutes an FFD policy violation.

Section 26.185(a) [MRO review required] of the final rule amends portions of former Section 2.9(a) in Appendix A to Part 26. The former section established requirements for the MRO's review of test results from the HHS-certified laboratory. The final rule expands the MRO's responsibilities to include assisting the licensee or other entity in determining whether a donor has attempted to subvert the testing process. These responsibilities may include, but are not limited to, reviewing positive, adulterated, substituted, dilute, or invalid test results and authorizing the testing at an HHS-certified laboratory of any suspicious substance discovered in a donor's pockets that could be used to adulterate or substitute a urine specimen. The change meets Goal 3 of the rulemaking as it relates to improving the effectiveness of FFD programs and is consistent with the NRC's increased concern with potential subversion of the testing process, as discussed with respect to § 26.31(d)(3)(i). This provision also deletes the former reference to ''nuclear power plant worker'' and replaces it with ''individual'' because persons other than nuclear power plant workers are subject to the requirement. In addition, this provision eliminates the former requirement for the MRO to review blood test results from the HHS-certified laboratory because the rule no longer permits donors to request testing of a blood specimen for alcohol, as discussed with respect to § 26.83(a). However, the provision retains the former requirement that the MRO must complete the review of any positive, adulterated, substituted, invalid, and, at the licensee's or other entity's discretion, dilute test results before transmitting results to a licensee's or other entity's designated representative.

With regard to the proposed rule, the NRC received a public comment stating that the MRO should not be required to determine whether a donor has violated the FFD policy because MRO expertise is exclusively medical. The NRC believes that an MRO has the medical expertise and detailed knowledge of possible alternate medical explanations that is essential to the review process. Therefore, the NRC maintains that the MRO is required to determine whether a donor has violated the FFD policy.

Section 26.185(b) [Reporting of initial test results prohibited] of the final rule retains the intent of the requirement in the last sentence of former Section 2.9(a) in Appendix A to Part 26. Specifically, this provision continues to prohibit the MRO from communicating to licensees and other entities any positive, adulterated, substituted, dilute, or invalid initial test results reported by the HHS-certified laboratory before confirmatory testing has been completed and the MRO has conducted his or her review. However, this provision extends the prohibition to MRO staff, consistent with Goal 7 of this rulemaking and the

addition of requirements related to MRO staff in § 26.183(d), as discussed with respect to that provision.

Section 26.185(c) [Discussion with the donor] of the final rule amends former Section 2.9(c) in Appendix A to Part 26. This provision continues to require the MRO to discuss a positive confirmatory drug test result with the donor before determining that the FFD policy had been violated. This provision adds a requirement for the MRO to discuss adulterated, substituted, dilute or invalid confirmatory validity test results with the donor as part of the review process, consistent with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i). This provision also adds a reference to ''other occurrence'' to address circumstances when the donor may have engaged in a subversion attempt that would be detected through other means, including, but not limited to, the specimen collection process in Subpart E [Collecting Specimens for Testing]. This provision eliminates the former requirement for the MRO to contact the EAP. Under this provision, referral to the EAP is at the licensee's or other entity's discretion, as documented in FFD procedures. The NRC has eliminated the former requirement because most licensees terminate the employment of individuals who have a confirmed positive, adulterated, or substituted drug test result. It is inappropriate to require licensees and other entities to provide EAP services to persons they will no longer employ. If a licensee or other entity plans to consider granting authorization to the individual after his or her authorization has been terminated unfavorably for the FFD policy violation, this provision requires the licensee or other entity to meet the applicable requirements of § 26.69 [Authorization with potentially disqualifying fitness-for-duty information]. The NRC has made these changes in the paragraph for consistency with other changes to the regulation and to meet Goal 3 of the rulemaking as it relates to increasing efficiency in FFD programs.

The NRC has added § 26.185(d) [Donor unavailability] to the final rule to clarify the circumstances when the MRO may confirm a positive, adulterated, substituted, dilute, or invalid test result, or other occurrence, as an FFD policy violation without having first discussed the test result or occurrence with the donor. These circumstances include when—

(1) The donor expressly declines the opportunity to discuss the possible FFD policy violation with the MRO, as specified in § 26.185(d)(1);

(2) The donor fails to contact the MRO within one business day after being contacted by the licensee or other entity, or an MRO staff member, as specified in § 26.185(d)(2); and

(3) The MRO is unable to contact the donor after making a reasonable effort to do so as specified in § 26.185(d)(2).

These provisions provide more detailed guidance than the first sentence of former Section 2.9(c) in Appendix A to Part 26 in response to many questions that have arisen regarding implementation of the requirement for MROs to discuss test results with the donor. The revisions also respond to stakeholders' requests during the public meetings discussed in Section I.D. In questions to the NRC staff and during the public meetings, licensees have pointed out that the former rule made no provision for these circumstances that do occasionally arise. Therefore, these provisions address these circumstances. The NRC believes that these provisions give the donor adequate opportunity to be contacted, consistent with Goal 7 of this rulemaking to protect the rights of individuals subject to Part 26, while allowing licensees to make ''reasonable efforts'' to contact the donor; thus meeting Goal 3 of this rulemaking as it relates to improving efficiency in the FFD program.

For the same reasons, § 26.185(e) [Additional opportunity for discussion] of the final rule specifies procedures for addressing a circumstance when the donor was unable to be contacted by the MRO to discuss a positive, adulterated, substituted, dilute, or invalid test result, or other occurrence. This provision permits the donor to present information to the MRO documenting the circumstances that unavoidably prevented the donor from being contacted by or from contacting the MRO, and permits the MRO to reopen the procedure for determining whether the donor had violated the FFD policy. This provision also permits the MRO to modify the initial determination based on the information that the donor provides.

The requirements in § 26.185(d) and (e) incorporate the related requirements in 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944; August 9, 2001). Therefore, in addition to responding to implementation questions from licensees and stakeholder requests, the provisions meet Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The NRC has added § 26.185(f) through (i) to the final rule to establish requirements for the MRO's review of validity test results. The NRC has added these paragraphs for consistency with the addition of requirements to conduct validity testing throughout the rule, as discussed with respect to § 26.31(d)(3)(i) to meet Goal 3 of this rulemaking to increase the effectiveness and efficiency of Part 26 programs.

Section 26.185(f) [Review of invalid specimens] clarifies the MRO's responsibilities if the HHS-certified laboratory reports that a specimen is invalid. This provision is consistent with related provisions in the HHS Guidelines and is necessary because MRO actions in response to an invalid specimen are not specified in the former rule. Section 26.185(f) provides the MRO with the following several alternative courses of action if a specimen is declared to be invalid by the laboratory:

Section 26.185(f)(1) requires the MRO to consult with the HHS-certified laboratory to determine whether additional testing by another HHS-certified laboratory may be useful for completing testing of the specimen. Another laboratory may use different testing methods that could provide more definitive test results regarding the invalid specimen, such as the ability to identify a new adulterant or obtain valid drug test results despite the presence of an interfering substance in the specimen. If the MRO and laboratory agree that additional testing would be useful, the MRO shall direct the laboratory to forward an aliquot of the specimen to a second HHS-certified laboratory for further testing.

Section 26.185(f)(2) requires the MRO to contact the donor to determine whether there is an acceptable medical explanation for the invalid result if the MRO and HHS-certified laboratory agree that testing at a second laboratory would not be useful. If the MRO determines that there is an acceptable medical explanation for the invalid result, the MRO would report to the licensee or other entity that no FFD policy violation had occurred, but that a negative test result had not been obtained. Because the specimen did not yield negative test results, the licensee or other entity could not use the invalid test result in the decision to grant or deny authorization. However, this provision also requires the MRO to assess whether the medical condition would similarly affect a second specimen collection. If the MRO determines that the medical condition is temporary and would not

affect a second specimen, he or she would direct the licensee or other entity to collect another specimen from the donor. The licensee or other entity would then rely upon the results of the second test to make an authorization decision. This provision does not require the second specimen to be collected under direct observation in this situation because there is no reason to believe that the individual may have attempted to subvert the testing process. If the MRO determines that the medical condition would likely affect the validity of further urine specimens, the MRO may authorize an alternative method for drug testing. At this time, the NRC declines to specify the alternative methods that the MRO may authorize, which may include, but are not limited to, testing of alternate specimens, such as hair, oral fluids, or sweat. The NRC leaves the selection of an alternative method to the professional judgement of the MRO. This provision also prohibits licensees and other entities from taking management actions or imposing sanctions on the basis of an invalid test result from a medical condition because no FFD violation would have occurred.

Section 26.185(f)(3) requires the MRO to direct the licensee or other entity to collect another specimen under direct observation, if testing by another laboratory would not be useful in obtaining a valid result and the donor did not provide an acceptable medical explanation for the invalid specimen. The invasion of privacy associated with a directly observed collection is warranted in this situation because the invalid specimen may be the result of a subversion attempt. This provision requires the licensee or other entity to rely on the test results from the directly observed collection in authorization decision-making because the result from the invalid specimen would be neither negative nor positive, adulterated, substituted, or invalid, and could not meet the requirements for granting authorization to an individual in Subpart C [Granting and Maintaining Authorization] or serve as the basis for imposing the sanctions specified in Subpart D [Management Actions and Sanctions].

The NRC has added § 26.185(g) [Review of dilute specimens] to the final rule to establish requirements for the MRO's review of positive confirmatory drug test results from dilute specimens. The NRC has added this paragraph because reviewing test results from a dilute specimen is complex and MRO actions in response to a dilute specimen are not addressed in the former rule.

Section 26.185(g)(1) requires the MRO to confirm a drug-positive FFD violation for a dilute specimen in which drugs or drug metabolites are detected, if the MRO determines that there is no legitimate medical explanation for the presence of the drugs or metabolites in the specimen. The final rule amends the proposed rule by clarifying that a clinical examination is one of the criteria that must be met before the MRO can confirm a drug-positive FFD violation, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rulemaking. There are many legitimate reasons for submitting a dilute specimen, which is the basis for omitting the submission of a dilute specimen as one type of subversion attempt for which a permanent denial of authorization is required in § 26.75(b). Although neither the submission of a dilute specimen nor the presence of drugs or drug metabolites in a dilute specimen establishes that the donor has attempted to subvert the testing process without additional evidence of subversion, the presence of drugs or metabolites in a dilute specimen without a legitimate medical explanation is a sufficient basis for the MRO to confirm that the donor has violated the FFD policy.

The final rule modifies and clarifies § 26.185(g)(2) of the former and proposed rules. This provision specifies the conditions that must be met in order for the MRO to determine whether the positive and dilute specimen is a refusal to test. These conditions include when—

(1) The HHS-certified laboratory conducts the special analysis of dilute specimens permitted in 26.163(a)(2) and the results show the presence of drugs or drug metabolites in the specimen;

(2) The MRO determines there is no legitimate medical explanation for the presence of drugs or drug metabolites in the specimen; and

(3) a clinical examination has been conducted in accordance with this section.

The provision also specifies when the MRO shall determine that drug test results are positive and the donor has violated FFD policy. These changes are consistent with the changes the NRC has made to procedures for processing dilute specimens, as discussed in § 26.163(a)(2).

Section 26.185(g)(2)(i) through (g)(2)(iii) defines the circumstances that may constitute a reason to believe that a donor may have attempted to subvert the testing process and provide a sufficient basis for the MRO to require the additional testing permitted in § 26.185(g)(2). These circumstances are the same as those specified in § 26.115(a)(1) through (a)(3). The final rule clarifies this provision of the proposed rule by specifying that these circumstances must be considered by the MRO, if applicable, and are not the exclusive grounds to believe the donor may have diluted the specimen in a subversion attempt. This NRC has made this change in response to public comment and to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.185(g)(3) clarifies that the MRO may also require the additional testing of a dilute specimen that is permitted in § 26.185(g)(2) if the specimen was collected under direct observation. This provision adds this permission for consistency with the related provisions in the FFD rule.

Section 26.185(g)(4) requires the MRO to determine whether there is clinical evidence of the illegal use of opiates or if opiates other than 6–AM at any concentration are detected in a dilute specimen before the MRO verifies that the donor has violated the FFD policy. This provision does not require an evaluation for clinical evidence of illegal use of opiates for 6–AM because its presence in a specimen is proof of heroin use. However, the provision does not establish cutoff levels below and above which an evaluation for clinical evidence of illegal opiate use is not required (in contrast to those contained in paragraph (j) of this section) because the concentration of opiates in a dilute specimen does not bear any known relationship to the concentration of opiates in vivo (i.e., in the donor's body). For similar reasons, this provision also requires an evaluation for clinical evidence of abuse before the MRO determines that the donor has violated the FFD policy when drugs or drug metabolites are detected in a dilute specimen, indicating that the donor has used prescription or over-the-counter medications.

The NRC has added § 26.185(g)(5) to the final rule, with respect to the proposed rule, to specify the circumstances under which MRO review is not required. This change is consistent with related provisions in the HHS guidelines.

The NRC has added § 26.185(h) [Review of substituted specimens] to the final rule to establish requirements for the MRO review of substituted test results. These provisions have been added because MRO actions in determining an FFD policy violation for a substituted specimen are consistent with the related provisions in the HHS

Guidelines and are not addressed in the former rule.

Section 26.185(h)(1) requires the MRO to contact the donor to determine whether there is a legitimate medical reason for the substituted result. This provision requires the MRO to give the donor the opportunity to provide legitimate medical evidence, within 5 business days of being contacted by the MRO, that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. The final rule, with respect to the proposed rule, specifies that a qualified and experienced physician, as verified by the MRO, shall submit the medical evidence. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity in this provision to specify the NRC's intent. This provision also provides examples of donor claims that the MRO may not consider to be legitimate medical explanations, including, but not limited to, race, gender, body weight, and dietary factors.

Section 26.185(h)(2) directs the MRO to report to the licensee or other entity that the specimen was substituted if the MRO determines that there is no acceptable medical explanation for the substituted test result.

Section 26.185(h)(3) directs the MRO to report to the licensee or other entity that no FFD policy violation has occurred if the MRO determines that the donor has provided an acceptable medical explanation for the substituted test result.

Section 26.185(i) [Review of adulterated specimens] of the final rule establishes requirements for the MRO's review of adulterated test results. This provision has been added because MRO actions in determining an FFD policy violation for an adulterated specimen are not addressed in the former rule. Section 26.185(i)(1) requires the MRO to contact the donor and offer him or her the opportunity to provide an acceptable medical explanation for the adulterated result within 5 business days after the donor produced the adulterated result. The final rule, with respect to the proposed rule, specifies that a qualified and experienced physician, as verified by the MRO, shall submit the medical evidence. The NRC has made this change because after publishing the proposed rule, it recognized the need for additional clarity in this provision to specify the NRC's intent. If the MRO determines that there is no legitimate acceptable medical explanation for the adulterated result, § 26.185(i)(2) requires the MRO to report to the licensee or other entity that the specimen is adulterated. If the donor provides an acceptable medical explanation, § 26.185(j)(3) requires the MRO to report that no FFD policy violation had occurred. These requirements are consistent with the related provisions in the HHS Guidelines.

Section 26.185(j) [Review for opiates, prescription and over-the-counter medications] of the final rule amends former Section 2.9(d) in Appendix A to Part 26. It addresses circumstances that have arisen since Part 26 was first published and about which licensees have sought guidance from the NRC. These changes are consistent with Goal 3 of the rulemaking to improve the effectiveness of FFD programs. The paragraph amends the former requirements in Section 2.9(d) in Appendix A to Part 26 and adds others, as follows:

Section 26.185(j)(1) incorporates updated requirements from the HHS Guidelines related to the MRO's review of a positive drug test result for opiates. The rule revises but retains the meaning of the requirement for the MRO to determine that there is clinical evidence of illegal use of opiates, which appeared in former Section 2.9(d) in Appendix A to Part 26. Because some licensees and other entities rely on MROs who work off site and are not available to conduct the required assessment, the rule permits the MRO to designate another licensed physician who has knowledge of the clinical signs of drug abuse to conduct the evaluation. This change ensures that the clinical assessment is performed by a qualified physician while reducing unnecessary burden by permitting FFD programs to continue to rely on off site MROs. Therefore, the change meets Goal 5 of this rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

This provision eliminates the examples of clinical signs of opiate abuse in former Section 2.9(d) in Appendix A to Part 26 because these signs are addressed as part of the training that MROs must obtain in order to pass the comprehensive certification examination required in § 26.183(a) [Qualifications]. The rule retains the provision in former Section 2.9(d) that permits the MRO to omit the evaluation for clinical evidence of abuse if the laboratory identifies 6–AM in the specimen. However, the rule adds permission for the MRO to omit the evaluation if the morphine or codeine concentration in the specimen is equal to or greater than 15,000 ng/mL without a legitimate medical explanation for the presence of opiates at or above this concentration. The NRC has made this change because, in the experience of other Federal programs, such concentrations without a legitimate medical explanation can only indicate substance abuse. In addition, the rule prohibits the MRO from considering consumption of food products as a legitimate medical explanation for the specimen having morphine or codeine concentrations at or above 15,000 ng/mL because food consumption could not result in a concentration at this level.

Section 26.185(j)(2) retains the last sentence of former Section 2.9(d) in Appendix A to Part 26. This provision requires the MRO to determine whether there is clinical evidence of abuse of these substances or their derivatives, in addition to the positive confirmatory test result.

The NRC has added § 26.185(j)(3) to the final rule to provide greater consistency in MRO determinations related to a donor's use of another person's prescription medication. The NRC is aware that MROs in different FFD programs have varied in their determinations as to whether the use of another person's prescription medication is an FFD policy violation. The paragraph clarifies the NRC's intent with respect to these circumstances. In the final rule, if a donor claims, and the MRO confirms, that a positive, adulterated, substituted, or invalid drug test result is due to the unauthorized use of another person's prescription medication, the rule requires the MRO to evaluate or ensure that the donor is evaluated for clinical evidence of abuse. If no clinical evidence of abuse is identified, the MRO shall report to the licensee or other entity that a violation of the FFD policy regarding misuse of a prescription medication had occurred. If clinical evidence of abuse is identified, the MRO will confirm that the test results are positive for the drug or metabolites detected.

The NRC has added § 26.185(j)(4) to the final rule to assure greater consistency in MRO determinations related to a donor's use of a prescription or over-the-counter medication that the donor obtained legally in a foreign country. Again, the NRC is aware that MROs in different FFD programs have varied in their determinations as to whether the use of medications legally obtained in a foreign county is an FFD policy violation. The paragraph clarifies the NRC's intent with respect to these circumstances. At the licensee's or other entity's discretion and in accordance with the FFD policy and procedures, the rule permits the MRO to confirm a test result as negative if there is a legitimate medical use for the medication that the donor obtained legally in a foreign

country and the donor has used it properly for its intended medical purpose. The rule prohibits the MRO from confirming a test result as negative if the drug used has no legitimate medical purpose, including, but not limited to phencyclidine and heroin.

The NRC has added § 26.185(j)(5) to prohibit the MRO from considering the consumption of food products, supplements, and other preparations that are available over-the-counter as a legitimate medical explanation for the specimen having drugs or drug metabolites above the cutoff levels specified in § 26.163, including, but not limited to hemp products and coca leaf tea. In so doing, the rule provides guidance concerning a potential subversion technique that has become an issue for several licensees (i.e., claims of ingestion of hemp food products as the basis for a positive marijuana test). Ingestion of food products containing hemp seeds or extracts has produced marijuana positive test results even though the seller claimed that the seeds or extracts were sterilized to remove the THC metabolite. The NRC endorses the Federal policy in this matter that was published by the DOT, with the concurrence of the Departments of Justice and Health and Human Services and the Office of National Drug Control Policy. MROs must never accept an assertion of consumption of a hemp food product as a basis for confirming that a marijuana test is negative. Consuming a hemp food product is not a legitimate medical explanation for a prohibited substance or metabolite in an individual's specimen. When a specimen is positive for THC, the only legitimate medical explanation for its presence is a prescription for marinol. Under § 26.29(a)(6) and (a)(7), individuals who are subject to Part 26 receive training in order to be able to avoid ingesting substances that could result in positive drug test results, such as over-the-counter medications, food products, supplements, and other preparations.

The NRC has added § 26.185(j)(6) to the final rule to prohibit the MRO from accepting the use of any drugs that are listed in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law. Drugs that are listed in Schedule I of section 202 of the Controlled Substances Act have the following characteristics:

(1) The drug or other substance has a high potential for abuse;

(2) The drug or other substance has no currently accepted medical use in treatment in the United States; and

(3) There is a lack of accepted safety for use of the drug or other substance under medical supervision.

The prohibition is primarily intended to address the medical use of marijuana, which some States permit, as well as the use of certain hallucinogenic drugs. Although some have argued that the use of such drugs under State laws may not adversely reflect on an individual's trustworthiness and reliability, the requirement is necessary to ensure that individuals who are subject to this part can be trusted and relied upon to comply with Part 26 requirements and are not impaired from using these drugs when performing duties that require them to be subject to this part.

Section 26.185(k) [Results consistent with legitimate drug use] of the final rule amends former Section 2.9(f) in Appendix A to Part 26. The former provision instructed the MRO to report to the licensee that a drug test result is negative if, after review, the MRO determines that there is a legitimate medical explanation for the positive test result and that use of the substance identified through testing in the manner and at the dosage prescribed does not reflect a lack of reliability and is unlikely to create on-the-job impairment. However, the former provision did not provide instructions for MRO action in the case of an individual whose drug use is legitimate but may cause impairment on duty. Therefore, if the MRO determines that a risk exists, the final rule requires that a determination of fitness must be performed. Because the MRO determined that the drug test result was negative, the licensee or other entity shall not impose sanctions on the individual. However, the results of the determination of fitness may indicate a need to establish controls and conditions on the individual's performance of certain duties in order to ensure that any impairment from the drug use does not result in adverse impacts on public health and safety or the common defense and security. By providing greater assurance that individuals who are subject to the rule are fit to safely and competently perform their duties, the provision meets Goal 3 of this rulemaking to improve the effectiveness of FFD programs.

Section 26.185(l) [Retesting authorized] of the final rule amends former Section 2.9(e) in Appendix A to Part 26. This provision permits the MRO to authorize retesting of an aliquot of a specimen or the analysis of any split specimen (Bottle B) if there is any question about the accuracy or scientific validity of a drug test result in order to determine whether the FFD policy has been violated. The final rule retains the provisions in former Section 2.9(e) that permitted a donor to request a retest of an aliquot of a single specimen or a split specimen if the FFD program follows split specimen procedures. However, the final rule updates the former requirement for consistency with the terminology used throughout the final rule (e.g., ''Bottle B'' to refer to a split specimen), as discussed with respect to § 26.5. The final rule also includes a requirement that the retesting must be conducted at a second HHS-certified laboratory that did not conduct the original tests. The requirement that retesting must be performed at a second HHS-certified laboratory ensures the independence of the second testing and provide additional protection of donors' due process rights under the rule. In addition, the requirement increases the consistency of Part 26 with related provisions in the HHS Guidelines, consistent with Goal 1 of the rulemaking to update and enhance the consistency of Part 26 with advances in other Federal rules and guidelines.

The proposed rule required the donor to request the retest in writing in order to ensure donors' control over the specimen and rights to privacy under § 26.135(b). However, the final rule eliminates the provision that the donor's authorization for re-testing must be in writing. This change is in response to public comment stating that obtaining a written request poses an unnecessary logistical burden on the donor and the MRO and that verbal requests are and have been sufficient in the past. Therefore, the NRC has made this change, consistent with other Federal regulations and Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

Section 26.185(m) [Results scientifically insufficient] of the final rule amends the first sentence of the former Section 2.9(g) in Appendix A to Part 26. This provision permits the MRO to determine that a positive, adulterated, substituted or invalid test result is scientifically insufficient for further action. The final rule instructs the MRO to report that the drug or validity test result is not an FFD policy violation in these circumstances, but that a negative test result was not obtained. The NRC has made this change for consistency with other changes in the rule related to invalid test results (see § 26.185(f)). A test result that the MRO determines to

be scientifically insufficient for further action (as well as an invalid test result) could not be a basis for a licensee or other entity to grant or deny authorization or impose sanctions because it would be neither a negative nor positive, adulterated, or substituted test result. Therefore, the change meets Goal 6 of this rulemaking to improve clarity in the language of the rule. The NRC has changed some of the terminology used in the former paragraph in the final rule for consistency with the terminology used throughout the final rule (e.g., ''samples'' is changed to ''specimens''). The final rule also makes the following changes to this provision:

The final rule also adds a statement to the former paragraph to indicate that the MRO is neither expected nor required to request retesting of the specimen unless, in the sole opinion of the MRO, such retesting is warranted. The final rule includes this statement because, in the experience of other Federal agencies, some MROs have been pressured by the organization to whom they provide services to request retesting of specimens that the MRO has confirmed to be positive, adulterated, substituted, or invalid. Although the NRC is not aware of any such instances in Part 26 programs, the rule clarifies that the MRO alone is authorized to request retesting to further protect the independence of the MRO function.

In addition, the NRC has moved the last sentence of former Section 2.9(g), which contained records retention requirements, to § 26.215(b)(11) of Subpart N [Recordkeeping and Reporting Requirements] of the final rule. The NRC has moved this provision to group it with other records retention requirements in the rule for organizational clarity.

Section 26.185(n) [Evaluating results from a second laboratory] establishes new requirements for the MRO's determination of an FFD policy violation based on a retest of a single specimen or a test of the specimen in Bottle B of a split specimen. This provision specifies that the test result(s) from the second HHS-certified laboratory supersede the confirmatory test results provided by the HHS-certified laboratory that performed the original testing of the specimen. The final rule incorporates these requirements from the HHS Guidelines because the former rule did not address MRO actions in response to test results from a second laboratory. Therefore, the provision is consistent with the related provisions in the HHS Guidelines and meets Goal 1 of this rulemaking to update and enhance the consistency of Part 26 with advances in other relevant Federal rules and guidelines.

The NRC has added § 26.185(o) [Re-authorization after a first violation] to the final rule. This provision addresses the MRO's review of drug test results following a first violation of the FFD policy based on a confirmed positive drug test result. The former rule did not require the MRO to evaluate whether drug test results in these instances indicated subsequent drug use after a first confirmed positive drug test result, and MROs from different FFD programs have implemented different policies. Specifically, the final rule requires the MRO to determine whether subsequent drug test results indicate further drug use since the first positive drug test result was obtained. For example, because marijuana metabolites are fat-soluble and may be released slowly over an extended period of time, a second positive test result for marijuana from a test that is performed within several weeks after a first confirmed positive test result for marijuana may not, in fact, indicate further marijuana use. Therefore, in this case, the provision prohibits the MRO from determining that a second FFD policy violation for marijuana had occurred if the quantitative results from confirmatory testing of the second specimen are positive for marijuana metabolites, but at a concentration that is inconsistent with additional marijuana use since the first positive, adulterated, substituted, or invalid test result was obtained. If the MRO concludes that the concentration of marijuana metabolites identified by confirmatory testing is inconsistent with further marijuana use since the first positive test result, the MRO would declare the test result as negative, even if the quantitative test result exceeds the 15 ng/mL confirmatory cutoff level specified in this part or a licensee's or other entity's more stringent cutoff level. The provision prevents individuals from being subject to a 5-year denial of authorization for a second confirmed positive drug test result under § 26.75(e), when the donor has not engaged in further drug use, consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process rights) of individuals who are subject to Part 26.

Section 26.185(p) [Time to complete MRO review] of the final rule amends former § 26.24(e). This provision requires the MRO to complete his or her review of test results and notify management of the results of his or her review within 10 business days after an initial positive, adulterated or substituted test result. The rule replaces the former phrase, ''initial presumptive positive screening test result,'' with the phrase, ''initial positive, adulterated or substituted test result,'' for consistency with the terminology used throughout the rule (see § 26.5). This provision also requires the MRO to report his or her determination that a test result is an FFD policy violation in writing to the licensee or other entity and in a manner that ensures the confidentiality of the information. The NRC has made these changes for consistency with the related provisions in the HHS Guidelines, consistent with Goal 1 of this rulemaking.

Section 26.187 Substance Abuse Expert

The NRC has added § 26.187 to the final rule. This section establishes minimum requirements for a new position within FFD programs, the ''substance abuse expert'' (SAE). These added provisions meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.187(a) [Implementation] to the final rule. This provision requires SAEs to meet the requirements of this section within 2 years of the date on which the final rule is published in the **Federal Register**. The NRC has imposed the 2-year period in order to ensure that professionals who may currently be performing determinations of fitness, but who do not meet these proposed requirements, have the time necessary to obtain the required credentials, knowledge, and qualification training. With respect to the proposed rule, the final rule adds a sentence that allows an MRO who meets the requirements of this section to serve as both an MRO and as an SAE. The NRC has made this change in response to a public comment suggesting that allowing the MRO, if qualified, the option to function as the SAE would avoid any unnecessary financial burden for licensees that have an MRO that can make SAE determinations.

The NRC has added § 26.187(b) [Credentials] to the final rule to establish the credentials required for an individual to serve as an SAE under this part. The rule requires that the SAE must possess the extensive education, training, and supervised clinical experience that are prerequisites for obtaining the professional credentials listed in § 26.187(b)(1) through (b)(5). Further, § 26.187(c) through (e) requires an SAE to possess additional knowledge and experience directly related to substance abuse disorders and the requirements of this part.

The NRC has added § 26.187(c) [Basic knowledge] and (d) [Qualification

training] to the final rule to establish the specific areas of expertise and training that are required for an individual to serve as an SAE under this part. The knowledge and training requirements in these two paragraphs are necessary to ensure that SAEs possess the knowledge and clinical experience required to perform the SAE function effectively in a Part 26 program.

Section 26.187(c) requires SAEs to possess the following types of knowledge: (1) Knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled-substance abuse disorders, in § 26.187(c)(1); (2) knowledge of the SAE function as it relates to individuals who perform the duties that require an individual to be subject to this part, in § 26.187(c)(2); and (3) knowledge of this part and any changes to its requirements, in § 26.187(c)(3).

Section 26.187(d) establishes the topical areas in which an SAE must be trained. The qualification training requirements include training in the following areas: (1) The background, rationale, and scope of this part, in § 26.187(d)(1); (2) key drug and alcohol testing requirements of this part, in § 26.187(d)(2) and (d)(3), respectively; (3) SAE qualifications and prohibitions, in § 26.187(d)(4); (4) the role of the SAE in making determinations of fitness, and developing treatment recommendations and followup testing plans, in § 26.187(d)(5); (5) procedures for consulting and communicating with licensee or other entity officials and the MRO, in § 26.187(d)(6); (6) reporting and recordkeeping requirements of this part as they related to the SAE function, in § 26.187(d)(7); and (7) appropriate methods for addressing issues that SAEs confront in carrying out their duties under this part, in § 26.187(d)(8).

The NRC has added § 26.187(e) [Continuing education] to the final rule to ensure that SAEs maintain the knowledge and skills required to perform the SAE function. The paragraph requires SAEs to complete at least 12 continuing professional education hours relevant to performing the SAE function during each 3-year period following completion of initial qualification training. Section 26.187(e)(1) describes the topics that must be covered in the continuing education training, to include, but not limited to, new drug and alcohol testing technologies, and any rule interpretations or new guidance, rule changes, or other developments in SAE practice under this part since the SAE completed the qualification training requirements in § 26.187(d). Section 26.187(e)(2) requires documented assessment of the SAE's understanding of the material presented in the continuing education activities in order to ensure that the SAE learned the material. These continuing education requirements are necessary to ensure that SAEs maintain updated knowledge and skills to continue performing the SAE function effectively under this part.

The NRC has added § 26.187(f) [Documentation] to the final rule to specify the records that the SAE must maintain in order to demonstrate that he or she meets the requirements of this section. The SAE is required to provide the documentation, as requested, to NRC representatives, and to licensees or other entities who rely on the SAE's services. Licensees and other entities who intend to rely upon a determination of fitness that is made by an SAE under another FFD program are also required to have access to this documentation. These requirements are necessary to ensure that licensees and other entities, and the NRC, have access to the documentation required to verify that the SAE's knowledge, training, and practice meet the requirements of this part. The final rule, with respect to the proposed rule, adds a cross-reference to ensure that this provision is consistent with the protection of information requirements in § 26.37 of this part.

The NRC has added § 26.187(g) [Responsibilities and prohibitions] to the final rule to specify the responsibilities of SAEs within a licensee's or other entity's FFD program and their limitations.

Section 26.187(g)(1) specifies at least three circumstances in which the SAE is responsible for making a determination of fitness under the rule. In § 26.187(g)(1)(i), an SAE may be called upon to make a determination of fitness regarding an applicant for authorization when the self-disclosure, the suitable inquiry, or other sources of information identify potentially disqualifying FFD information about the applicant. In § 26.187(g)(1)(ii), an SAE may be called upon to make a determination of fitness when an individual has violated the substance abuse provisions of a licensee's or other entity's FFD policy, including, but not limited to a first confirmed positive drug test result. Related provisions in § 26.69 require the licensee or other entity to rely upon the results of the SAE's determination of fitness when making a decision to grant or maintain an individual's authorization and implement any recommendations from the SAE for treatment and followup testing. In § 26.187(g)(1)(iii), an SAE may be called upon to make a determination of fitness when there is a concern that an individual may be impaired as a result of the use of prescription or over-the-counter medications or alcohol. Related provisions in § 26.77 [Management actions regarding possible impairment] require the licensee or other entity to rely upon the results of the SAE's determination of fitness when determining whether an individual may perform duties that require the individual to be subject to this part. Therefore, the NRC has added the paragraph for consistency with other related provisions in the rule.

The NRC has added § 26.187(g)(2) to the final rule to require the SAE to act as a referral source to assist an individual's entry into an appropriate treatment or education program. The provision also prohibits the SAE from engaging in any activities that could create the appearance of a conflict of interest. Section 26.187(g)(2)(i) prohibits the SAE from referring an individual to any organization with whom the SAE has a financial relationship, including the SAE's private practice, to avoid creating the appearance of a conflict of interest. However, § 26.187(g)(2)(ii)(A) through (g)(2)(ii)(D) specifies circumstances in which the prohibition in § 26.187(g)(2)(i) does not apply. In general, the rule permits the SAE to refer an individual to an entity with whom the SAE has a financial relationship in situations where treatment and educational resources may be limited by cost considerations or geographical availability. These provisions are necessary to ensure that the SAE's determinations are not influenced by financial gain and that individuals who are subject to the rule and the public can have confidence in the integrity and independence of the SAE function in Part 26 programs.

Section 26.189 Determination of Fitness

The NRC has added § 26.189 to the final rule to present in one section and amend former requirements related to the determination that an individual is fit to safely and competently perform the duties that require individuals to be subject to this part.

The final rule replaces the terms ''medical assurance'' and ''medical determination of fitness'' used in various sections of the former rule (e.g., § 26.27(a)(3), (b)(2) and (b)(4)) with the term ''determination of fitness'' as defined in this section. The NRC has made this change in terminology because the rule permits healthcare professionals other than licensed physicians to conduct determinations of fitness, as discussed with respect to § 26.187 [Substance abuse expert].

Therefore, the change meets Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC has added § 26.189(a) to the final rule. The first sentence of the paragraph defines the term ''determination of fitness.'' This term refers to the process entered when there are indications that an individual may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties. The final rule amends this definition as it was proposed, due to public comment, to clarify the intent of the provision.

In general, the final rule requires that professionals who perform determinations of fitness must be qualified and possess the requisite clinical experience, as verified by the licensee or other entity, to assess the specific fitness issues presented by an individual whose fitness may be questionable. The approach to designating the healthcare professionals who may conduct a determination of fitness focuses on the appropriateness of the professional's expertise for addressing the subject individual's fitness issue, rather than on the professional's organizational affiliation [see the discussion of § 26.69(b)(4)] or whether the individual is a licensed physician. Therefore, § 26.189(a)(1) through (a)(5) provides examples of the healthcare professionals who are qualified to address various fitness issues that may arise in a FFD program. When a decision must be made to determine whether an individual may be granted or maintain authorization and a substance abuse disorder is involved, only professionals who meet the requirements to serve as an SAE are permitted to make determinations of fitness under § 26.189(a)(1). The final rule permits other healthcare professionals to perform determinations of fitness that involve assessing and diagnosing impairment from causes other than substance abuse, such as clinical psychologists in § 26.189(a)(2), psychiatrists in § 26.189(a)(3), physicians in § 26.189(a)(4), or an MRO in § 26.189(a)(5), consistent with their professional qualifications. The final rule also permits other licensed and certified professionals who are not listed in the paragraph, such as registered nurses or physicians' assistants who have the appropriate training and qualifications, to perform a determination of fitness regarding specific fitness issues that are within their areas of expertise. However, the critical tasks of assessing the presence of a substance abuse disorder, providing input to authorization decisions, and developing treatment plans are reserved for healthcare professionals who have met the specific training, clinical experience, and knowledge requirements for an SAE under § 26.187 for the reasons discussed with respect to that section.

The final rule also prohibits healthcare professionals who may conduct a determination of fitness for a Part 26 program from addressing fitness issues that are outside of their specific areas of expertise, consistent with the ethical standards of healthcare professionals' disciplines as well as State laws. The rule adds this prohibition to clarify that the ethical standards and State laws also apply to making determinations of fitness under Part 26 because a determination of fitness conducted by a professional who is not qualified to address the specific fitness issue would be of questionable validity. Therefore, the prohibition is necessary to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, as well as Goal 7 to protect the privacy and other rights (including due process rights) of individuals who are subject to Part 26.

Section 26.189(b)(1) through (b)(4) of the final rule lists and presents together the circumstances in which a determination of fitness must be performed, as required in other sections of the rule. Although this paragraph is redundant with other sections of the rule, these circumstances are listed in one paragraph to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule, by grouping related requirements together in the order in which they would apply to licensees' and other entities' FFD processes.

Section 26.189(b)(1) reiterates the requirement in former Section 2.9(f) in Appendix A to Part 26 and § 26.185(k) of the final rule that a determination of fitness must be performed when there is a medical explanation for a positive, adulterated, substituted, or invalid test result, but a potential for impairment exists. For example, legitimate use of some psychotropic medications or medications for pain relief may cause impairment in some individuals and it may be necessary to limit the types of tasks the individual performs until the medication is no longer necessary or the person adjusts to its effects.

Section 26.189(b)(2) reiterates requirements in former § 26.27(b)(1) and (b)(4) and § 26.69(b) [Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization] of the final rule that a determination of fitness must be performed before an individual is granted authorization following an unfavorable termination or denial of authorization for a violation of a licensee's or other entity's FFD policy.

Section 26.189(b)(3) reiterates the requirement in § 26.69(c) [Granting authorization with other potentially disqualifying FFD information] that a determination of fitness must be performed before an individual is granted authorization when potentially disqualifying FFD information is identified that has not been previously addressed and resolved under the requirements of this subpart.

Section 26.189(b)(4) addresses other circumstances in which a determination of fitness may be required. For example, a determination of fitness may be necessary if an FFD concern has been raised regarding another individual, as required in § 26.27(c)(4), and if a licensee's or other entity's reviewing official requires one, under § 26.69(c)(3) and (d)(2).

The NRC has added § 26.189(c) to the final rule to establish requirements for a determination of fitness that is conducted ''for cause.'' Specifically, § 26.189(c) requires that a determination of fitness that is conducted for cause must be conducted through face-to-face interaction. With respect to the proposed rule, the final rule clarifies that a face-to-face interaction is required only when there is observed behavior or a physical condition. This provision ensures that the professional who is performing the determination has available all of the sensory information that may be required for the assessment, such as the smell of alcohol or the individual's physical appearance. The NRC does not require a for-cause determination of fitness to be conducted under this section if there is an absence of physical or sensory information (*i.e.,* based solely on receiving information that an individual is engaging in substance abuse). The immediacy of the decision limits the amount of information that can be gathered and made available to the professional by others. The provision does not require that determinations of fitness for other purposes be conducted face-to-face. These other purposes may include, but are not limited to, the determination of fitness that is required when an applicant for authorization has self-disclosed potentially disqualifying FFD information. Determinations of fitness in these other circumstances would focus primarily on historical, rather than immediate, information. In these cases, the professional would have access to information that could be gathered by others about the individual,

and no time urgency would be involved in the evaluation. Therefore, NRC has added the paragraph to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs. This provision also requires a face-to-face assessment in some circumstances where electronic means of communication could not provide the requisite information for the evaluation. It also permits other means of conducting the assessment when those means provide increased flexibility to licensees and other entities while continuing to achieve the goal of the evaluation.

Section 26.189(c)(1) through (c)(2) specifies the required outcomes of a for cause determination of fitness. The final rule provides an increased level of detail in these requirements to increase consistency in implementing the for cause determination of fitness process among FFD programs for the reasons discussed with respect to § 26.187.

Section 26.189(c)(1) requires that, if there is neither conclusive evidence of an FFD policy violation nor a significant basis for concern that the individual may be impaired while on duty, then the individual must be determined to be fit for duty. The licensee or other entity shall permit the individual to perform the duties that require the individual to be subject to this part.

Section 26.189(c)(2) requires that, if there is no conclusive evidence of an FFD policy violation, but there is a significant basis for concern that the individual may be impaired while on duty, then the individual must be determined to be unfit for duty. Such a determination does not constitute a violation of Part 26 or the licensee's or other entity's FFD policy. Therefore, no sanctions shall be applied. Examples of circumstances in which an individual may be determined to be unfit under this paragraph could include a temporary illness, such as a severe migraine headache, or transitory but severe stress in a personal relationship. These circumstances may impact an individual's ability to work safely for a short period, but would have no implications for the individual's overall fitness to perform the duties that require the individual to be subject to this part. In addition, the final rule requires the professional who conducts the determination of fitness to consult with the licensee's or other entity's management personnel to identify and implement any necessary limitations on the impaired individual's activities to ensure that the individual's condition would not affect workplace or public health and safety. If appropriate, the individual may be referred to the EAP for assistance.

The NRC has added § 26.189(d) to the final rule to prohibit licensees and other entities from seeking a second determination of fitness if a determination of fitness under Part 26 has already been performed by a qualified professional who is employed by or under contract to the licensee or other entity. The paragraph also requires that the professional who made the initial determination must be responsible for modifications to the initial determination based on new or additional information. However, if the initial professional is no longer available, then the licensee or other entity is required to assist in arranging for consultation between a new professional and the professional who is no longer employed by or under contract to the licensee or other entity. The paragraph is necessary to ensure consistency and continuity in the treatment of an individual who may be undergoing treatment, aftercare, and followup testing. Therefore, this addition meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Subpart I—Managing Fatigue

Section 26.201 Applicability

Section 26.201 specifies the licensees and other entities to whom the requirements in Subpart I apply. This section replaces, with limited editorial changes, § 26.195 of the proposed rule. Subpart I applies to licensees who are authorized to operate a nuclear power reactor (under § 50.57 [Issuance of operating license] of this chapter) and holders of a combined license after the Commission has made the finding under § 52.103(g) [Operation under a combined license] of this chapter, as specified in § 26.3(a), and licensees and other entities specified in § 26.3(c) at the time the licensee or other entity receives special nuclear material in the form of fuel assemblies. Also, Subpart I applies to Contractors/Vendors (C/Vs) who implement FFD programs or program elements upon which these licensees rely, as specified in § 26.3(d). As discussed in Section IV.D, the final rule requires nuclear power plant licensees to implement the requirements in Subpart I for the following reasons:

(1) Fatigue and decreased alertness can substantively degrade an individual's ability to safely and competently perform his or her duties.

(2) Conditions that contribute to worker fatigue are prevalent in the U.S. nuclear power industry.

(3) With the exception of NRC orders limiting the work hours of security personnel, the former NRC regulatory framework did not include consistent requirements to prevent worker fatigue from adversely impacting safe operations and the former requirements are difficult to readily and efficiently enforce.

(4) Reviews of nuclear power plant licensees' controls on work hours have repeatedly identified practices that are inconsistent with the NRC Policy on Worker Fatigue, including excessive work hours and the overuse of work hour limit deviations.

(5) The former regulatory framework was comprised of requirements that were inadequate and incomplete for effective fatigue management.

(6) Ensuring effective management of worker fatigue through rulemaking substantially enhances the effectiveness of FFD programs (i.e., the new requirements are cost-justified safety enhancements) and,

(7) Preventing the fatigue of workers in safety-critical positions through regulation is consistent with practices in foreign countries and other industries in the United States.

The requirements in the final rule also apply to C/Vs who implement FFD programs or program elements, to the extent that nuclear power plant licensees rely upon those C/V FFD programs or program elements to meet the requirements of this part. This final rule provision permits a licensee to rely on the fatigue management program of a C/V, which is consistent with former § 26.23(a), so long as the C/V relies on licensee-approved FFD programs and program elements, as retained in § 26.3 [Scope].

Subpart I does not apply to the materials licensees who are otherwise subject to Part 26 (see § 26.3) for two reasons. First, NRC analyses indicate that significant offsite radiological exposure is not a realistic accident consequence at a materials facility that is subject to Part 26 regulations because of the nature of the radioactive materials that are involved and the multiple layers of controls that NRC regulations require. Second, no analysis has been done to date to determine if there is evidence of excessive overtime use by the materials licensees. Therefore, at this time, the final rule does not impose the requirements of Subpart I on materials licensees. However, requirements to prevent fatigue from adversely affecting the job performance of security personnel at materials facilities provide a substantial enhancement to the security of these facilities. In SRM–COMSECY–04–0037,

''Staff Requirements: Fitness-For-Duty Orders to Address Fatigue of Nuclear Facility Security Force Personnel,'' dated September 1, 2004, the Commission determined that FFD program enhancements related to the fatigue of security force personnel at independent spent fuel storage installations, decommissioning reactors, Category I fuel cycle facilities, gaseous diffusion plants, and the natural uranium conversion facility should be pursued as a separate rulemaking activity with additional stakeholder interactions.

Section 26.203 General Provisions

Section 26.203 establishes fatigue management requirements for licensees' FFD programs. This section replaces § 26.197 of the proposed rule with limited editorial changes. These editorial changes include the addition of recordkeeping requirements under § 26.197(d) and the removal of collective work hour requirements from § 26.197(e)(2) of the proposed rule. The general provisions in this section establish requirements for licensees' fatigue management policies, procedures, training, examinations, recordkeeping, and reporting. The NRC's objective in establishing these general provisions is to facilitate integrating fatigue management into licensees' FFD programs, as discussed in Section IV.D.

Section 26.203(a) [Policy] requires each licensee to have a written policy statement that describes its management's expectations and methods for managing fatigue to ensure that fatigue does not adversely affect any individual's ability to safely and competently perform his or her duties. This section replaces § 26.197(a) of the proposed rule with limited editorial changes. The policy required in this section will apply to all individuals subject to the licensee's FFD program and not just those individuals subject to the work hour requirements presented in § 26.205 [Work hours], which contains the revised work hour requirements presented in proposed § 26.199. The NRC considers the responsibility for ensuring that each individual is fit to safely and competently perform his or her duties to be shared between the licensee and the individuals who perform duties on the licensee's behalf. Therefore, the final rule requires each licensee's FFD policy to delineate the licensee's fatigue management policy. Thus, individuals who are subject to this policy will be aware of and can comply with the fatigue management requirements for which they will be held accountable. The final rule requires each licensee to incorporate the fatigue management policy statement into the written FFD policy that is required under § 26.27(b) [Policy]. As discussed with respect to § 26.27(b), the final rule requires the policy statement to be clear, concise, and readily available, in its most current form, to all individuals who are subject to the policy.

The NRC's past experience with worker fatigue, such as that documented in NRC Regulatory Issue Summary (RIS) 2002–007, ''Clarification of NRC Requirements Applicable to Worker Fatigue and Self-Declarations of Fitness-For-Duty,'' dated May 10, 2002 (referred to in this document as RIS 2002–007), indicates that a need exists for individuals to clearly understand their own fatigue management responsibilities, as well as those of the licensee. These responsibilities include the individual's duty to report FFD concerns, including concerns related to the impact of fatigue on the individual's ability to safely and competently perform his or her duties, as well as concerns related to others, and the licensee's obligation to assess such fatigue-related FFD concerns. Further, the final rule does not prohibit licensees from imposing sanctions on individuals who fail to comply with the portions of the licensees' fatigue management policies that assign certain responsibilities to individuals. For example, a licensee may impose sanctions on an individual who fails to seek recommended treatment for a sleep disorder that, as part of a determination of fitness performed in accordance with § 26.189 [Determination of fitness], a healthcare professional has determined is adversely affecting the individual's job performance and potentially could be medically resolved. The final rule does not establish minimum sanctions for specific failures to comply with such fatigue management requirements because the reasons that an individual may report to work in a fatigued state are varied and often highly personal. Rather, the NRC prefers to permit licensees and the appropriate healthcare professionals to respond to such circumstances on a case-by-case basis. However, to protect an individual's rights under the rule, it is necessary for a licensee's fatigue management policies to communicate any sanctions that the licensee may impose on an individual for failing to comply with the policy's requirements.

Section 26.203(b) [Procedures] requires each licensee to develop, implement, and maintain procedures to carry out the fatigue management policy that § 26.203(a) [Policy] requires. Procedures are necessary to ensure that licensees' fatigue management programs are properly and consistently implemented. This section replaces § 26.197(b) of the proposed rule with limited editorial changes.

Section 26.203(b)(1) requires licensees to develop, implement, and maintain procedures that describe the process that an individual subject to the licensee's FFD program should follow when reporting to a supervisor that he or she is unfit for duty because of fatigue (i.e., he or she makes a self-declaration). In RIS 2002–007, the NRC noted that self-declaration is an important adjunct to behavioral observation in meeting the requirements of the performance objective in former § 26.10(b) (as retained in § 26.23(c)), which is ''to provide reasonable measures for the early detection of persons who are not fit to perform the duties that require them to be subject to this part.'' Because individuals are the first line of defense against the potential for fatigue-related impairment to adversely affect their job performance, it is essential that all individuals who are subject to a licensee's FFD program understand when and how to make a self-declaration that they are unfit for duty. Individuals must also understand how the licensee's response to a worker's self-declaration will differ from a licensee's response to an individual's general statement of fatigue (e.g., casually commenting to a co-worker, ''I'm really tired today''), if the individual does not express a concern that is specific to his or her FFD (e.g., formally stating to a supervisor, ''I am too tired right now to check these valve lineups accurately'').

Section 26.203(b)(1)(i) requires the licensee's self-declaration procedure to describe the responsibilities and rights of individuals and licensees and the actions they must take with respect to an individual's self-declaration of fatigue. The licensee's self-declaration procedure may explain the employees' right to know what is going to happen to them if they self-declare, including any sanctions that may be imposed on them. The procedure may also describe the employees' right to privacy regarding the causes for the self-declaration. This section ensures that all parties involved in the self-declaration process understand the process and responsibilities and the extent and limitations of their rights related to self-declaration. The NRC has considered industry experience with individuals refusing to report to work on the basis that they were too tired. The NRC concluded that detailed procedures are necessary to specify (1) the individual's

responsibility to be available at work for a fatigue assessment, which must be conducted face-to-face under § 26.211(b) for the reasons discussed with respect to that section, (2) the individual's responsibility to cooperate with the fatigue assessment process by providing the necessary information (see the discussion of § 26.211(c)(2)), and (3) the licensee's responsibility for conducting a fatigue assessment in response to an individual's self-declaration, as required under § 26.211(a)(2), to determine whether, and under what controls and conditions if any, the individual is permitted or required to work. Section 26.211 [Fatigue assessments] retains with, limited editorial changes, the requirements in proposed § 26.201 [Applicability].

Section 26.203(b)(1)(ii) requires the licensee's self-declaration procedure to describe requirements for establishing controls and conditions under which an individual is permitted or required to perform work after that individual declares that he or she is not fit for duty as a result of fatigue. This portion of the procedure ensures correct and consistent implementation of the requirements in § 26.211(b), which states that a supervisor or staff member of the FFD program must conduct the fatigue assessment and determine whether, and under what conditions, an individual who has self-declared can be returned to duty. For example, the licensee's procedure will provide guidance on establishing appropriate controls and conditions under which an individual could be permitted or directed to return to work after declaring that he or she is unfit because of fatigue. Controls and conditions will include, but will not be limited to, (1) controls on the type of work to be performed (e.g., physical or mental, tedious or stimulating, individual or group, risk-significant or not), (2) the required level of supervision (continuous or intermittent) and other oversight (e.g., peer checks, independent verifications, quality assurance reviews, and operability checks), and (3) the need to implement fatigue countermeasures (e.g., naps, rest breaks). The purpose of the controls and conditions is to mitigate the risks to public health and safety or the common defense and security that a fatigue-induced human error could pose, as discussed in Section IV.D.

Section 26.203(b)(1)(iii) requires licensee procedures to describe the processes to be followed if an individual disagrees with the results of a fatigue assessment conducted in response to the individual's self-declaration. These procedures will address situations in which the individual disagrees with the licensee's determination either that the individual is capable of performing work safely (with appropriate controls and conditions, if necessary) or that the individual cannot safely be permitted to perform the duties listed in § 26.205(a) [Individuals subject to work hour controls] because of fatigue. For example, the licensee's procedure may refer an individual who disagrees with the outcome of the fatigue assessment to the bargaining unit to initiate a grievance process, the employee concerns program, or the corrective action program.

The final rule adds this requirement for several reasons. First, in RIS 2002–007, the NRC documented concerns associated with past instances of self-declaration. These instances indicate the need for licensees to describe the processes to be followed if an individual disagrees with the results of a fatigue assessment following a self-declaration. In addition, at the public meetings discussed in the preamble to the proposed rule, several stakeholders asked the NRC to add this provision to the final rule to ensure that individuals have recourse if they disagree with the results of a fatigue assessment conducted in response to a self-declaration. Some of the stakeholders expressed a concern for the potential impact on public health and safety if an individual is convinced that he or she is too fatigued to perform work safely, but the licensee requires the individual to work. Other stakeholders expressed concerns that an individual may experience adverse employment and financial consequences if he or she is prevented from working because of fatigue.

The NRC agrees that licensee policies and procedures related to implementing the requirements of this subpart must address these potential issues to protect the rights of individuals subject to the rule. However, the final rule does not establish specific requirements for the process(es) to be followed in such instances for two reasons, (1) licensees have already implemented a number of processes for addressing similar safety and employment issues that provide appropriate mechanisms for resolving fatigue-related issues, and (2) the wide variety of possible issues that may arise limits the ability of a single mechanism established in the final rule to appropriately address them all. Therefore, the final rule requires licensees to have procedures for addressing situations in which an individual who has self-declared disagrees with the outcome of a fatigue assessment, but it does not require a new process or specify the required characteristics of the licensees' process(es).

Section 26.203(b)(2) requires licensees to develop, implement, and maintain procedures that describe the process for implementing the work hour requirements in § 26.205. For example, the procedures will detail individual and organizational responsibilities and requirements, including items such as scheduling, tracking and calculating work hours, granting waivers from the individual work hour requirements, reviewing the implementation of the work hour requirements, documenting the results of the reviews, and implementing any necessary corrective actions. These procedures are necessary to ensure that individuals understand the work hour requirements to which they are subject and that licensees consistently implement the work hour requirements in § 26.205 as the NRC intends.

Section 26.203(b)(3) requires licensees to develop, implement, and maintain procedures that describe the process(es) they will follow in conducting a fatigue assessment, as required under § 26.211(a). These procedures will establish the methods by which the licensee will determine whether an individual is fatigued, whether the individual will be permitted or required to perform work, and whether controls and conditions are necessary for the individual to be able to perform work safely and competently. The licensee's procedure will address fatigue assessments that are conducted following an individual's self-declaration or an event, for cause, or to reassess an individual after returning the individual to work despite a self-declaration of fatigue (the situations in which the final rule requires licensees to conduct fatigue assessments are discussed in § 26.211(a)). Because of the potentially subjective and personal nature of the fatigue assessment task and the potential for conflict and sanctions (e.g., if an individual is found to have been asleep while on duty), comprehensive procedures are necessary to ensure consistent implementation of the fatigue assessment requirements in § 26.211. Therefore, the NRC expects these procedures to describe measures to ensure that fatigue assessments (1) are performed by properly trained personnel, (2) are free of bias, (3) methodically address the factors that commonly contribute to fatigue, (4) are based on complete and accurate information, (5) protect the privacy of the individuals being assessed, (6) recognize the fact that an individual can

be fatigued and unfit for duty even though he or she has not exceeded the work hour limits, (7) are thoroughly documented, and (8) are reviewed, as required by § 26.205(e)(1)(iii). These procedures are necessary to implement the requirements in this subpart and protect the privacy rights and other rights of individuals, consistent with Goal 7 of this rulemaking.

Section 26.203(b)(4) requires licensees to develop, implement, and maintain procedures that describe the disciplinary actions they may impose on individuals, if any, following a fatigue assessment (e.g., termination or leave without pay) and the conditions and considerations for imposing those disciplinary actions. In the final rule, the NRC revised § 26.203(b)(4) to replace the word ''sanctions'' with the words ''disciplinary actions'' to avoid confusion that might develop from the multiple meanings of the word ''sanctions.'' During the public meetings discussed in the preamble to the proposed rule, several industry representatives indicated that licensees may rely upon the results of a fatigue assessment as the basis for determining that an individual has not met management expectations for maintaining his or her FFD. Although the NRC neither endorses nor prohibits the imposition of disciplinary actions in cases of fatigue, clear communication regarding possible disciplinary actions and the considerations for taking those disciplinary actions is necessary for individuals to meet their responsibility for self-declaration without unwarranted fear of potential outcomes. For this reason, procedures are necessary to ensure that licensees fully disclose the conditions under which disciplinary actions will be considered; the nature of the possible disciplinary actions; and the process for administering and imposing the disciplinary actions, including management's expectations and the individual's right to a review of the determination that he or she has violated the FFD policy, as required under § 26.39 [Review process for fitness-for-duty policy violations].

Section 26.203(c) [Training and examinations] establishes fatigue-related training and examination requirements in addition to those required under § 26.29(a) [Training content] and (b) [Comprehensive examination]. This section retains without change the requirement in § 26.197(c) of the proposed rule. Several of the knowledge and abilities (KAs) requirements listed in § 26.29(a) ensure that individuals are familiar with a licensee's or other entity's fatigue policies and procedures. However, individuals who are subject to Subpart I should also have a working-level knowledge of specific, fatigue-related topics that may facilitate personal decisions and actions that are consistent with the objective of preventing, detecting, and mitigating the adverse effects of fatigue on worker job performance. Individual workers typically do not possess these KAs without training (Folkard and Tucker, 2003; Knauth and Hornberger, 2003; Monk, 2000). Therefore, the final rule requires licensee FFD training and testing programs to address the topics specified in § 26.203(c)(1) and (c)(2).

Section 26.203(c)(1) requires FFD training and examinations to ensure that individuals who are subject to Subpart I understand the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures. Examples of topics that licensee training and examinations will address that are related to this KA will include, but are not limited to, (1) the principal factors that influence worker fatigue, (2) knowledge that a worker's ability to perform and remain alert is influenced by physiological changes that follow a daily pattern, (3) the time periods during which workers are most likely to exhibit degraded alertness and performance, (4) the principal symptoms of common sleep disorders (e.g., sleep apnea and insomnia) and the conditions that can contribute to their onset, (5) the methods for optimizing sleep periods on a shiftwork schedule, and (6) how to safely and effectively counteract fatigue with measures such as caffeine and strategic napping. Knowledge of these topics is necessary to ensure that individuals are able to (1) self-manage fatigue that is caused by shiftwork and factors other than work hours, (2) take actions to maintain their alertness at work, and (3) recognize and seek treatment for sleep disorders that might be creating or exacerbating their own fatigue. In addition, training in methods for coping with the challenges of shiftwork may contribute to a more stable workforce by reducing worker turnover. A Circadian Technologies, Inc. survey of 550 facilities in the United States and Canada found that turnover at facilities with operations extending beyond 7 a.m. to 7 p.m. averaged 10 percent in 2003, compared with 3.4 percent in all U.S. companies. Facilities offering no training on specific coping strategies had an average turnover rate of 11.4 percent, compared to 7.6 percent for facilities that offered such training to their employees, and 2.9 percent for those offering the training to employees and their family members (Circadian Technologies, Inc., 2004).

Section 26.203(c)(2) requires FFD training and examinations to ensure that individuals who are subject to Subpart I have the ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace. Examples of topics that are related to this KA will include, but are not limited to, (1) behavioral symptoms of fatigue (e.g., yawning, red eyes, prolonged or excessive blinking, irritability), (2) task conditions that may contribute to degraded alertness and increased fatigue (e.g., repetitive tasks, tasks with high cognitive or attentional demands, tasks that require the individual to be sedentary, tasks that limit social interaction), and (3) environmental conditions that may contribute to degraded alertness and increased worker fatigue (e.g., high heat and humidity, low lighting, and low-frequency noise/white noise). Requiring individuals to be trained on this KA is necessary to ensure that an individual is able to determine when it is appropriate to self-declare that he or she is unfit for duty because of fatigue, as permitted under § 26.209 [Self-declarations] and § 26.211(a)(2), and to determine when it is appropriate to report an FFD concern about another individual who, based on behavioral observations, is exhibiting indications of fatigue, as required under § 26.33 [Behavioral observation].

Section 26.203(d) [Recordkeeping] establishes recordkeeping requirements related to the implementation of Subpart I. This section includes, with revisions, the requirements presented in § 26.197(d) of the proposed rule. Specifically, § 26.203(d)(1), which retains § 26.197(d)(1) of the proposed rule without change, requires licensees to retain records of the number of hours worked by individuals who are subject to the work hour requirements established in § 26.205. Section 26.203(d)(2) requires licensees to retain records of shift schedules and shift cycles of individuals who are subject to the work hour requirements established in § 26.205. The NRC added this requirement to the final rule. Section 26.203(d)(3) through (d)(5) retains the requirements in proposed § 26.197(d)(2) through (d)(4) without changes. Specifically, § 26.203(d)(3) requires licensees to retain records of the number of, and the bases for, waivers they have granted, § 26.203(d)(4) requires licensees to retain documentation of the work hour reviews that are required under § 26.205(e)(3) and (e)(4), and

§ 26.203(d)(5) requires retaining documentation of any fatigue assessments licensees conduct. The NRC removed the proposed § 26.197(d)(5) from the final rule because the NRC eliminated the collective work hour requirements. The final rule establishes these recordkeeping requirements for four reasons: (1) These records are necessary to ensure that documentation of the licensee's fatigue management program is retained and available for NRC inspectors to verify that licensees are complying with the work hour requirements and waiver and fatigue assessment provisions, (2) the documentation is necessary for a review process under § 26.39 or in legal proceedings related to a determination that an individual has violated the fatigue provisions of an FFD policy, (3) the documentation is necessary to perform the trending and self-assessments that § 26.205(e) [Reviews] requires; and (4) the documentation is necessary to meet the reporting requirements in § 26.203(e) [Reporting]. To ensure that the records remain available for NRC inspections and the review process or legal proceedings, the final rule requires licensees to retain these records for 3 years or until the completion of any related legal proceedings, whichever is later.

Section 26.203(e) [Reporting] requires licensees to report to the NRC certain data related to their fatigue management programs as part of the annual FFD program performance report, which § 26.717 [Fitness-for-duty program performance data] requires. This requirement replaces, with revisions, § 26.197(e) of the proposed rule. This section is revised to specify that reports are required in a standard format. The final rule requires licensees to include the following information in the annual report: (1) Information on the number of waivers granted from work hour requirements in the previous calendar year, and (2) a summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments. This section does not retain the requirements in the proposed § 26.197(e)(2) for the reporting of information pertaining to the control of collective work hours because the final rule does not include collective work hour limits. In addition, this section does not retain the proposed rule requirement for licensees to report a summary of instances of fatigue assessments that the licensee conducted.

The NRC considered comments that the requirements for including fatigue management information should be deleted from the rule because they will not provide new or unique information to the NRC, are unnecessary to protect public health and safety, are unnecessary to facilitate NRC oversight of the revised rule, and are unduly burdensome. In choosing to retain reporting requirements for waiver use, the NRC considered several aspects of the work hour requirements in the final rule. First, the NRC established the work hour limits in the final rule at levels such that the potential for fatigue is substantive for individuals working in excess of those limits. Second, the rule permits licensees to authorize waivers of the limits only for circumstances in which the additional work hours are necessary to prevent or mitigate a condition adverse to safety or security. Finally, the rule only requires a waiver if the individual is operating or maintaining an SSC that a risk-informed evaluation process has shown to be important to the protection of public health and safety or if the individual is performing specified functions that are essential to an effective response to a fire, plant emergency, or implementation of the site security plan. As a result, information concerning licensee use of waivers indicates (1) the number of hours worked on risk-significant activities by individuals at increased potential for impairment, and (2) how often a licensee must mitigate or prevent a condition adverse to safety while using individuals at increased potential for impairment. The NRC considers this unique information, not otherwise reported, to be relevant to the agency's mission.

The NRC similarly considered the need to retain reporting requirements regarding fatigue assessment and any management actions in response to the fatigue assessments. The NRC concluded that the fatigue assessment information that would have been reported under the proposed rule requirements are more the purview of a licensee's corrective action program, and would have been more detailed than the program performance data for drug and alcohol testing required under § 26.717(c) of the final rule. Accordingly, the final rule requires licensees to report a summary of corrective actions, if any, resulting from the licensee's analysis of waiver and fatigue assessment data. As a consequence, the required reports will provide information that will focus more on licensee performance in managing worker fatigue and will enable the NRC to review licensee reporting of waivers in the context of associated corrective actions.

The NRC expects that the information provided by licensees in response to the annual reporting requirements in Subpart I will facilitate NRC oversight of the implementation of the requirements through the following means:

- Consistency, efficiency, and continuity of NRC oversight—Information provided through the annual FFD program performance reports concerning fatigue management will enable the NRC to achieve a higher level of consistency and efficiency in the oversight of the implementation of the requirements in Subpart I and in the enforcement of those requirements. Without the reporting requirements, the NRC's inspection of licensee FFD programs would likely be limited to individual inspectors evaluating licensee fatigue management for a sample of workers at a site for a limited time period. These assessments would necessarily be conducted without the benefit of broader contextual information of the site and industry normative information that would be available through the annual reports. In contrast, the annual reports will help ensure a common perspective and maintain consistency among inspectors conducting the oversight process. In addition, the annual reports can enhance the efficiency of the NRC inspection process by providing information necessary to allow the agency to focus inspection resources on duty groups (e.g., security or maintenance) or issues (e.g., self-declaration) that may warrant review. The reports will enable the NRC to be better focused in preparing for the inspection, reduce the burden of onsite inspection hours, and potentially reduce the total number of hours required for a baseline inspection. Furthermore, the annual reporting will also help to achieve a more complete and continuous assessment of licensee performance because the NRC intends to conduct the baseline inspection of FFD programs only once every 2 years.
- Evaluation of rule implementation for lessons learned—Although the NRC and stakeholders have made extensive efforts to ensure clear and enforceable requirements that are effective and practical for the management of worker fatigue, the rule introduces the potential for unintended consequences and lessons learned. In addition, changes in the size and composition of the nuclear industry may have unforeseen implications for site staffing and fatigue management. The NRC expects that the site-specific and normative information obtained through the annual reports can provide important insights regarding opportunities to amend the rule to

improve its effectiveness or reduce unnecessary burden. The NRC notes that such information was the basis for reducing the random testing rate for drugs and alcohol required in the final rule.

• Consistent interpretation of waiver criterion—The final rule provides licensees the discretion to use waivers to exceed the work hour limits, thereby allowing levels of work hours that could adversely affect worker FFD. The principal basis for allowing waivers is to reduce the additional staffing burden that licensees would otherwise incur if waivers were not available to address exigent circumstances. The annual reporting of waiver use will enable the NRC to ensure that licensees use this discretion in a manner consistent with the objectives of the rule and not as a means to compensate for a lack of adequate staffing. Furthermore, although the use of waivers is limited to conditions when the work hours are ''necessary to prevent or mitigate a condition adverse to safety or security,'' the NRC recognizes the potential for licensees to develop different interpretations regarding this criterion. Some industry commenters on the proposed rule took exception to the NRC's characterization of high levels of waiver use at some sites as abuse. These commenters suggested that differences in licensee waiver practices could be attributed to the policy being subject to a number of interpretations during the many years that it has been in effect. Regardless of the cause of the differences in licensee use of work hour control waivers, the NRC considers it prudent to address, through rulemaking, the lessons learned from past implementation of the policy and provide a level of oversight through the annual reporting requirement that will ensure consistent implementation of the waiver criteria in the future.

In addition to the reasons cited in the preceding paragraphs explaining the need for reporting requirements to ensure the effective and efficient oversight of the implementation of the rule, the NRC considers the reporting requirements to be justified and beneficial for the following additional reasons:

• Consistency with Part 26 requirements and performance objective—The final rule retains the requirement that licensees report the results of drug and alcohol testing and the performance objective for reasonable assurance that individuals are not impaired from any cause (§§ 26.719 [Reporting requirements] and 26.23(b) of the final rule, respectively). In addition, several studies discussed in detail in Section IV.D of this document have demonstrated that worker fatigue can produce levels of impairment that are comparable to blood alcohol concentrations above the levels permitted by this rule. Furthermore, given the frequency of worker concerns regarding fatigue and the work scheduling practices that are common during outages, the incidence of impairment from fatigue is likely to be greater than the very low incidence of drug and alcohol use that is detected through testing. The NRC therefore considers the reporting of information pertaining to licensee management of worker fatigue to be consistent with (1) the requirements for reporting information pertaining to drug and alcohol testing, (2) the performance objective of this rulemaking for licensees to implement a comprehensive FFD program, and (3) the NRC's belief that the management of worker fatigue is no less important to worker FFD than the effective detection and deterrence of drug and alcohol use.

• Public confidence—Public interest groups such as the UCS and the Project on Government Oversight have commented at public meetings that relevant information regarding worker fatigue is withheld to either protect alleger identity or, in the case of security personnel, plant security. In addition, several public media articles have been published during the past 2 years reporting instances of guards sleeping and guards fearing repercussions for refusing forced and excessive overtime. Information submitted by licensees in the annual reports will be publicly available and will reassure public stakeholders that the NRC is appropriately cognizant of licensee actions regarding fatigue management and that the NRC's oversight of these activities is transparent to all stakeholders.

• The burden is limited and justified—Section 26.203(e) requires licensees to report information concerning management of worker fatigue as part of the annual FFD program report. As a result, the burden associated with this reporting requirement is an incremental change to the reporting requirement for drug and alcohol testing. In addition, the fatigue management information required by § 26.203(e) is largely information that licensees will have already generated to demonstrate compliance with other provisions of Subpart I. As a result, the burden associated with the report will be largely associated with compiling the information in an appropriate form and reviewing that compilation. The NRC has reviewed the public comments suggesting that the agency underestimated the number of clerical and management hours associated with this requirement and has taken these comments into consideration in estimating the burden of the reporting requirements in § 26.203(e) of the final rule. Nevertheless, the NRC considers the burden associated with the annual reporting requirements to be justified for the reasons described in this and the preceding paragraphs.

The NRC also considered comments that the reporting requirement ignores significant duplication in licensee efforts. The NRC agrees that § 26.205(e) of the final rule requires licensees to periodically review and assess the effectiveness of the work hour controls and that the licensee's corrective action program, which is routinely inspected by the NRC, will document and trend these reviews. However, as noted previously, the NRC considers the annual reports to be a limited burden that will enable the NRC to provide more effective and consistent oversight and achieve other objectives for the effective implementation of the requirements in Subpart I.

Section 26.203(e)(1) requires licensees to provide the NRC with an annual summary of all instances during the previous calendar year in which the licensee waived each of the work hour controls specified in § 26.205(d)(1) and (d)(2) for each of the duties listed in § 26.4(a)(1) through (a)(5). This section revises the requirements in proposed § 26.197(e)(1). The agency revised this reporting requirement in response to comments that the required information would not provide a meaningful indication of licensee performance in managing work hours because a number of valid conditions may warrant waivers of work hour controls.

Section 26.203(e)(1) revises the reporting requirements in proposed rule § 26.197(e)(1) to clarify that licensees are required to report the number of waivers for each work hour requirement and not the sum total of all waivers for all work hour requirements. For example, if the licensee permits an operator to work 18 hours in a 24-hour period three times in a year, another operator to work 80 hours in a 7-day period, and another operator to take a rest break of only 6 hours between shifts, then the licensee will report that it granted three waivers of § 26.205(d)(1)(i), one waiver of § 26.205(d)(1)(iii), and one waiver of § 26.205(d)(2)(i), for the operations group that year. This clarification ensures that the waiver information is reported at a level of detail that will enable the NRC to know which limits

are most frequently exceeded and therefore better understand the specific scheduling challenges to licensee management of worker fatigue.

Section 26.203(e)(1) also requires licensees to include only those waivers under which work was actually performed in the annual report. This section contains requirements presented in § 26.197(e)(1)(i) of the proposed rule. The final rule retains this provision of the proposed rule because it may sometimes be unnecessary for individuals to work the extended hours for which a licensee planned when granting a waiver. Licensees may anticipate that it will be necessary to waive one or more of the work hour controls listed in § 26.205(d)(1) and (d)(2) in order to complete a task and so will implement the process specified in § 26.207 [Waivers and exceptions] for granting waivers. However, on some occasions, the work will be finished sooner than the licensee anticipated with the result that the waiver was granted but no one was required to work an extended work period. The final rule requires licensees to exclude waivers under which no work was performed from the annual report because this circumstance provides no meaningful information about the licensee's management of fatigue during extended work periods.

Section 26.203(e)(1) further specifies that licensees shall report all waivers granted for each of the work hour controls in § 26.205(d)(1) through (d)(5) for those instances in which a single extended work period required a waiver of more than one work hour control. This section contains the requirements presented in § 26.197(e)(1)(ii) of the proposed rule. For example, if an individual works 12 hours on day 1 and on day 2 the licensee needs the individual to work more than 16 hours to resolve a condition adverse to safety, the licensee would need to authorize and report a waiver of § 26.205(d)(1)(i), for exceeding 16 hours in a 24-hour period, and (d)(1)(ii), for exceeding 26 hours in a 48-hour period. Although this example included only one work period, both waivers are required and must be reported because the potential for fatigue results not only from the length of the workday (e.g., exceeding 16 hours of work in a 24-hour period) but also the cumulative effect of prior work (e.g., exceeding 26 hours of work in a 48-hour period).

Section 26.203(e)(1)(i) and (e)(1)(ii) requires licensees to report whether work hour controls are waived for individuals working on normal plant operations or working on outage activities. In establishing this requirement the NRC considered comments that the use of waivers should be considered in context. Through its review of authorized waivers from the work hour limits in plant technical specifications, the NRC has found that waivers are most frequently associated with outage activities. Accordingly, the NRC has revised the final rule to require licensees to report whether a waiver of the work hour requirements in § 26.205 was associated with an outage activity. This revision will enable the NRC to better understand a site's changes in waiver use over time and understand why certain annual reports for a given site may indicate a heightened level of waiver use relative to the site's other reports.

The NRC recognizes that outages are not the only cause of waivers; however, the agency expects that most other causes of waiver use will be for substantially shorter periods of time or involve smaller groups of workers and that these other conditions would not have a substantive effect on overall waiver use. For unique causes that may have more substantive effects (e.g., licensee response to hurricanes), the NRC is likely to be aware of or able to identify these conditions if they were to significantly affect waiver use. Furthermore, the NRC intends to consider waiver use in conjunction with the reported fatigue assessment information. Therefore, the agency will be able to determine whether waiver use may be associated with the incidence of fatigue assessments conducted for cause, following events, or in response to self-declarations by individuals asserting that they are not able to safely and competently perform their duties because of fatigue. The NRC notes that the frequency of waiver use (i.e., how often individuals exceed the work hour limits while performing functions important to safety and security) indicates the potential for worker fatigue to affect the performance of these functions, regardless of whether a waiver is the result of an activity associated with an outage or a cause that is beyond the licensee's control.

Section 26.203(e)(1)(i) requires licensees to report the number of instances in which each work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), and (d)(3)(i) through (d)(3)(iv) was waived for individuals not working on outage activities. Section 26.203(e)(1)(ii) requires licensees to report the number of instances in which each work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(iv), and (d)(4) and (d)(5)(i) was waived for individuals working on outage activities. The differences between § 26.205(e)(1)(i) and (e)(ii) in the work hour requirements specified reflects whether requirements are applicable to outage activities.

Section 26.203(e)(1)(iii) requires licensees to report a summary that shows the distribution of waiver use among the individuals within each category of individuals § 26.4(a) identifies. This summary will show, for example, how many individuals received only one waiver during the reporting period, how many individuals received two waivers, how many received three waivers, and so on. This reporting requirement enables the NRC to determine the extent to which waivers are concentrated among a few individuals or distributed more broadly within a group of individuals who perform the same duties. The NRC incorporated this requirement in the final rule in response to comments that the rule should also require licensees to report the number of workers covered under § 26.199(a) of the proposed rule to provide an appropriate context for the annual reporting of waivers. The NRC understood that the intent of this comment was to provide a basis for evaluating the number of waivers from the work hour controls relative to the number of individuals subject to those controls. The NRC chose not to require licensees to report the number of individuals covered under § 26.4(a) of the final rule because that number will vary throughout the course of the reporting period, particularly when the reporting period includes a unit outage. In addition, the NRC believes that the required distribution of waivers more effectively provides context to the waiver use by indicating if the waivers were concentrated among individuals performing a certain duty and if the waiver use in a duty group was associated with relatively few individuals or distributed among many individuals.

The waiver data that licensees are required to report to the NRC under § 26.203(e)(1)(i) through (e)(1)(iii) are important because waivers represent ''assumed risk.'' As discussed in Section IV.D, fatigued workers experience impaired cognitive functioning, including difficulties in decisionmaking and maintaining attention. If a licensee permits an individual to work extended hours that cause the individual to become fatigued, the individual may experience momentary lapses in attention or degraded decisionmaking from fatigue. These performance degradations can be mitigated by establishing controls and conditions

under which the individual is permitted to work, as required under § 26.211(e). However, controls and conditions can reduce, but not eliminate, the potential risks from fatigue-induced errors. The more often that a licensee permits individuals to exceed work hour limits, the more risk from fatigue-induced errors a licensee is assuming. The risk of fatigue-induced errors increases further when an individual is permitted to exceed more than one of the work hour limits contained in § 26.205(d)(1)(i) through (d)(1)(iii) because of the potential for the combined effects of both acute and cumulative fatigue. Any waivers from the rest breaks that are required under § 26.205(d)(2) or the minimum day off requirements of § 26.205(d)(3) through (d)(5) will also contribute to the accumulation of a sleep deficit, especially when inadequate rest breaks are combined with long work hours. Repeated and continual use of waivers may indicate a staffing or other programmatic weakness at a site that warrants additional inspection resources. Therefore, the NRC considers the number of waivers granted from the work hour limits to be a key element in evaluating FFD program performance.

Section 26.203(e)(2) requires that licensees include in the annual report the reporting of corrective actions resulting from the analyses of waiver and fatigue assessment data. The NRC considers the reporting of a summary of corrective actions to be consistent with the requirement of § 26.717 for reporting of drug and alcohol test results. For example, the NRC views the number of for-cause drug and alcohol tests that a licensee conducts each year to be one indicator of the health of the licensee's behavioral observation program and its effectiveness in meeting the rule's performance objective identified in § 26.23(c) to provide for the early detection of individuals who are not fit to perform the duties that require them to be subject to this part. The NRC similarly views the reporting of corrective actions resulting from the analyses of these data, including fatigue assessments, to be another indicator of the health of the licensee's behavioral observation and self-declaration processes with respect to fatigue. Annual reports, which will include the distribution of waiver use among individuals performing the same duties, will enable NRC to determine the extent to which waivers are concentrated among a few individuals or distributed broadly among individuals within each category specified in § 26.4.

Collectively, the reporting of waivers required in § 26.203(e)(1) and the reporting of corrective actions required in § 26.203(e)(2) provides important information concerning the effectiveness of fatigue management at a licensee site. The reports permit the NRC to (1) efficiently monitor the ongoing effectiveness of licensees' fatigue management programs by providing interpretable data, (2) efficiently allocate inspection resources, (3) track the effectiveness of the requirements of Subpart I in controlling the fatigue of nuclear power plant workers, (4) assess whether the objectives of the final rule are being achieved, and (5) determine whether any further changes to the requirements are necessary to ensure that worker fatigue is managed consistent with the intent of the provisions.

Section 26.203(f) [Audits] requires the licensee to audit the management of worker fatigue as part of the overall FFD program audits required in § 26.41 [Audits and corrective action]. This section does not add a new requirement, but is included in Subpart I for clarity.

Section 26.205 Work Hours

The NRC substantively revised § 26.199 of the proposed rule in response to public comments. The revised provisions are in § 26.205 of the final rule and establish controls on the work hours of select individuals who are subject to nuclear power plant licensees' FFD programs, as follows.

Section 26.205(a) [Individuals subject to work hour controls] establishes the scope of individuals who are subject to the work hour requirements in § 26.205. These individuals are subject to the work hour requirements, in addition to the training, behavioral observation, and self-declaration requirements of Subpart I that apply to all individuals who are subject to nuclear power plant licensees' FFD programs. In determining the scope of personnel who are subject to the work hour controls, the NRC considered the burdens on individuals and licensees associated with the practical control of work hours in conjunction with the potential for individuals' work activities to affect public health and safety or the common defense and security if their performance is degraded by fatigue. The NRC also considered the nature of these individuals' work activities and work environments relative to their potential to induce or exacerbate fatigue (e.g., whether the work is monotonous or the environment is not stimulating), the risk significance of the work, and the potential for other controls to prevent or mitigate the consequences of a fatigue-related error. As a result of these deliberations, the rule requires that individuals who perform the duties specified in § 26.4(a)(1) through (a)(5) must be subject to work hour controls. The duties specified in § 26.4(a)(1) through (a)(5) are the same as the duties that were specified in § 26.199(a)(1) through (a)(5) of the proposed rule. Rather than list the duties in § 26.205(a), the final rule references § 26.4(a) which provides a consolidated list of individuals subject to the requirements of Part 26.

Section 26.205(a) requires that individuals identified in § 26.4(a)(1) (i.e., individuals who operate or provide onsite direction of the operation of systems and components that ''a risk informed evaluation process has shown to be significant to public health and safety'') must be subject to the work hour requirements in this section. To implement the work hour requirements, nuclear power plant licensees are required to delineate the operations personnel who are subject to the work hour requirements, on the basis of the risk significance of the safety SSCs being operated. At a minimum, this must include personnel who are performing activities on SSCs that are determined to be significant to public health and safety. To delineate the scope of the operations duty group, licensees can use, for example, the risk-significance determination process and criteria that they currently employ to meet the requirements of § 50.65(a)(4) of this chapter for assessing and managing the risk associated with maintenance activities. The work hour requirements of § 26.205 would typically apply to individuals who are operating or directing, while on site, the operation of SSCs that are included within the scope of an assessment required by § 50.65(a)(4). Therefore, the work hour requirements would apply to the individuals who most directly affect the operation of those SSCs most important to the protection of public health and safety. Controlling the work hours of these individuals would achieve the NRC's objective to minimize the potential for fatigue-related errors in operating these risk-significant SSCs.

Licensed operators who perform the duties specified in § 26.4(a)(1) are responsible for correctly performing actions that are necessary for the safe operation of nuclear power plants and the mitigation of accidents at these facilities. These responsibilities include monitoring the plant for off-normal conditions and taking appropriate actions to prevent these conditions from challenging the reactor core, safety systems, and fission product barriers. The importance of licensed operator actions to the protection of public health and safety is reflected in the 10

CFR Part 55, ''Operators' Licenses,'' requirements that are applicable to these individuals, including specific licensing, examination and testing, requalification, and FFD requirements. In addition to performing actions that are necessary for accident mitigation, operator actions, if performed incorrectly, can be accident initiators. Section IV.D discussed the effects of fatigue on decisionmaking, risk-taking, communications, and other key skills. Fatigued operators have an increased potential to commit errors, raising the probability of component failures, system misalignments, and incorrect execution of accident mitigation strategies. Operator actions are highly dependent on cognitive skills (e.g., attention, decisionmaking) that are susceptible to fatigue, and operators are frequently exposed to conditions that can induce fatigue (e.g., long work hours, shiftwork). The NRC highlighted this concern in 1982 by issuing its Policy on Worker Fatigue. The Policy specifically addressed the need for ''controls to prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition.''

Despite the NRC's Policy on Worker Fatigue and subsequent technical specifications to limit operator work hours, an NRC staff review of technical specification implementation from 1997–99 found that a significant percentage of licensed and non-licensed operators worked more than 600 hours of overtime in a year (Attachment 1 to SECY–01–0113, ''Rulemaking Plan: Fatigue of Workers at Nuclear Power Plants''). This level of overtime is two to three times the level that is permitted for operations personnel at some foreign nuclear plants and twice the level recommended by a 1985 expert panel (NUREG/CR–4248). In addition, the NRC staff has noted that some licensees appeared to be abusing the authority to permit deviations from the technical specification limits on working hours, including deviations for operators. For example, data provided by NEI on August 29, 2000, from J. W. Davis, NEI, to G.T. Tracy (ADAMS Accession No. ML003746495), indicated that during a sample of 37 refueling outages conducted in 1999, licensees authorized more than 1,800 deviations for licensed operators and more than 1,100 deviations for non-licensed operators. This frequency of deviations is inconsistent with the intent of the NRC's Policy on Worker Fatigue that deviations should be authorized only for ''very unusual circumstances.'' The failure of some licensees to limit the work hours of operations personnel, considered together with the risk significance of the activities performed by operators, indicates the need for more readily enforceable work hour limits for operators whose job duties are important to protect public health and safety.

Further, the work hour requirements in § 26.205 also apply to individuals who direct risk-significant operations on site. These individuals include management on shift, such as shift operations management or special outage managers, if those individuals provide direction to operators. Individuals to whom the work hour requirements apply also include engineers who provide onsite technical direction to operations, such as test directors or reactor engineers. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem-solving, decisionmaking, communications) and are susceptible to fatigue-induced errors, as described in Section IV.D. Incorrect technical direction provided to operators can significantly challenge licensed operators and increase the possibility of errors or events, particularly when the direction is provided by an individual who supervises the operators or an individual who the operator reasonably expects to have specialized technical knowledge of the system or component being operated.

Section 26.205(a) requires that individuals identified in § 26.4(a)(2) (i.e., individuals who perform health physics or chemistry duties that are required of the onsite emergency response organization minimum shift complement) must be subject to the work hour requirements of this section. Although § 26.207(d) [Plant emergencies] exempts licensees from applying the work hour controls during declared emergencies, the intent of this provision is to provide reasonable assurance that the work schedules of these individuals during non-emergency conditions ensure that fatigue does not compromise their abilities to safely and competently perform their duties should an emergency occur. NUREG–1465, ''Accident Source Terms for Light-Water Nuclear Power Plants,'' concluded that significant fission product releases from the bulk of the fuel can occur within 30–60 minutes after the onset of an accident. As a function of the accident and its severity, certain areas within the plant, while predictable and benign during normal operations, could present elevated levels of airborne/external radiation levels (greater that 300 Rad/hour). Additionally, industrial hazards (e.g., explosive mixtures, smoke, toxic gas, oxygen deficiency) that may be immediately dangerous to life and health could be present. In these circumstances, health physics technicians (HPTs) support necessary plant staff actions to assess conditions, perform search and rescue missions, and take timely mitigation actions (e.g., local manual operations by operators). The overall success of responding safely and appropriately to emergencies and the protection of public health and safety depends, in part, on the ability of HPTs to safely and competently perform their emergency response duties.

Similarly, NUREG–0654, Revision 1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' issued March 2002, identifies the need for an on-shift chemistry/radiochemistry emergency response capability. An on-shift chemistry technician(s) provides an important component for a successful response at the onset of a radiological emergency. The independent and timely actions of the chemistry technician(s) in response to a radiological event can provide key information for assessing core status and estimating the source term of a potential release. By providing defense-in-depth support for operations personnel, chemistry technicians also assist with offsite dose calculations and ancillary radiological protection tasks, such as sampling spaces for toxic gases or explosive mixtures. Chemistry technicians may also be needed to conduct analyses for the detection of hydrogen and oxygen gas concentrations in both the reactor coolant and the containment atmosphere. These analyses support severe accident management decisions with respect to minimizing radiological release potential. As a consequence, ensuring that chemistry technicians are able to safely and competently perform their emergency response duties is essential to the overall success of responding safely and appropriately to emergencies and to the protection of public health and safety.

Section 26.205(a) requires that individuals identified in § 26.4(a)(3) (i.e., individuals who are performing the duties of a fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability) must be subject to the work hour requirements of this section. The work hour requirements are applicable to the members of the fire brigade who are responsible for providing the control room operators and fire brigade leader with information that is critical to implementing a fire mitigation strategy

to maintain safe shutdown capability for the reactor. Attachment 1 to SECY–99–140, ''Recommendation for Reactor Fire Protection Inspections,'' dated May 20, 1999, states that ''based on IPEEE results, fire events are important contributors to the reported core damage frequency (CDF) for a majority of plants. The reported CDF contribution from fire events can, in some cases, approach (or even exceed) that from internal events.'' Fire brigade members must retain their cognitive abilities to be able to determine the best way to suppress a fire to prevent additional damage to safety-related equipment, evaluate equipment affected by a fire to report to control room operators concerning equipment availability, make decisions concerning smoke ventilation to prevent the fire effects from affecting other plant operations, and coordinate fire brigade activities with control room operators.

As discussed in Section IV.D, fatigue can substantially degrade an individual's decisionmaking and communication abilities, cause an individual to take more risks, and maintain faulty diagnoses throughout an event. The abilities to make accurate and conservative decisions, communicate effectively, and accurately diagnose events are key to the duties of the fire brigade members who are responsible for providing the control room operators and fire brigade leader with information that is critical to implementing a fire mitigation strategy to maintain the safe-shutdown capability for the reactor. Degradations of these abilities could have significant consequences on the outcome of an event involving a fire. For instance, a fatigued individual could incorrectly decide to vent smoke or toxic gas to an area required for alternate shutdown, which could prevent or impair access to equipment needed for safe shutdown of the plant. In addition, a fatigued worker could incorrectly apply the wrong fire suppressant, which could affect additional equipment in the plant. Further, impaired decisionmaking could lead a worker to fail to properly control flooding, which could impact other needed equipment, or to incorrectly determine whether an area contains critical equipment and improperly apply a suppressant in that area. Impaired communications could also lead to incomplete disclosure of information to licensed operators in the control room, which could adversely impact the decisionmaking of those operators. If information known to the impaired fire brigade member is not properly communicated, operators may not initiate appropriate actions to mitigate the fire effects, or the effects of suppressant activities, on critical equipment. As a consequence, ensuring that fire brigade members, who are responsible for understanding the effects of fire and fire suppressants on safe-shutdown capability, are able to safely and competently perform their duties is essential to the overall success of the fire mitigation strategy and the protection of public health and safety.

In addition, the NRC periodically grants exemptions from the requirements of Appendix R [Fire Protection Program for Nuclear Power Facilities Operating Prior to January 1, 1979] to 10 CFR Part 50, ''Domestic Licensing of Production and Utilization Facilities,'' based on protection of the levels of defense in depth listed in Section II(A) of Appendix R to Part 50, which are ''To prevent fires from starting; to detect, rapidly control, and extinguish promptly those fires that do occur; to provide protection for structures, systems, and components important to safety so that a fire that is not promptly extinguished by the fire suppression activities will not prevent the safe shutdown of the plant.'' Granting these exemptions is often predicated on effective manual suppression of the fire by the fire brigade. Therefore, it is necessary to ensure that fire brigade members who are responsible for understanding the effects of fire and fire suppressants on safe-shutdown capability remain rested so that they are able to safely and competently perform their duties in plant events involving a fire.

Section 26.205(a) requires that individuals identified in § 26.4(a)(4) (i.e., individuals who are performing maintenance or the onsite directing of maintenance of systems, structures, or components that ''a risk informed evaluation process has shown to be significant to public health and safety'') must be subject to the work hour requirements in this section. Section 26.5 [Definitions] includes a definition of ''maintenance'' to clarify the scope of individuals described by § 26.4(a)(4). To implement this requirement, licensees are required to delineate the maintenance personnel, as well as the personnel who direct maintenance on site, who would be subject to the work hour controls on the basis of the risk significance of the SSCs that they maintain. At a minimum, this must include personnel who maintain SSCs that are determined to be significant to public health and safety. To delineate the scope of the maintenance job duty group, licensees can use, for example, the risk-significance determination process and criteria that they currently employ to meet the requirements of § 50.65(a)(4) for assessing and managing the risk associated with maintenance activities. As a consequence, the work hour requirements of § 26.205 would typically apply to individuals who are maintaining or directing on site the maintenance of SSCs that are included within the scope of an assessment required by § 50.65(a)(4). Therefore, the work hour requirements would apply to the individuals who most directly affect the maintenance of SSCs that are most important to the protection of public health and safety, which would achieve the NRC's objective to minimize the potential for fatigue-related errors in maintaining these risk-significant SSCs.

Nuclear power plant maintenance personnel perform tasks that are often highly dependent on cognitive skills (e.g., the ability to comprehend oral and written instructions, problem-solving, communication) that are susceptible to fatigue, as described in Section IV.D. These tasks may require extensive physical effort in high heat, humidity, and noise conditions that can exacerbate fatigue. In addition, maintenance personnel are subject to the work scheduling conditions of round-the-clock operations and emergent work conditions that also can exacerbate fatigue (e.g., long work hours, unscheduled overtime, shiftwork). Compared to rested workers, fatigued maintenance personnel would have a higher probability of (1) taking longer to complete maintenance activities or using non-conservative work practices, (2) making errors that would increase the risk of failure of the affected SSCs to perform their functions or operate for their required mission time during post-maintenance testing, thus delaying their return to unrestricted service, and (3) making errors that could introduce latent defects that may not be readily detected by post-maintenance testing, but that may cause degraded reliability (i.e., degraded performance or failure of the SSCs at a later time). Collectively, the effects of fatigue on the performance of maintenance personnel have the potential to decrease the availability and reliability of SSCs that are important to the protection of public health and safety. Therefore, the rule requires these maintenance personnel to be subject to the work hour requirements to ensure that fatigue does not compromise their abilities to safely and competently perform their duties relative to the maintenance of these SSCs.

The work hour requirements also apply to those who direct risk-significant maintenance on site. For example, these individuals include maintenance supervisors who provide

direction to maintenance technicians and engineers who provide onsite technical direction to maintenance crews, during key outage maintenance activities. These individuals perform tasks that are often highly dependent on cognitive skills (e.g., problem solving, decisionmaking, communications) that are susceptible to fatigue, as discussed in Section IV.D. Incorrect technical direction provided to maintenance technicians can significantly challenge maintenance technicians and increase the possibility of errors or events, particularly when that direction is provided by an individual who supervises them or an individual who the maintenance technician reasonably expects to have specialized technical knowledge of the system or component being maintained.

Section 26.205(a) requires that individuals identified in § 26.4(a)(5) (i.e., individuals who are performing the duties of an armed security force officer, alarm station operator, response team leader, or watchperson at a nuclear power plant) must be subject to the work hour requirements of this section. Individuals who perform these duties are the members of licensees' security forces who are responsible for implementing the licensees' physical security plans. To ensure that these individuals are able to meet their responsibilities for maintaining the common defense and security, it is necessary to ensure that they are not subject to fatigue, which could reduce their alertness and ability to perform the critical job duties of identifying and promptly responding to plant security threats. Security personnel are the only individuals at nuclear power plants who are entrusted with the authority to apply deadly force. Decisions regarding the use of deadly force are not amenable to many of the work controls (e.g., peer checks, independent verification, post-maintenance testing) that are implemented for other personnel actions at a nuclear plant to ensure correct and reliable performance. In contrast to most other nuclear power plant job duty groups, security personnel are typically deployed in a configuration in which some members of the security force have very infrequent contact with other members or with other plant personnel. A lack of social contact can exacerbate the effects of fatigue on individuals' abilities to remain alert (Horne, 1988). In addition, these deployment positions can be fixed posts where very little physical activity is required, further promoting an atmosphere in which fatigue could transition into sleep. Many security duties are largely dependent on maintaining vigilance, and vigilance tasks are among the most susceptible to degradation from fatigue (Rosekind, 1997; Monk and Carrier, 2003). Finally, unlike operators, security forces lack automated backup systems that can prevent or mitigate the consequences of an error caused by fatigue. For these reasons, and in light of the excessive hours that some security force personnel were required to work following the elevated threat condition(s) in effect after the terrorist attacks of September 11, 2001, the Commission issued orders for Compensatory Measures Related to Fitness-for-Duty Enhancements Applicable to Nuclear Facility Security Force Personnel on April 23, 2003. The security force personnel who are subject to work hour controls in the orders are the same individuals who are subject to the work hour requirements in this section.

Section 26.205(b) [Calculating work hours] specifies the time periods that licensees shall include when calculating the work hours of the individuals listed in § 26.205(a) for the purposes of this subpart. This requirement replaces, with editorial and substantive modifications, the requirements presented in § 26.199(b) of the proposed rule. The editorial changes are renumbering and reorganization of the requirements for clarity. The substantive change is the deletion of the provisions concerning the calculation of collective work hours as a conforming change resulting from the deletion of the collective work hour controls as described with respect to § 26.205(d)(3).

The NRC's Policy on Worker Fatigue established guidelines for the control of work hours but did not define the concept of ''work hours'' or establish criteria for calculating them. As a consequence, licensees have inconsistently defined and calculated work hours when implementing the Policy through their technical specifications and administrative procedures. This inconsistency has contributed to some licensees permitting individuals to work excessive hours that caused them to become fatigued. Therefore, the rule defines work hours and requirements for calculating them, as well as certain specific periods that may be excluded from the calculation to ensure consistent implementation of the work hour controls established in § 26.205(d) [Work hour controls].

The rule requires licensees to calculate work hours as the amount of time that an individual performs duties for a licensee, including all within-shift break times and rest periods during which there are no reasonable opportunities or accommodations appropriate for restorative sleep. The rule also details the periods excluded from the calculation.

The rule specifically does not limit work hours to hours that are assigned to an individual by the licensee, that are worked on site, or that are worked as part of a scheduled shift, but does require licensees to include hours during which an individual performs duties for the licensee. The rule defines hours worked in this broad manner because the NRC is aware that some licensees permit individuals to perform duties on behalf of the licensee from offsite locations and during periods when the individual is not assigned to a shift or scheduled by the licensee to be working on site. For example, because of the large amount of administrative work that is frequently assigned to individuals in the shift manager role, some shift managers stay at work to review and act upon administrative matters after the end of their scheduled shifts in order to complete the reviews and meet deadlines. Anecdotal reports from these individuals have indicated that they may work for 3–4 hours after going off shift to manage their workload, with the result that the hours they have available for personal obligations and sleep are reduced. Many licensees operate multiple sites and at times send personnel to other sites for short periods to fill in or to extend expertise. This time away from their normal duty site must be included when calculating work hours. If the rule limited the calculation of work hours to only those hours that an individual is paid by the licensee, works on shift, works on site, and/or is scheduled to be working by the licensee, many individuals may continue to be permitted to work excessive hours, thereby becoming fatigued. Therefore, § 26.205(b) [Calculating work hours] requires licensees to include these work hours in their work hour calculations.

Section 26.205(b)(1) [shift turnover] excludes the time periods during which an individual participates in shift turnover from the calculation of the individual's work hours. Section 26.199(b)(1) of the proposed rule defined the specific shift turnover activities that licensees may exclude from their work hour calculations. The final rule defines shift turnover as only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. Shift turnover is a vital activity, but it also contributes to the length of the workday,

and therefore, to worker fatigue. The NRC understands that shift turnovers routinely add approximately 30 minutes to the length of a shift and typically no more than 2–2.5 hours to the length of a typical work week. Stakeholder comments during the public meetings described in the preamble to the proposed rule highlighted the importance of this activity for communicating plant status information between work crews and expressed concern that including turnover time in work hour calculations could cause indirect pressure on individuals to abbreviate shift turnovers in order to ensure that work hour limits would not be violated. This pressure could compromise the quality of shift turnovers and have unintended adverse safety consequences, such as omitting important equipment or maintenance status information. Although some stakeholders believe that turnover is part of the workday and, therefore, should be included in the calculation of hours worked, the NRC concluded that the benefit of including turnover for managing worker fatigue would be outweighed by the potential adverse consequence on the quality of shift turnovers.

The exclusion of shift turnover from work hour calculations is consistent with current requirements in most licensee technical specifications for the control of work hours for personnel performing safety-related functions and with GL 82–12, ''Nuclear Power Plant Staff Working Hours,'' dated June 15, 1982. For example, most technical specifications state, ''An individual should not be permitted to work more than 16 hours in any 24-hour period, nor more than 24 hours in any 48-hour period, nor more than 72 hours in any 7-day period, all excluding shift turnover time'' (see SECY–01–0113, Attachment 1, Table 2). However, the final rule more clearly describes the activities that may be included in turnover and the activities that may not be included. This provision addresses the NRC concerns arising from observations that some licensees have occasionally excluded 2 or more hours from calculated work hours on the basis that the individuals were engaged in ''turnover.'' To ensure that turnover is not hurried, the rule does not establish a time limit for an acceptable turnover period. However, by clearly delineating the activities that licensees may consider to be turnover activities, the rule reduces the potential for individuals and/or licensees to use the shift turnover exclusion to perform other work activities.

Section 26.205(b)(2) [Within shift break and rest periods] permits licensees to exclude within-shift breaks and rest periods from their work hour calculations if the individual has both a reasonable opportunity and accommodations for restorative sleep. The rule permits licensees to exclude breaks from the accounting of work hours only when the exclusion can be justified on the basis that the break substantively mitigates fatigue. The exclusion allows workers to be scheduled for round-the-clock duties (e.g., dedicated fire brigades) during which they are on site and available to respond as needed but the licensee provides sleeping accommodations and the individuals are allowed periods of time to obtain restorative sleep. This exclusion also permits licensees to make use of strategic napping, a well-proven fatigue countermeasure (McCallum, et al., 2003; Petrie, et al., 2004; Rosekind, et al., 1994, 1995; Dinges, et al., 1988; Kemper, 2001; Schweitzer, et al., 1992; Sallinen, et al., 1998), without requiring the nap period to be included in work hour calculations.

The exclusion is limited to that portion of a break or rest period that provides a reasonable opportunity for restorative sleep. For example, a 15-minute coffee break would not provide a reasonable opportunity for restorative sleep. The rule limits the exclusion to the amount of time the individual has available to actually sleep and does not include transit time to and from the sleep accommodations. The term ''restorative sleep'' means an amount of sleep that mitigates fatigue, which is generally considered to be a minimum of approximately 30 minutes (Buxton, et al., 2002; McCallum, et al., 2003; Sallinen, 1998; Rosekind, 1995).

The final rule also requires that individuals must have reasonable accommodations available for sleep in order to exclude the break period from the calculation of the individual's work hours. Reasonable accommodations would include a sleep surface (e.g., bed, recliner) in a darkened, quiet room (Priest, 2000).

The degree of specificity in this section is necessary because some licensees currently exclude within-shift breaks from the calculation of work hours required by their technical specifications. Excluding break periods from the calculation of work hours can add up to as many as 12 hours over the course of a week, which permits individuals to work an additional 12-hour shift. As a consequence, licensees may assign seven consecutive 12-hour shifts to individuals, but only include 72 hours in their work hour calculations, rather than the 84 hours that the individuals are actually at work. The discussion of § 26.205(d)(1)(iii) details the basis for limiting individuals to 72 work hours per week.

Although breaks without sleep have some fatigue mitigation value (Tucker, Folkard, and Macdonald, 2003), the benefits are principally limited to short-term improvements in vigilance. Horne (1988), Mitler and Miller (1996), and Dinges, et al. (1997) have pointed out that the only non-pharmacological cure for fatigue is sleep. The duration of within-shift break times is normally insufficient to allow a worker to obtain sleep and, consequently, these periods add to the total amount of time an individual remains awake while at work. Time since awakening is a principal determinant of worker fatigue (Folkard and Akerstedt, 1992; NTSB, 1994; Akerstedt, 2004) and performance generally declines as a function of the amount of time that an individual remains awake (Dawson and Reid, 1997). Because within-shift breaks and rest periods provide only short-term mitigation of fatigue (Kruger, 2002; Baker, et al., 1990), the rule requires licensees to include short breaks in the calculation of work hours.

Section 26.205(b)(3) [Beginning or resuming duties subject to work hour controls] permits licensees to assign individuals, who are qualified to perform the duties listed in § 26.4(a), to duties other than those listed § 26.4(a), without controlling their work hours in accordance with the work hour controls contained in § 26.205(d). However, if these individuals are assigned or returned to performing any duties that are listed in § 26.4(a) during the calculation period, the rule requires the licensee to include all of the hours that they worked when calculating their work hours and to subject the individual to the work hour controls in § 26.205(d). For example, if a licensed operator was assigned to training for an entire calculation period, then his or her work hours would not be subject to § 26.205(d) for that period because he or she would not be performing any of the duties listed in § 26.4(a). However, if the same individual were assigned to training for only a portion of the calculation period and performed the duties listed in § 26.4(a) during the remainder of the calculation period, all of his or her hours, including those worked while assigned to training, would be included in the calculation of the individual's work hours as if the individual were performing operations duties for the entire calculation period. Licensees would be required to count the hours that the individual worked

performing other duties if an individual begins performing the duties listed in § 26.4(a) during the calculation period because the individual's level of fatigue is largely dependent on the total number of hours he or she has worked, regardless of where the work was performed or the nature of the work itself. Therefore, including the hours worked performing other duties would provide assurance that fatigue would not compromise that individual's ability to safely and competently perform the duties that are specified in § 26.4(a).

Section 26.205(b)(4) [Unannounced emergency preparedness exercise and drills] allows licensees to exclude certain time associated with unannounced emergency preparedness exercises and drills from the calculation of an individual's work hours. Only the time an individual works unscheduled work hours for the purpose of participating in the actual conduct of an unannounced emergency preparedness exercise or drill can be excluded. This exclusion is incorporated in the final rule in response to stakeholder comments that adjusting work schedules in anticipation of an unscheduled exercise or drill would negate the element of surprise for the individuals. The nature of such drills is that they are relatively infrequent and short in duration. Therefore, they would not have a major impact on individual fatigue and any impact would be offset by the potential contribution to safety.

Section 26.205(b)(5) [Incidental duties performed off site] allows licensees to exclude from the calculation of an individual's work hours unscheduled work performed off site (e.g., technical assistance provided by telephone from an individual's home) provided the total duration of the work does not exceed a nominal 30 minutes during any single break period. For the purposes of compliance with the minimum break requirements of § 26.205(d)(2) and the minimum day off requirements of § 26.205(d)(3) through (d)(5), such duties do not constitute work periods or work shifts. The final rule includes this exclusion in response to stakeholder comments regarding the necessity of obtaining expert advice or details on recent operating experience that may not have been included in a turnover and the burden that would be imposed by resetting the clock to account for the disruption in a break period. The nominal 30-minute reduction in the break period is not expected to have a detrimental impact on the individual's overall fatigue level and would be offset by the potential contribution to safety.

Proposed § 26.199(b)(2) would have established requirements for calculating the collective work hours of certain job duty groups that would have been subject to the collective work hour limits in proposed § 26.199(f). The final rule does not include these requirements because the NRC eliminated the concept of collective work hours in the final rule, as discussed in § 26.205(d)(3) of this section-by-section analysis. Therefore, to conform with other changes in the final rule, § 26.205(b) does not include those aspects related to calculating collective work hours.

Section 26.205(c) [Work hours scheduling] requires licensees to schedule the work hours of individuals who are subject to this section in a manner that is consistent with the objective of preventing impairment from fatigue resulting from the duration, frequency, or sequencing of successive shifts. This section retains the requirement presented in § 26.199(c) of the proposed rule. The NRC intends for the maximum work hour and minimum break and day off requirements specified in § 26.205(d) to apply to infrequent, temporary circumstances and not be considered guidelines or limits for routine work scheduling. In addition, the work hour controls in § 26.205(d) do not address several elements of routine schedules that can significantly affect worker fatigue, such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation. Therefore, § 26.205(c) requires licensees to schedule personnel consistent with preventing impairment from fatigue from these scheduling factors.

The rule requires licensees to address scheduling factors because human alertness and the propensity to sleep vary markedly through the course of a 24-hour period. These variations are referred to as circadian rhythms and are the result of changes in physiology brought about by a circadian clock or oscillator inside the human brain that is outside the control of the individual. Work may be scheduled, and the consequent timing of periods of sleep and wakefulness, in a manner that either facilitates an individual's adaptation to the work schedule or challenges the individual's ability to get adequate rest. Therefore, the duration, frequency, and sequencing of shifts, particularly for personnel who work rotating shifts, are critical elements of fatigue management. Section IV.D also discusses the effects of circadian rhythms on worker fatigue. The importance of these elements for fatigue management is reflected in guidelines for work scheduling, such as EPRI NP–6748 (Baker, et al., 1990), and in technical reports, such as, NUREG/CR–4248 and the Office of Technology Assessment's report, ''Biological Rhythms: Implications for the Worker'' (Liskowsky, 1991). For example, the EPRI guidelines address issues related to the sequencing of day, evening, and night shifts and the use of break periods between shifts to optimize the ability of personnel to obtain adequate sleep and effectively transition from one shift to another. Although research provides clear evidence of the importance of these factors in developing schedules that support effective fatigue management, the NRC also recognizes that the complexity of effectively addressing and integrating each of these factors in work scheduling decisions precludes a prescriptive requirement. Therefore, § 26.205(c) establishes a non-prescriptive, performance-based requirement.

Stakeholder interactions have interpreted this requirement as a performance-based approach in that licensees' fatigue management performance could be assessed in terms of adherence to the schedules developed in response to § 26.205(c). Although the NRC had intended this requirement to be limited to the development of work schedules, the NRC acknowledges the benefit of implementing this provision as a performance-based requirement applicable to licensee control of the actual hours worked by individuals performing the duties specified in § 26.4(a)(1) through (a)(5) and adopts this interpretation for the final rule. As a consequence, this provision of the final rule requires the work hours of individuals subject to the requirements of this section to be controlled in a manner that prevents impairment from fatigue resulting from elements of routine schedules that can significantly affect worker fatigue, such as shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation.

Section 26.205(d) [Work hour controls] requires licensees to establish work hour controls for individuals who are subject to the requirements of § 26.205. The provision requires licensees to establish controls that limit work periods and provide for breaks that are of sufficient length to allow the individual to obtain restorative rest. This requirement replaces § 26.199(d) of the proposed rule, with limited editorial changes.

Section 26.205(d)(1) establishes work hour limits for consecutive, rolling periods of 24 and 48 hours and 7 days. The majority of licensees have incorporated the work hour controls

from the NRC's Policy on Worker Fatigue, as disseminated by GL 82–12, into either their technical specifications or administrative procedures. The Policy (including the bases for the individual requirements) has been in place for over 20 years and was the subject of a substantive review documented in Attachment 1 to SECY–01–0113. The work hour limits from GL 82–12 also were the subject of substantial stakeholder comments during the public meetings described in the preamble of the proposed rule. In developing the requirements in this section, the NRC staff considered the information gained through these stakeholder interactions.

Section 26.205(d)(1)(i) limits the number of hours that an individual may work in any 24-hour period. The section permits individuals to work no more than 16 hours in any 24-hour period. This provision retains without change the requirement in § 26.199(d)(1)(i) of the proposed rule. This limit is identical to that specified in GL 82–12. Attachment 1 to SECY–01–0113 provides the basis for this limit, which is summarized as follows. Studies have shown that task performance declines after 12 hours on a task (Folkard, 1997; Dawson and Reid, 1997; Rosa, 1991). Other studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Hanecke, et al., 1998; Colquhoun, et al., 1996; U.S. DOT, 49 CFR Parts 350, et al., Proposed Rule, May 2, 2000, 65 FR 25544). Further, nine experts who met in 1984 to develop recommendations for NUREG/CR–4248 recommended a maximum of 12 work hours per day. Therefore, in originally developing its Policy on Worker Fatigue, the NRC had planned a 12-hour maximum limit, but revised it to 16 hours in response to practical concerns raised by the industry that the 12-hour limit required personnel who worked 8-hour shifts to split shifts when they work overtime. Those practical concerns remain valid, and the final rule retains a 16-hour limit.

Although the rule permits 16-hour shifts, other work hour limits in the rule would effectively limit the number of 16-hour shifts that licensees could assign. The NRC's response to a comment from PROS on this issue is discussed in the preamble to the proposed rule.

Section 26.205(d)(1)(ii) limits the number of hours that an individual may work in any 48-hour period. This provision retains without change the requirement presented in § 26.199(d)(1)(ii) of the proposed rule. The section permits an individual to work no more than 26 work hours in a 48-hour period; by contrast, GL 82–12 limits individuals' work hours to 24 work hours in any 48-hour period. This change accommodates the fact that most licensee sites are now routinely working 12-hour shifts, rather than 8-hour shifts, as was the case when the NRC published GL 82–12. At that time, the basis for the 24-hour limit was to permit a worker to work one 16-hour double shift, followed by an 8-hour break, and then start another 8-hour shift at the worker's normal starting time, but only in very unusual circumstances. With the majority of plants now routinely working 12-hour shifts, the rule increases the maximum work hours in a 48-hour period from 24 to 26 hours to decrease the burden on licensees by accommodating situations in which a worker's relief is delayed or similar circumstances. For example, a 12-hour shift worker is able to work up to 14 hours in one day and still return to work at his or her normal time the next day, but can only work 12 hours that day. In the extreme, the 26-hour limit permits an individual to work up to 16 hours one day, followed by a minimum 10-hour break, as required in § 26.205(d)(2)(i). The individual is then limited to 10 hours of work over the next 22 hours.

When developing this requirement, which effectively relaxes by 2 hours the NRC's policy guideline in GL 82–12 for the maximum hours individuals should work in 48 hours, the NRC considered: (1) The burden associated with granting a waiver for the additional 2 hours; (2) the increased stringency of the criteria for granting a waiver of the work hour limits in § 26.207 relative to those in plant technical specifications; and (3) the increased potential for worker fatigue and fatigue-related errors that may accrue from working 26 hours in a 48-hour period versus working 24 hours in that same period.

The increase of 2 additional work hours during a 48-hour period will likely contribute to some increase in fatigue and fatigue-related errors, particularly when these hours come at the end of a work period of 12 or more hours or coincide with a decrease in an individual's circadian level of alertness, as might be expected at the end of a 12-hour day shift. However, because the revised criteria for granting a waiver of the work hour limits in § 26.207 are expected to substantially reduce the number of waivers that are granted, the licensee will have to either delay or turn over any work that the individual is performing when it is necessary for him or her to go off shift. Either delaying or turning over work could contribute to errors. In addition, licensees commonly use waivers to exceed the 24-hours of work in any 48-hour period limit for short durations. As a result, the NRC concluded that the relaxation will principally reduce the paperwork burden, rather than increase the hours that individuals would have actually worked under the proposed rule. Accordingly, the relaxation provides a substantive reduction in burden with a limited net effect on human performance reliability.

Section 26.205(d)(1)(iii) limits the number of hours an individual may work in any 7-day period. This section retains without change the requirement presented in § 26.199(d)(1)(iii) of the proposed rule. The requirement limits an individual to working no more than 72 hours in any 7-day period. This limit is identical to the related limit specified in GL 82–12. Attachment 1 to SECY–01–0113 provides the basis for this limit, which is summarized in this section. In the absence of the break and day off requirements in § 26.205(d)(2) and (d)(3), respectively, the limit would permit a worker to work six 12-hour shifts per week continuously. Studies have shown that longer work schedules cause fatigue (Colquhoun, 1996; Rosa, 1995). Human reliability analysis experts have recommended that the NRC set ''a maximum of 60 hours in any 7-day period and a maximum of 100 hours in any 14-day period,'' noting studies indicating that fatigue from long work hours can result in personnel developing their own subjective standards of what is important in their jobs (NUREG/CR–1278, ''Handbook on Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications''). Further, NUREG/CR–4248 recommends a limit of 60 hours of work in a 7-day period. However, in its Policy on Worker Fatigue, the NRC established a 72-hour maximum limit based on the expectation that individuals would work up to this limit on an infrequent and temporary basis. The rule codifies this expectation, in part, through § 26.205(d)(3), which requires licensees to ensure a minimum number of days off per week, averaged over a shift cycle, for individuals who are subject to the work hour controls. The rule effectively prevents an individual from consistently working six 12-hour shifts in a week.

Section 26.205(d)(2) requires licensees to provide adequate rest breaks for individuals who are performing the duties listed in § 26.4(a). This section contains, with substantial revisions, the requirements presented in § 26.199(d)(2) of the proposed rule.

Although § 26.205(d)(2) retains without change the requirement presented in proposed rule § 26.199(d)(2)(i) for a 10-hour break, the final rule revises the 24-hour break requirement proposed in § 26.199(d)(2)(ii) and replaces the 48-hour break requirement proposed in § 26.199(d)(2)(iii) with an alternative break requirement. The following section-by-section discussion of § 26.205(d)(2) and (d)(3) provides a rationale for these specific changes.

Section 26.205(d)(2) is necessary to ensure that licensees provide individuals with sufficient time off between work periods (shifts) to permit them to recuperate from fatigue and provide reasonable assurance that acute and cumulative fatigue do not compromise the abilities of these individuals to safely and competently perform their duties. Acute fatigue results from excessive cognitive work, especially if an individual is missing significant amounts of sleep, and is readily relieved by obtaining adequate rest and sleep. Cumulative fatigue results from receiving inadequate amounts or poor quality sleep for successive days. An extensive body of research has shown that a lack of adequate days off and extended workdays result in a cumulative sleep debt and performance impairment (Williamson and Feyer, 2000; Tucker, 1999; Colquhoun, 1996; Baker, et al., 1994; Webb and Agnew,1974; U.S. DOT (65 FR 25546, May 2, 2000)).

Section 26.205(d)(2) defines a rest break as an interval of time that falls between successive work periods during which the individual does not perform any duties for the licensee. For example, individuals would not perform work-related duties during rest breaks such as completing paperwork reviews, mandatory reading, or required self-study. Rest breaks could include periods during which an individual is ''on-call'' because actual demands on an individual's time while he or she is on-call would be infrequent and of limited duration, such as answering a phone call. However, if an individual who is ''on-call'' is ''called-in'' to report to the site, the licensee would be required to include the hours that the individual worked as work hours, not as break time, because the individual would be performing duties on behalf of the licensee while on site.

Section 26.205(d)(2)(i) requires licensees to provide a 10-hour break between successive work periods, but permits 8-hour breaks in limited circumstances in which a shorter break is necessary for a crew's scheduled transition between work schedules. Current licensee technical specifications and administrative procedures that are based on GL 82–12 require a minimum 8-hour break between work periods. Section 26.205(d)(2)(i) increases the minimum break period from 8 hours to 10 hours to provide greater assurance that individuals have an adequate opportunity to obtain the 7–8 hours of sleep that is recommended by most experts in work scheduling and fatigue. When considering shift turnover and commute times, which do not provide individuals with opportunities for rest and recovery, a nominal rest break of 8 hours actually leaves the individual with approximately 6 hours available to meet personal needs, including sleep (8 hours off-duty minus an average 1.5-hour round-trip commute minus an average 0.5 hours spent in shift turnover, equaling 6 hours available for personal needs). However, individuals typically also require 0.5 hours for preparing (or buying) and eating at least one meal off-shift and 0.5 hours for personal hygiene, which leaves, at best (i.e., assuming no social or domestic commitments that day), a total of 5 hours available for sleep. By contrast, the 10-hour break ensures that individuals generally have 7 hours available each day for sleep, which is close to the 7–8 hours of sleep needed by adults in the United States (National Sleep Foundation, 2001; Monk, et al., 2000; Rosekind, et al., 1997; Rosa, 1995).

The scientific literature provides strong evidence of the negative effects on performance and alertness of a week when sleep is restricted to 5 hours per day. Dinges, et al., 1997, and Belenky, et al., 2003, who have headed key laboratories in the field of sleep deprivation (the University of Pennsylvania and the Walter Reed Army Institute of Research, respectively), have conducted studies in this area. Belenky, et al. (2003) clearly demonstrates that limiting sleep to 5 hours per night leads to significant impairment in both alertness and actual performance, which builds up over the week, when compared to the alertness and performance of individuals who obtain 7 hours of sleep per night. The difference was found to be significant on all days during which sleep was restricted to 5 hours. Compared to the research subjects' performance after two baseline nights during which they obtained 7 hours of sleep, the subjects' performance after nights during which they were restricted to 5 hours of sleep showed more than twice as many lapses (extra slow responses). Dinges, et al. (1997) obtained similar results. From the second baseline day (the last day during which a full 7 hours of sleep was obtained) through the 7 partial sleep restriction days, the research subjects' sleepiness and performance became progressively worse and these effects achieved a high level of statistical significance. The Dinges, et al. study also concluded that ''recovery from these deficits appeared to require two full nights of sleep.''

The importance of adequate sleep and the need to provide adequate opportunity for sleep in work schedules are reflected in studies (e.g., Kecklund and Akerstedt, 1995; Wylie, et al., 1996), guidelines (Pratt, 2003; Baker, et al., 1990), handbooks (Tepas and Monk, 1987), and the panel recommendations of sleep and fatigue experts (e.g., NUREG/CR–4248). An EPRI/NEI Work Hours Task Force white paper, ''Managing Fatigue in the Nuclear Energy Industry: Challenges and Opportunities'' (ADAMS Accession No. ML0221740179), also notes the importance of providing an opportunity for at least 8 hours of sleep. The report, prepared by Mark Rosekind, states that ''the strongest and most extensive data demonstrate that sleep is a critical factor in promoting alertness and performance in subsequent wakefulness. Data clearly show that acute and cumulative sleep loss degrade subsequent alertness and performance. Therefore, any 'hours of service' policy should emphasize the provision of an appropriate sleep opportunity prior to duty.'' More specifically, human reliability analysis experts have recommended that the NRC require ''a break of at least 12 hours between all work periods'' (NUREG/CR–1278). Similarly, a panel of sleep and fatigue experts criticized a DOT requirement for an 8-hour break for motor carriers as inadequate because 8 hours of off-duty time does not translate into 8 hours of sleep. The DOT has since amended its regulations for motor carriers to require 10-hour rest breaks (68 FR 22456–22517, April 28, 2003).

Although a longer minimum rest break requirement would provide greater assurance that individuals have adequate opportunities for sleep, the 10-hour break requirement provides adequate opportunity for rest when used infrequently, as is expected given other requirements in this rule. For example, § 26.205(d)(1)(ii) limits individuals to working 26 hours in any 48-hour period. Although licensees could use routine 10-hour breaks in conjunction with atypical shift durations (e.g., alternating 12- and 14-hour shifts), the practical implications of these schedules, such as varied start times, make their use improbable. As a consequence, the 10-hour break requirement is sufficient to

assure adequate rest during infrequent circumstances in which individuals work extended hours (e.g., more hours than their typical 8-,10-, or 12-hour shift) and that rest opportunities will typically vary between 12 and 16 hours in duration.

The minimum 10-hour break duration also accommodates most scheduling circumstances for the common shift durations that are currently in use in the industry. A notable exception is that the 10-hour break requirement could potentially prevent an individual who has worked 16 hours straight (e.g., two consecutive 8-hour shifts) from returning to duty at the start of his or her next regularly scheduled shift. However, the 10-hour break requirement appropriately prevents the individual from working in this circumstance because the potential for degraded job performance resulting from fatigue would be substantial given the individual's continuous hours of work and limited opportunity to sleep.

Section 26.205(d)(2)(i) permits licensees to schedule a minimum 8-hour break in only one circumstance: if the 8-hour break is necessary to accommodate a crew's scheduled transition between work schedules. During the public meetings described in the preamble of the proposed rule, the NRC received comments that a 10-hour break requirement would occasionally interfere with a transition from 12-hour shifts to 8-hour shifts. This transition typically occurs at the end of an outage for individuals who normally work an 8-hour shift, but work a 12-hour shift during outages. Although the exception provides individuals with less time for recovery, the shorter break is limited to one break occurring on a very restricted frequency. Therefore, the permission for an 8-hour break for the specific circumstances of a shift transition provides scheduling flexibility with minimal potential to adversely affect an individual's ability to safely and competently perform his or her duties.

Section 26.205(d)(2)(ii) replaces and revises § 26.199(d)(2)(ii) of the proposed rule which would have required a minimum 24-hour break in any rolling 7-day period. Section 26.205(d)(2)(ii) of the final rule requires a minimum 34-hour break in any rolling 9-day period. This provision requires a periodic long duration break thereby preventing an excessive number of consecutive work shifts that would not otherwise be prevented by the requirements of § 26.205 of this rule.

Break periods longer than the minimum 10 hours between shifts required by § 26.205(d)(2)(i) are necessary on a regular basis in order to maintain reliable human performance. For example, Belenky, et al. (2003) found that the performance of subjects whose sleep periods were restricted to 7 hours per night over 7 consecutive days increasingly degraded as the number of sleep-restricted days increased. Van Dongen, et al. (2003) similarly found that the performance of subjects whose sleep was limited to 8-hours per night also declined over a 2-week period. The only subjects in these studies who did not show any performance decrements were those who were permitted 9-hour sleep periods in the Van Dongen study. These results clearly demonstrate that individuals require more rest than a 10-hour break provides over time to prevent performance degradation from cumulative fatigue, including that which accrues from a series of days of mild sleep restriction (e.g., 7 hours per night). Recent changes in the DOT regulations for the work hours of commercial truck drivers also reflect the need for longer breaks to mitigate fatigue. On April 28, 2003, the DOT published final regulations (68 FR 22456–22517) for hours-of-service for drivers of motor carriers, which amended 49 CFR Parts 385, 390, and 395. These regulations require a minimum 34-hour break after any period of 8 consecutive days with no more than 70 hours on duty. The intent of this 34-hour break is to provide for two consecutive sleep periods.

Further, a 10-hour break provides an opportunity for 7 hours of sleep only if one assumes the minimal times for meals, hygiene, and commuting described with respect to § 26.205(d)(2)(i), with no other daily living obligations. These assumptions are realistic only for unusual circumstances and limited periods of time during which individuals may be able to temporarily defer their other obligations. As the number of consecutive days increases in which individuals have only a 10-hour break available to meet these other obligations, the pressure on individuals to restrict sleep time in order to meet these other obligations increases. In addition, after a series of moderately restricted sleep periods (i.e., 6 hours per night), individuals' subjective feelings of sleepiness stabilize and they report feeling only mild sleepiness (Van Dongen, et al., 2003), which may further encourage individuals to restrict their sleep periods in order to meet daily living obligations. Van Dongen, et al. noted ''the lack of reports of intense feelings of sleepiness during chronic sleep restriction may explain why sleep restriction is widely practiced—people have the subjective impression they have adapted to it because they do not feel particularly sleepy.'' However, results of the Van Dongen study also demonstrated that the performance of subjects in that study continued to degrade as the number of consecutive restricted sleep periods increased over a 2-week period, including the performance of subjects who were permitted 6- and 8-hour sleep periods.

Section 26.199(d)(2)(ii) of the proposed rule would have established a requirement for a minimum 24-hour break in any 7-day period. The NRC revised the maximum number of days between the breaks in response to stakeholder comments that the proposed requirement would have substantially reduced licensee flexibility in scheduling 8-hour shifts. Stakeholders noted that many licensees currently use 8-hour schedules that include periods of 7 consecutive days. In revising the proposed requirement, the NRC considered that, although the final rule allows more consecutive days for 8-hour and 10-hour shifts, the final rule allows licensees the flexibility to more readily optimize 8-hour shift schedules to minimize the transitions between day, evening, and night shifts that can lead to worker fatigue. Although this relaxation also allows more consecutive shifts for individuals on 10-hour shifts, individuals on 10-hour shifts typically do not work a rotating schedule and thereby do not experience the disruption of their circadian cycle that exacerbates the cumulative fatigue effects of consecutive work shifts. The final rule also provides flexibility to accommodate other practical considerations such as scheduling training on a Monday through Friday basis and allows a contingency day in 8-hour shift schedules that includes a series of seven consecutive 8-hour shifts as part of the routine shift cycle.

The final rule also revises the minimum duration of the break period from 24 hours, as specified in § 26.199(d)(2)(ii) of the proposed rule, to a minimum 34-hour break. The revision more clearly states the NRC's intent to require a periodic ''day off'' in which individuals have the opportunity for two consecutive sleep periods without an intervening work period. The 34-hour break duration provides opportunity for two consecutive sleep periods without an intervening work period, supports use of forward rotating and fixed shifts, and allows for the possibility that individuals may work 26 hours in a 48-hour period contiguous to the break.

Given these considerations, the NRC concluded that § 26.205(d)(2)(ii) of the final rule provides a level of assurance of worker FFD relative to fatigue that is comparable to that which would have been achieved through the requirement in § 26.199(d)(2)(ii) of the proposed rule. The provision for a 34-hour break in any rolling 9-day period serves both to prevent and mitigate cumulative fatigue. The 34-hour break periods will not only provide some opportunity for recovery sleep, but also time that individuals need to meet the many daily living obligations that they cannot otherwise readily meet. Without such long break opportunities, individuals must either forego activities that can be important to general mental and physical fitness (e.g., family interactions, exercise, recreation, doctor appointments) or sacrifice sleep and increase their sleep debt (Presser, 2000), resulting in impairment on the job.

Section 26.205(d)(2) of the final rule does not retain the requirement for a minimum 48-hour break in any rolling 14-day period as would have been required by § 26.199(d)(2)(iii) of the proposed rule. The NRC received many stakeholder comments in opposition to the 48-hour break requirement. One commenter stated that fixed break requirements and collective work hour restrictions will lead to significant safety implications and could affect a licensee's ability to restore inoperable equipment in a timely manner. This view was echoed by many other commenters. Another commenter found fault with focusing on days off without considering the number of hours worked in a particular day and the breaks between work periods. In addition, many commenters raised the issue of work schedule disruption as a result of the 48-hour break requirement. They asserted that, for workers on the night shift, having one day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, which reduces the risk of accidents on the job. Two days off, however, may interfere with his or her sleep cycle, and as a result, the individual would have to readjust to the night shift after the 2-day break. According to the commenters, some workers have stated that having 2 days off is worse than having no days off. They also argued that a 1-day break in any 7-day period is more than adequate when combined with other rule provisions to address cumulative fatigue. Thus, commenters requested that the 48-hour break requirement during outage periods be deleted.

In response to stakeholder comments, the NRC replaced the requirement proposed in § 26.199(d)(2)(iii) with alternative requirements that ensure that each worker receives a minimum number of days off per week, on average, while the plant is operating or receives a minimum number of days off in each consecutive 15-day period of a plant outage. Security personnel subject to the requirements of § 26.205 are also subject to requirements for minimum days off in 15-day periods during security system outages and increased threat conditions. These alternative extended break requirements are in § 26.205(d)(3) through (d)(5) of the final rule and are addressed in the section-by-section analysis applicable to those requirements. In adopting the alternative requirement for the final rule, the NRC considered that, whereas the alternative requirements assured that workers subject to the requirement would receive a minimum number of days off, which would serve to limit the potential for cumulative fatigue, the requirements would not assure that any of the days off would be consecutive, as would have been required by the minimum 48-hour break requirement of proposed § 26.199(d)(2)(iii). In proposing the 48-hour break requirement, the NRC cited several studies that demonstrate the benefits of consecutive days off, noting that one night of unrestricted sleep is not sufficient to fully recover from the cumulative fatigue that can result from restricted sleep and extended work hours. However, the NRC also considered that the minimum day off requirements would, in effect, limit each individual's average number of work hours and the average number of consecutive work shifts between days off, thereby reducing the potential for cumulative fatigue. As a consequence, the final rule's requirements reduce the need for consecutive days off to prevent or mitigate fatigue. The NRC also expects that common scheduling constraints and worker preferences will cause licensees to schedule days off in succession. In addition, the NRC considered that the alternative requirements of § 26.205(d)(3) and (d)(4) of the final rule provides licensees greater flexibility in meeting scheduling demands and minimizing circadian disruption for workers.

Section 26.205(d)(3) requires individuals subject to the requirements of § 26.205 to have a minimum average number of days off per week. The specific number of days off depends upon the length of shifts in the work schedule of the individual. This requirement replaces the requirements presented in proposed § 26.199(f) [Collective work hour limits], which would have required licensees to control the collective work hours of each group of individuals performing the duties subject to the work hour requirements and ensure that the collective work hours of each job duty group would not have exceeded an average of 48 hours per person per week in any averaging period. Section 26.205(d)(3), by requiring a minimum number of days off, indirectly limits average weekly work hours to levels comparable to those that would have been permitted by the collective work hour limits of the proposed rule. Consequently, § 26.205(d)(3) of the final rule performs the same function as the requirements of proposed § 26.199(f), providing reasonable assurance that the FFD of individuals subject to the work hour requirements is not impaired by cumulative fatigue. As described with respect to § 26.205(d)(2), this requirement also addresses an objective of the 48-hour break requirement of the proposed rule by limiting the potential for the cumulative fatigue of individuals while the plant is operating. The provision does not require that days off be provided consecutively, as would have been required by proposed § 26.199(d)(2)(iii), but rather allows licensees discretion, within the constraints of the other work hour limit and break requirements, in distributing days off throughout the shift cycle. As a consequence, § 26.205(d)(3), like proposed § 26.199(d)(2)(iii), is intended to ensure that individuals receive sufficient days off on a periodic basis to prevent cumulative fatigue.

The minimum day off requirements of § 26.205(d)(3) will ensure that licensees manage during periods of normal plant operation the potential for cumulative fatigue (i.e., fatigue from successive weeks of overwork or inadequate rest) to adversely affect the abilities of individuals to perform functions that are important to maintaining the safety and security of the plant. The requirements prevent excessive use of the maximum work hours and minimum rest breaks that are permitted under § 26.205(d)(1) and (d)(2). In addition, proactively controlling work hours to ensure individuals receive a minimum weekly average number of days off while the plant is operating is likely to reduce the need for licensees to grant waivers of the work hour requirements in § 26.205(d)(1) and (d)(2). Individuals will be better rested and less susceptible to cumulative fatigue from the increased work hours that are common during outages and that are necessary to augment security

staffing during increased threat conditions. Therefore, the minimum day off requirement is essential for limiting cumulative fatigue and augments other important elements of licensees' fatigue management programs.

Requiring a minimum number of days off that results in a maximum average work week of approximately 48–54 hours per week helps to ensure that licensees meet a fundamental objective of the NRC's Policy on Worker Fatigue. The Policy, promulgated in GL 82–12, is intended to ensure that there are a sufficient number of operating personnel available to ''maintain adequate shift coverage without routine heavy use of overtime.'' Routine overtime can cause cumulative fatigue, thereby degrading workers' abilities to safely and competently perform their tasks. Section 26.205(d)(3) establishes requirements that are expected to result in maximum average work weeks in the range of 48–54 hours, thereby ensuring that work hours approaching the limits in § 26.205(d)(1) and NRC's Policy on Worker Fatigue are the exception and not routine.

The minimum day off requirements of § 26.205(d)(3) also address, in part, the cumulative fatigue concerns reported by security personnel in the months following the terrorist attacks of September 11, 2001. These individuals questioned their readiness and ability to perform their required job duties because of the adverse effects of cumulative fatigue. The NRC reviewed the actual hours worked by security personnel and determined that, in the vast majority of cases, individual work hours did not exceed the guidelines specified in the NRC's Policy on Worker Fatigue. However, the review confirmed that individuals had been working up to 60 hours per week for extended periods. Individual concerns regarding their FFD, in light of work schedules that did not exceed the specific guidelines of the policy, as well as relevant technical research supporting the basis for cumulative fatigue, led the NRC to conclude that the work hour guidelines of the Policy are inadequate for addressing cumulative fatigue. The NRC obtained additional support for this conclusion following a review of worker fatigue concerns and work hours during a long-term outage at the Davis Besse nuclear plant (NRC Inspection Report 05000346/2004003, dated March 31, 2004, ADAMS Accession No. ML040910335).

Through public interactions during the development of order EA–03–038, the NRC developed a collective work hour requirement, rather than a limit on individual work hours, in response to stakeholder comments regarding differences among individuals in their abilities and desires to work overtime. The proposed rule would have permitted a group of workers who perform similar duties to average 48 hours of work over a period not to exceed 13 weeks. Because the proposed limit would have been imposed on a job duty group's average number of work hours during an averaging period, licensees would have been able to distribute overtime among their workers based on their assessment of individuals' abilities and desires to work overtime. Stakeholder comments on the proposed requirement for collective work hour controls raised several concerns.

Some stakeholders expressed the concern that the collective work hour controls were not an effective means for addressing fatigue. One stakeholder expressed the concern that the collective work hour controls would allow licensees to force individuals to work overtime. Another stakeholder expressed the opinion that collective work hour controls are not an effective means to address the known physiological fatigue risks contributed by individual operators. Other stakeholders expressed the concern that licensees may be able to manipulate the collective work hour calculations. Other commenters asserted that the collective work hour controls were unnecessary to mitigate the effects of cumulative fatigue and that the controls would limit the flexibility to increase work hours in a job-duty group based on operational needs. These commenters stated that other rule provisions, such as the work schedule, individual work hour limits, and individual break requirements, as well as the provisions concerning fatigue assessments and the self-declaration process adequately address cumulative fatigue.

Although the NRC acknowledges that Subpart I provisions concerning fatigue assessment and self-declaration are important for the detection of cumulative fatigue, these provisions, like the individual work hour limit and break requirements of the proposed rule, do not adequately address the prevention of cumulative fatigue. Accordingly, the final rule addresses the comments on the limitations of the collective work hour requirements by replacing the requirements of § 26.199(f) of the proposed rule with the minimum day off requirements in § 26.205(d)(3) of the final rule. The minimum day off requirements were largely derived from a work hour control proposal submitted by NEI as a comment on the proposed rulemaking. Although in several instances the NRC did not adopt the specific minimum number of days off that NEI proposed in its comments, § 26.205(d)(3) establishes requirements similar to those proposed by NEI by requiring each individual subject to the requirements of § 26.205 to have a minimum average numbers of days off per week.

Section 26.205(d)(3) defines, for the purposes of Subpart I, the term *day off* as a calendar day in which an individual does not start a work shift. The definition ensures consistent licensee implementation of the requirements in § 26.205(d)(3). In developing the definition, the NRC considered the alternative of defining the requirements of § 26.205(d)(3) in terms of 24-hour break periods. A stakeholder at the March 29, 2006, public meeting concerning this rulemaking noted that the number of 24-hour breaks in a schedule could be readily influenced by the number of rotations between shifts and therefore could encourage scheduling practices that achieved compliance with the requirement through schedules that were adverse to the circadian adjustment of workers. As defined in the final rule, use of the term *day off* does not encourage such adverse scheduling practices and results in requirements that establish uniform limits for all schedule designs. In addition, the definition enables workers and schedulers to readily determine the number of days off in a schedule without the need to calculate the duration of break periods.

Section 26.205(d)(3)(i) through (d)(3)(iv) specifies the minimum number of days off for each individual subject to the requirements of § 26.205 in terms of a minimum number of days off per week, averaged over the shift cycle. The requirements in this section thereby allow the number of days off for an individual to vary from week to week, but mandate that over the duration of the shift cycle, the average number of days off per week meets the specified minimum. Section 26.205(d)(3) requires that, for the purposes of calculating the average number of days off required in this section, the duration of a shift cycle may not exceed 6 weeks. This maximum duration of a shift cycle limits the period over which licensees are permitted to average the number of days off and thereby limits the potential for cumulative fatigue by preventing an excessive number of consecutive weeks in which individuals may be working the maximum hours allowed by § 26.205(d)(1) while having only the minimum breaks required by

§ 26.205(d)(2). The 6-week maximum for shift cycles also corresponds to the longest shift cycle commonly used in the U.S. nuclear industry.

Section 26.205(d)(3)(i) requires individuals who are working 8-hour shift schedules to have at least 1 day off per week, averaged over the shift cycle. This minimum day off requirement allows an average of 48 hours of work per week, assuming individuals receive the minimum number of days off with no work shifts extended beyond 8 hours. This requirement is therefore generally consistent with the 48-hour collective work hour requirement of § 26.199(f) of the proposed rule, though it imposes the requirement on an individual rather than a group basis. This requirement is also consistent with the NEI proposal for an average of 1 day off per week, averaged over a shift cycle, for predominantly 8-hour shift schedules.

In developing requirements to address cumulative fatigue, the NRC considered several types and sources of information, including (1) past recommendations from experts and expert panels on work scheduling and maintaining worker alertness in the nuclear industry, (2) surveys of nuclear power plant workers on their desire and ability to work overtime, (3) data on the amount of overtime worked by security personnel, and (4) the requirements and practices in other industries.

EPRI NP–6748 (Baker, et al., 1990) and NUREG/CR–4248 are two of the most comprehensive documents on worker fatigue in the U.S. nuclear industry. Like the collective work hour limits of the proposed rule, the minimum average number of days off requirement is a new concept developed to meet the rule's objectives while also addressing stakeholders' unique circumstances and specific concerns. As a consequence, neither of the documents provides specific guidelines for establishing collective work hour limits. Nevertheless, the documents contain information and guidelines relevant to this requirement. Collectively, the shift scheduling guidelines of EPRI NP–6748 and NUREG/CR–4248 suggest a maximum routine work schedule of 44–46 hours per week. This maximum includes an assumed turnover time of 30 minutes per shift. The NRC also considered the recommendations of experts concerning the use of overtime. The expert panel that developed the guidelines for NUREG/CR–4248 also addressed overtime use and recommended an individual limit of 213 hours per month, including shift turnover time. The expert panel emphasized that overtime should not be approved for an entire crew, noting that this individual maximum on overtime should not be a group norm. Work schedules that meet the minimum day off requirements will result in levels of individual work hours that are typically in the middle of the range of work hours defined by the maximum routine scheduling limits and maximum individual overtime. The expert panel further recommended that the NRC authorize no more than 400 hours of overtime in a year. A limit of 400 hours of overtime annually is very similar to a 48-hour average (i.e., 52 weeks × 8 hours = 416 hours).

In addition to considering the opinions of experts in work scheduling and fatigue, the NRC staff also considered the opinions of individuals who work in nuclear power plants. These opinions were expressed in surveys conducted by PROS and EPRI.

In 2002, PROS surveyed the attitudes of its members towards work hours and the development of a proposed rule concerning fatigue of workers at nuclear power plants (ADAMS Accession No. ML05270310). One of the survey questions was, ''What is your personal tolerance for overtime?'' The responses indicated that 75 percent of the respondents had a ''tolerance'' for up to 350 hours per year. Only 13 percent expressed a tolerance for more than 350 hours of overtime.

The work conducted in the development of EPRI NP–6748 also included a survey of operators. The results were consistent with the PROS survey, indicating that the amount of overtime that operators wanted to work ranged from 100 to 400 hours per year. A survey of nuclear power plant personnel in the United Kingdom yielded similar results.

A minimum day off requirement will limit individuals to approximately 400 to 500 hours of overtime in a year. Therefore, the minimum day off requirements permit levels of overtime while the plant is operating that are at the upper extreme of the number of overtime hours for which nuclear power plant personnel have expressed a tolerance. In addition, the minimum day off requirements are less restrictive than the limit implied by worker opinions because the minimum day off requirements of § 26.205(d)(3) would not apply during the first 60 days of plant outages, and for security personnel, during the first 60 days of plant outages, security system outages, or increased threat conditions.

Together with expert and worker opinions, the NRC considered industry practices concerning the use of overtime for security personnel. The NRC collected work scheduling data for security personnel at all nuclear power plants following the events of September 11, 2001, as part of the process of evaluating the need to require licensees to implement compensatory measures to address security personnel fatigue. The NRC's analysis, as described in letters from the NRC to licensees (e.g., ADAMS Accession No. ML031880257), indicated that at some of the sites (31 percent), security personnel worked more than 55 hours per week and at a few sites (11 percent) they worked 60 hours or more per week. The data also indicated that at the majority of the sites (58 percent) security personnel typically worked 50 hours per week or less. The NRC also reviewed work hours data collected by NEI (ADAMS Accession No. ML003746495) and found that, although individual sites varied substantially, the average annual overtime for licensed operators was 375 hours and 361 hours for non-licensed operators. These findings suggest that an average work week of approximately 48 hours is an achievable objective for operations personnel as well, although it was not a current practice at a small fraction of nuclear power plants.

The minimum day off requirements are comparable to, though less restrictive than, limits on workers in other industries within the United States and the limits imposed by other countries that regulate overtime for nuclear power plant workers. The NRC staff noted that several other countries address cumulative fatigue of nuclear power plant personnel through individual monthly and/or annual work hours limits on overtime. These limits, summarized in Table 6 of Attachment 1 to SECY–01–0113, are generally more restrictive than the minimum day off requirements because they directly limit hours of work, rather than work days, and permit fewer hours of work (e.g., Finland limits overtime to 250 hours per year). Table 5 of Attachment 1 to SECY–01–0113 includes a summary of limits on work hours in other industries in the United States.

The NRC also considered the requirements of the European Union (EU) Working Times Directive (WTD) (Council Directive, 1993). The WTD establishes requirements concerning the working hours of workers across various industries in EU member nations. The WTD establishes a requirement that ''workers cannot be forced to work more than 48 hours per week averaged over 17 weeks.''

Moreover, the amount of overtime permitted by the minimum day off requirements would be greater than the

amount used in most continuous operations. Circadian Technologies, Inc., a consulting firm that is expert in fatigue management, regularly surveys U.S. and Canadian companies conducting 24/7 operations. Its 2000 survey of 550 major companies indicates that shift workers at 89 percent of the companies surveyed averaged less than 400 hours of overtime per year (Circadian Technologies, Inc., 2000). Circadian Technologies, Inc., noted that the average overtime for workers in extended operations in the United States was 12.6 percent above the standard work week in the first 8 months of 2003, with utilities averaging 14.9 percent (Circadian Technologies, Inc., 2003).

Therefore, the minimum day off requirements establish appropriate limits on work schedules while the plant is operating. The requirements would ensure that individuals subject to the work hour requirements of § 26.205 have sufficient days off to prevent fatigue. The minimum day off requirements will indirectly permit levels of overtime at the upper extreme desired by most nuclear power plant workers while limiting overtime to levels comparable to those recommended by work scheduling and fatigue experts.

Section 26.205(d)(3)(ii) requires that individuals who are working 10-hour shift schedules have at least 2 days off per week, averaged over a shift cycle. Individuals working schedules that meet the minimum day off requirements of this section would therefore be working, on average, five 10-hour shifts (50 hours) per week. In developing this requirement the NRC considered the NEI proposal for a minimum of 1 day off per week average for 10-hour shift schedules. The NRC concluded that such a limit would allow excessive work hours (i.e., an average of 60 hours per week) for routine scheduling, thus creating the potential for cumulative fatigue. The NRC would not expect such a limit for long-term work hour control to prevent fatigue concerns such as those reported by security personnel working on the order of 60 hours per week in the months following the terrorist attacks of September 11, 2001. The section-by-section analysis for § 26.205(d)(3)(i) addresses in detail the basis for minimum day off requirements that effectively limit work schedules to work weeks averaging approximately 48 hours per week. Section 26.205(d)(3)(i) would permit an average work schedule of approximately 50 hours. Although this requirement for 10-hour schedules would allow 2 more hours per week than the requirement for 8-hour schedules, 10-hour schedules are not typically used for rotating shift schedules. As a consequence, the individuals on those schedules are less likely to experience the disruption of their circadian cycles that is caused by rotating shifts and therefore better able to cope with the additional work hours.

Section 26.205(d)(3)(iii) requires that individuals performing the duties described in § 26.4(a)(1) through (a)(3) have at least 2.5 days off per week averaged over a shift cycle and individuals described in § 26.4(a)(4) have at least 2 days off per week, averaged over a shift cycle. In developing this requirement, the NRC considered NEI's proposal to require a minimum of 2 days off per week for all individuals working 12-hour shifts subject to the work hour requirements, except security personnel. For individuals performing the duties described in § 26.4(a)(1) through (a)(3), the NRC judged 2 days off per week to be insufficient for routine scheduling of 12-hour shifts because it would allow an average work week of 60 hours, which the NRC expects would lead to cumulative fatigue. Furthermore, such a requirement would ensure substantially fewer days off than would be recommended by the scheduling guidelines contained in EPRI NP–6748 (Baker, et al., 1990) and NUREG/CR–4248.

In developing § 26.205(d)(3)(iii), the NRC also considered the effect of scheduled training weeks on the overall work hours of operations personnel. Operators have 1 week of requalification training in most shift cycles. The training week typically consists of four 9-hour days or five 8-hour days. As a consequence, § 26.205(d)(3)(iii) has the effect of limiting covered operations personnel to an average work week ranging from 48.8 hours to 52 hours, in most shift cycles (i.e., when the shift cycle contains a training week). The specific number of hours depends on the number of weeks in the shift cycle and the training week schedule. This estimate also assumes that individuals do not work longer than their scheduled 12-hour shift.

Section 26.205(d)(3)(iv) of the rule requires that licensees ensure that individuals who are working 12-hour shifts while performing the maintenance duties described in § 26.4(a)(4) have a minimum of at least 2 days off per week, averaged over a shift cycle. For individuals described in § 26.4(a)(4) the NRC judged 2 days off per week to be sufficient for routine scheduling of 12-hour shifts. Relative to the duties described in § 26.4(a)(1)–(a)(3) and (a)(5), the duties described in § 26.4(a)(4) involve fewer and less prolonged periods of sedentary activities, which can contribute to degraded alertness, and monitoring activities, which are particularly susceptible to degraded vigilance.

Section 26.205(d)(3)(v) of the rule requires that licensees ensure that individuals who are working 12-hour shifts and performing the security duties described in § 26.4(a)(5) have a minimum of 3 days off per week, averaged over a shift cycle. This requirement limits the security personnel who are subject to this requirement to an average work week of 48 hours. In developing this requirement the NRC considered the technical basis described with respect to § 26.205(d)(3) and public comment on the collective work hour controls of the proposed rule. The NRC also considered its experience with implementing the group work hour controls that were required for security personnel by the compensatory measures of order EA–03–038. The NRC has generally found that licensees have implemented work hour controls consistent with the requirements of the compensatory measures. However, the NRC has received a limited number of concerns from security personnel stating that they are still experiencing excessive fatigue leading to the perception that the requirements have not been fully protective of all security personnel. The NRC also notes that it has received numerous reports of inattentive security personnel at U.S. nuclear powerplants within the last 2 years. In addition, the NRC considered the critical importance of mental alertness and maintaining vigilance to the effective performance of security personnel and the unique challenges of security duties and work environments to meeting these needs (see the section-by-section analysis of § 26.205(a) for a more detailed discussion of the relationship between security duties and fatigue). Given these considerations, the NRC concluded that it is appropriate to establish more stringent work hour requirements for security personnel than other individuals subject to the requirements of § 26.205. Accordingly, § 26.205(d)(3)(iv) requires a minimum of 3 days off per week, averaged over a shift cycle, for individuals working 12-hour shifts who are performing the security duties described in § 26.4(a)(5).

Section 26.205(d)(4) provides a limited exception from the minimum day off requirements in § 26.205(d)(3) for individuals performing the duties specified in § 26.4(a)(1) through (a)(4) (i.e., certain operations, chemistry,

health physics, fire brigade, and maintenance personnel). The exception from the minimum day off requirements is available during the first 60 days of a unit outage while a subject individual is working on outage activities. In these circumstances, § 26.205(d)(4) requires licensees to ensure that individuals specified in § 26.4(a)(1) through (a)(3) have a minimum of 3 days off in each successive (i.e., non-rolling) 15-day period and that individuals specified in § 26.4(a)(4) (maintenance personnel) have at least 1 day off in any 7-day period. If at any time during a unit outage an individual performs duties specified in § 26.4(a)(1) through (a)(4) on or for a unit that is not disconnected from the electrical grid, the individual is subject to the minimum day off requirements of § 26.205(d)(3) while the individual is performing those duties, except as permitted by § 26.205(d)(6). After the first 60 days of a unit outage, regardless of whether the individual is working on unit outage activities, the individual is again subject to the minimum day off requirements of § 26.205(d)(3), except as permitted by § 26.205(d)(6).

The minimum day off requirements in § 26.205(d)(3) address the long-term control of work hours while permitting the occasional use of extended work hours for short duration circumstances such as equipment failure, personnel illness, or attrition. The requirements in § 26.205(d)(4) address the control of work hours for unique plant conditions (i.e., unit outages) which require extended work hours for a more sustained period of time. In developing the minimum day off requirements of § 26.205(d)(4), the NRC considered several factors, including current policy, the bases for the policy, lessons learned from the policy implementation, and public comment on the proposed rule.

The NRC's Policy on Worker Fatigue provides guidelines for controlling work hours, ''on a temporary basis,'' during periods requiring substantial overtime. The Policy reflects the NRC's recognition that outages are unique, relatively short term, and involve levels of activity that are substantially higher than most non-outage operating periods. The policy also reflects the NRC's understanding that, although individuals are capable of working with limited rest without degraded performance for short periods of time, research has shown that the ability to sustain performance without adequate rest is clearly limited (Knauth and Hornberger, 2003; Pilcher and Huffcutt, 1996; Van Dongen, et al., 2003), as discussed in Section IV.D. However, as noted in SECY–01–0113, Attachment 1, the NRC has never defined the term ''temporary basis'' as used in the Policy. As a result, licensees have relied on this phrase in the guidelines to permit extended work hours for periods ranging from a few days to more than a year. Industry experience with conditions such as sustained plant shutdowns and the increased work hours of security personnel following the terrorist attacks of September 11, 2001, have demonstrated the need for the NRC to establish clearer and more readily enforceable requirements limiting the sustained use of extended work hours.

Differences between individuals, job demands, and work-rest schedules can each have a substantial effect on the period of time that an individual can work without compromising his or her ability to safely and competently perform duties. As a result, studies of work scheduling and fatigue provide insights into the potential for cumulative fatigue of workers, but do not provide a direct basis for establishing the maximum acceptable period for excluding plant outage work hours from the collective work hour controls. In setting the maximum duration of the exclusion period, the NRC considered that, by the end of 60 days of work at the limits permitted by § 26.205(d)(1) and (d)(2), individuals who are performing the duties specified in § 26.4(a)(1) through (a)(4) will have (1) worked 576 hours, including more than 200 hours of overtime, and (2) missed as many as 17 normally scheduled days off. The loss of the 17 normally scheduled days off represents a 60-percent reduction in the time available to recover and prevent cumulative fatigue. Further, with each passing week of increased work hours and decreased time off, deferring daily living obligations becomes increasingly difficult, causing increased pressure on individuals to reduce their sleep time in order to meet the demands of both work and daily life, resulting in an increased potential for cumulative fatigue.

In addition to considering the potential for cumulative fatigue, the NRC considered current industry data on the duration of unit outages in determining whether the cost to licensees imposed by limiting the exclusion period to 60 days is justified in terms of the benefit. The average outage duration, as indicated by outage data from 2000–2002, is approximately 39 days (Information System on Occupational Exposure Database, ADAMS Accession No. ML050190016). Eighty-nine percent of plant outages during this period were less than 8 weeks in duration. In reviewing the frequency of outages, by duration, the NRC found that it would be necessary to increase the exclusion period substantially to address a marginal number of additional outages of longer lengths. Many comments on the proposed rule recommended that the 8-week exclusion period be increased to a 10-week exclusion period. This increase in the exclusion period would substantially increase the period of time that an individual would be working with reduced recovery time. During the exclusion period, individuals are permitted to work up to 72 hours in a 7-day period and are assured of just 3 days off in each 15-day period. Individuals who work 12-hour shifts, which is common during outages, will average up to 67.2 hours per week, which represents 160 percent of their normally scheduled hours with less than half of their normally scheduled days off for recovery, for a period of up to 2 months. Extending the outage exclusion period to prolong these conditions would substantively increase the potential for cumulative fatigue and fatigue-related personnel errors. Therefore, the NRC did not adopt the recommendation to increase the duration of the exclusion period in the final rule.

The NRC also received several comments on the proposed rule which recommended that the NRC eliminate the exclusion for outage periods. In an early phase of developing the work hour requirements in Subpart I, the NRC considered establishing a set of uniform requirements that would be applicable regardless of whether a unit was operating or shut down. However, as noted with respect to § 26.205(d)(4), the NRC recognizes that individuals are capable of working with limited rest without degraded performance for short periods of time. As a consequence, the NRC considers it appropriate to allow flexibility within the work hour requirements to accommodate limited periods of more intensive work schedules, such as unit outages. However, the NRC limits this flexibility to infrequent circumstances, such as unit outages, to limit the potential for cumulative fatigue. Further, the NRC considered the substantial cost to licensees for meeting the requirements applicable to periods of plant operation through either increasing staffing (to minimize outage durations) or increasing outage durations to accommodate a less intensive work schedule. Given these considerations, the NRC concluded that a limited period of less restrictive work hour requirements, as included in the final

rule, is better justified by the costs and benefits.

The 60-day exclusion period that § 26.205(d)(4) permits from the minimum day off requirements of § 26.205(d)(3) replaces the 8-week exclusion period that proposed § 26.199(f) would have permitted from the collective work hour limits. The discussion with respect to § 26.205(d)(3) presents the issues the NRC considered in deciding to replace the collective work hour limits with minimum day off requirements. The NRC revised the maximum duration of the permitted exclusion period to a duration that is comparable to the 8-week (56-day) period of the proposed rule, but better conforms with the minimum day off requirements in § 26.205(d)(4) and (d)(5). For most categories of individuals, the final rule establishes minimum day off requirements in terms of 15-day periods, rather than weeks, as the proposed rule would have required. As a consequence, the NRC revised the maximum duration of the exclusion period to 60 days (4×15) to encompass four complete periods of time.

Section 26.205(d)(4) requires licensees to ensure that individuals performing the duties specified in § 26.4(a)(1) through (a)(3) have at least 3 days off in each successive (i.e., non-rolling) 15-day period during the first 60 days of a unit outage and that individuals specified in § 26.4(a)(4) (maintenance personnel) have at least 1 day off in any 7-day period. This requirement replaces, in part, proposed § 26.199(d)(2)(ii), which would have required that these individuals have a minimum 24-hour break in any 7-day period. This requirement also replaces, in part, proposed § 26.199(d)(2)(iii), which would have required that these individuals have a minimum 48-hour break in any 14-day period, except during the first 14 days of an outage. The NRC is replacing these requirements with § 26.205(d)(4) in response to public comment (see the discussion of public comment with respect to § 26.205(d)(2)(i) and (d)(3)). The combined effect of § 26.199(d)(2)(ii) and (d)(2)(iii) of the proposed rule would have been to require 2 days off in the first 2 weeks of the outage and 3 days off in each subsequent 14-day period. Section 26.205(d)(4) establishes a requirement that is similar to, though more flexible and less complex than, the requirements it replaces.

The NRC also received stakeholder comments on the proposed rule which recommended that the NRC eliminate the minimum day off requirements for outage periods. In additions, the NRC received comments asserting that attracting qualified supplemental workers is challenging in the entire commercial reactor industry, that for many supplemental workers the availability of overtime is a key factor in where they decide to work, and that the industry has already experienced cases where individuals have left during an outage to go to a job that offered more overtime. The final rule partially addresses these comments by requiring that maintenance personnel have at least 1 day off in any 7-day period instead of the requirement for at least 3 days off in each successive (i.e., nonrolling) 15-day period. The NRC notes that critical maintenance tasks performed by individuals within the scope of § 26.4(a)(4) are subject to quality assurance and corrective action programs and that these programs are subject to NRC inspection. In addition, post-maintenance testing provides additional assurances of equipment performance.

As described with respect to § 26.205(d)(2), the NRC received many stakeholder comments on the proposed rule regarding the 48-hour break requirement. Several commenters asserted that, for workers on the night shift, having 1 day off provides an additional rest period and allows the worker to maintain a consistent pattern of work and sleep habits, which reduces the risk of accidents on the job. However, two days off may interfere with his or her sleep cycle and, as a result, the individual would have to readjust to the night shift after the 2-day break. The NRC acknowledges that these concerns may be particularly applicable during outage periods when it is common for licensees to schedule many individuals on a fixed night shift for the duration of an outage. The final rule addresses this concern by providing licensees increased flexibility in the distribution of the days off. As a consequence, licensees may schedule single days off to limit circadian disruption for workers on the night shift. Alternatively, they may provide the days off in consolidated blocks to provide extended breaks of 2 or more consecutive unrestricted sleep periods which are important to reducing cumulative fatigue.

The objective of the requirement in § 26.205(d)(4) is to ensure that individuals performing the duties described in § 26.4(a)(1) through (a)(4) have sufficient periodic long-duration breaks to prevent cumulative fatigue from degrading their ability to safely and competently perform their duties. The minimum day off requirement in § 26.205(d)(4) serves the same general function as the minimum day off requirements of § 26.205(d)(3). However, whereas § 26.205(d)(3) is principally applicable to extended periods while a unit is operating, § 26.205(d)(4) is applicable to periods of limited duration during unit outages. As a consequence, the specific limits and details of these requirements differ to accommodate these different plant conditions and periods of applicability.

In its development of § 26.205(d)(4), the NRC considered industry work scheduling practices during outages and the applicability of other proposed requirements during these periods. In SECY–01–0113 and NRC staff reviews of records of deviations from technical specification work hour controls from 2003 and 2004, the most common deviation identified was to permit individuals to work more than 72 hours in 7 days, frequently by working more than six consecutive 12-hour days. These reviews also indicated that this practice was used extensively at a number of sites. Industry comments at the public meetings described in the preamble to the proposed rule also confirmed the NRC observation that some licensees were scheduling outages with several weeks of 12-hour shifts with no scheduled days off. The NRC also considered industry comments submitted during the public comment period that asserted 1 day off in 7 is adequate for maintaining worker performance and that offering schedules that included these levels of overtime is necessary to attract supplemental outage workers. The minimum day off requirement of § 26.205(d)(4) is the one requirement of this final rule that prevents individuals who perform the duties listed in § 26.4(a)(1) through (a)(3) from working 72 hours per week for the entire first 8 weeks of a unit outage. In addition, the minimum day off requirement of § 26.205(d)(4) is the one requirement of this final rule that prevents individuals from performing the duties listed in § 26.4(a)(4) with no scheduled days off for the entire first 8 weeks of a unit outage. In this regard, the NRC notes that the duties listed in § 26.4(a)(1) through (a)(4) are those the NRC considers most important for fatigue management because of their relationship to the protection of public health and safety. In particular, these duties include operating and maintaining systems and components that a risk-informed process has shown to be significant to public health and safety.

As described with respect to § 26.205(d)(2)(ii), break periods longer than the minimum 10 hours required by § 26.205(d)(2)(i) are necessary on a regular basis to maintain reliable human

performance. A 10-hour break provides an adequate opportunity to sleep (approximately 7 hours for most individuals) only if one assumes the minimal times for meals, hygiene, and commuting, as described with respect to § 26.205(d)(2)(i), with no other daily living obligations. During unit outages, work schedules of 12-hour shifts and limited days off are common. As the ratio of 12-hour work shifts to days off increases, the pressure on individuals to restrict sleep time in order to meet daily living obligations that cannot be deferred increases. Without periodic days off, individuals must either forego activities that can be important to general mental and physical fitness (e.g., family interactions, exercise, recreation, doctor appointments) or sacrifice sleep and increase their sleep debt (Presser, 2000). Such sleep restriction will compound the effect of the long (12-hour) work shift resulting in impairment on the job.

The NRC also considered ways to prevent and mitigate cumulative fatigue in roving outage crews and other transient workers who predominantly work during plant outages in the development of this requirement. During the stakeholder meetings discussed in the preamble to the proposed rule, many stakeholders expressed a strong desire for transient workers to be subject to work hour controls. One stakeholder observed that assuring transient outage workers are not impaired by fatigue is particularly important because these individuals typically do not have the extensive training in methods for maintaining reliable human performance that is provided to permanent plant personnel.

During development of the proposed rule, the NRC staff considered establishing long-term work hour controls. However, collective work hour controls would not be effective because these individuals typically work during outages when the collective work hour controls would not be applicable or practical. The NRC staff then considered individual long-term (quarterly and yearly) work hour limits for transient workers. However, industry representatives strongly objected because these transient workers move from one licensee to another, and the burden of obtaining work hour information for all of these individuals from other licensees would be extremely high. In part because of the practical difficulties of controlling long-term work hours for transient individuals, the NRC developed the 48-hour break requirement as a replacement for long-term work hour limits for transient individuals. As noted with respect to § 26.205(d)(4), the minimum day off requirement of this section replaces, in part, the 48-hour break requirement of the proposed rule, and is the single requirement that prevents individuals responsible for performing risk-significant duties from working extended periods of 72-hour work weeks or extended periods with no days off.

The NRC further considered that some transient personnel include licensee employees and long-term C/Vs. Many of these individuals may move from site to site within a fleet during plant outage periods. For large fleets, some individuals may work much of the spring and fall outage seasons under only the work hour limits and break requirements applicable to unit outage periods. For these individuals, the minimum day off requirement of § 26.205(d)(4) is the single requirement that will prevent such individuals from performing risk-significant duties while working with no days off for substantial portions of a year.

In developing the minimum day off requirements for the final rule, the NRC considered scheduling practices during outages and determined that it could not practically extend the same approach used in § 26.205(d)(3) because the requirements of this section are based on shift cycles which provide a defined period to which the average day off requirement will apply. The length of outages and increased threat conditions is variable and therefore does not provide a consistent averaging period. The NRC further considered establishing a requirement of a minimum of 3 days off in any 14-day period for individuals specified in § 26.4(a)(1) through (a)(3) because that would have been similar to the requirements it would have replaced. However, the NRC ultimately determined that 3 days off within a 15-day period provides licensees scheduling flexibility (e.g., establishing a schedule comprising a repeating series of 4 work shifts followed by 1 day off). As a consequence, the rule allows licensees the option to establish a schedule that is predictable, a characteristic desired by schedulers and workers, and that both mitigates and prevents cumulative fatigue by including periodic rest breaks.

During the development of the final rule the NRC also considered a graded approach to the minimum day off requirements for outages. Specifically, the staff considered an option which would have allowed licensees to defer 1 of the 3 required days off in a 15-day block to the subsequent 15-day block (i.e., licensees could provide individuals only 2 days off in a 15-day block but would be required to provide those individuals 4 days off in the subsequent 15-day block). This option would have required fewer days off for outages of less than 15 days and provided additional scheduling flexibility for longer outages. At the March 29, 2006 public stakeholder meeting regarding this rulemaking the staff discussed the potential of a graded approach and solicited stakeholder comment. Only one licensee representative stated that a graded approach may provide useful flexibility. The NRC subsequently considered the increased potential for cumulative fatigue that would result from deferring days off, the increased complexity of the rule and scheduling to meet the requirements, the minimal stakeholder interest in a graded approach, and determined that the option for deferring a required day off to a subsequent 15-day block was not warranted.

Section 26.205(d)(5) requires that during the first 60 days of unit outages, security system outages, and increased threat conditions, licensees control the hours worked by individuals performing the security duties specified in § 26.4(a)(5) in accordance with the requirements in § 26.205(d)(5)(i) and (d)(5)(ii). The effect of this section is to provide a 60-day exception from the minimum day off requirements in 26.205(d)(3) for these plant conditions. After the first 60 days of these periods, these individuals are again subject to the minimum day off requirements of § 26.205(d)(3), except as permitted by § 26.205(d)(6). The purpose of this exception is to allow licensees the flexibility provided by the less stringent day off requirements of § 26.205(d)(5)(i) and (d)(5)(ii) to provide the increased level of security staffing that is required by these unique circumstances. The requirements in § 26.205(d)(5)(i) and (d)(5)(ii) provide the restrictions necessary to prevent and mitigate excessive cumulative fatigue during these periods.

Section 26.205(d)(5)(i) provides an exception from the minimum day off requirements of § 26.205(d)(3) for personnel performing the duties described in § 26.4(a)(5) during unit outages or unplanned security system outage. The requirement limits this exception period to 60 days from the beginning of the outage and requires that individuals performing the security duties identified in § 26.4(a)(5) during this period have a minimum of 4 days off in each non-rolling 15-day period. This requirement replaces the collective work hour limit of 60 work hours per person per week that § 26.199(f)(2)(i) of

the proposed rule would have required for these individuals during the first 8 weeks of a unit outage or a planned security system outage.

Section 26.205(d)(5) permits licensees to meet the minimum day off requirements of § 26.205(d)(5)(i) as an exception to the more stringent minimum day off requirements in § 26.205(d)(3). The rule permits this exception for a limited duration, 60 days to accommodate the short-term demand for increased work hours associated with these outages while limiting cumulative fatigue. Therefore, the requirement provides reasonable assurance that security personnel will remain capable of safely and competently responding to a security incident or an increased security threat condition, should one occur during or shortly after a period of increased work hours.

The basis for limiting the duration of the exception from the requirements of § 26.205(d)(3) during unit outages is described with respect to § 26.205(d)(4). In addition to establishing a minimum day off requirement for personnel performing the security duties identified in § 26.4(a)(5) during the first 60 days of a unit outage, § 26.205(d)(5) establishes minimum day off requirements for these individuals for the first 60 days of a planned security system outage. Planned security system outages are typically of very short duration relative to unit outages and the NRC does not expect that planned security system outages will exceed 60 days. However, the rule establishes the 60-day limit for planned security system outages to simplify implementation of the rule by applying identical exclusion periods for all outages and increased threat conditions. Additionally, the ability of security personnel to perform their duties safely and competently during these outage and increased threat conditions is based on the length of time individuals work additional hours, not on the nature of the site condition.

Section 26.205(d)(5)(i) replaces, in part, the requirements limiting work hours of security personnel established by order EA–03–038 with alternative requirements that will achieve the same objective. Collectively, the requirements in Subpart I more effectively achieve the objectives of the compensatory measures and therefore the NRC intends to revoke order EA–03–038 following implementation of this rule. This requirement limits, with the exception specified in § 26.205(d)(6), the maximum duration of the outage requirements to 60 days instead of the 120-day period order EA–03–038 permits.

Since September 11, 2001, the NRC has received several reports of nuclear security officers found asleep while on duty. In addition, the NRC received numerous allegations from nuclear security officers that certain licensees have required them to work excessive amounts of overtime over long periods as a result of the post-September 11 threat environment. The nuclear security officers questioned their readiness and ability to perform their required job duties because of fatigue and stated that they feared reprisal if they refused to work assigned overtime. The NRC received similar information from newspaper articles and from interactions with public stakeholder groups. For example, the Project on Government Oversight (POGO) issued a report entitled, ''Nuclear Power Plant Security: Voices from Inside the Fences,'' and submitted this report to the NRC staff (ADAMS Accession No. ML031670987). POGO interviewed more than 20 nuclear security officers protecting 24 nuclear reactors (at 13 plants) to obtain material for its report. POGO reported that the security officers who were interviewed said, ''Their plants are heavily relying on increased overtime of the existing guard force * * *. These guards raised serious concerns about the inability to remain alert.'' After reviewing the work hours and FFD concerns of security personnel subsequent to September 11, 2001, the NRC issued Order EA–03–038 to limit the work hours of security personnel and ensure that they remain capable of safely and competently performing their duties. The order requires compensatory measures for limiting work hours to a collective work hour average of 48 hours per person per week during normal operations, as well as limiting work hours to an average of 60 hours per week for planned plant outages and planned security system outages.

Ensuring that work schedules incorporate adequate break periods is an important mitigation strategy for cumulative fatigue. The need for periodic long breaks was discussed with respect to § 26.205(d)(2) and (d)(3). The NRC's initial concept for compensatory measures to prevent fatigue of security personnel from the long work hours of outages included a feature that required a 48-hour break in any 7-day period for periods of increased work hours that exceeded 45 days (ADAMS Accession No. ML030300470). Through stakeholder interactions during development of the order, the NRC concluded that a 60-hour collective work hour limit would be an effective alternative to meet the same objective and would also provide more flexibility. The 60-hour limit of the proposed rule would have ensured that security force personnel who work a 12-hour shift receive, on average, 2 days off in every 7-day period, thereby reducing the potential for cumulative fatigue.

As discussed with respect to § 26.205(d)(3), stakeholder comments on the proposed rule expressed a range of concerns regarding the need for, and effectiveness of, collective work hour controls. As a consequence, the NRC replaced the collective work hour limits of the proposed rule with the minimum day off requirements outlined in § 26.205(d)(3) through (d)(5). More specifically, the requirement for a minimum of 4 days off in each 15-day period of the first 60 days of an outage required in § 26.205(d)(5)(i) establishes a requirement in the final rule that is comparable to the 60-hour collective work hour limit of the proposed rule, while addressing stakeholder comments regarding the importance of addressing worker fatigue on an individual basis. Although § 26.205(d)(5)(i) does not directly limit work hours, the requirement has the effect of limiting individuals to an average work week of 61.6 hours, assuming no work shifts exceed 12 hours. The NRC established the minimum day off requirement in terms of 15-day periods to establish requirements for security personnel in time periods consistent with the minimum day off requirements for other personnel to simplify licensee implementation of the requirements of this section.

For several reasons, control of work hours for security personnel must be more stringent than for other individuals who are subject to the work hour controls. First, security personnel are the only individuals at nuclear powerplants who are entrusted with the authority to apply deadly force. Decisions regarding the use of deadly force are not amenable to many of the work controls (e.g., peer checks, independent verification, post-maintenance testing) that are implemented for other personnel actions at a nuclear plant to ensure correct and reliable performance. Second, unlike most other work groups, security personnel are typically deployed in a configuration in which some members of the security force have very infrequent contact with other members of the security force or with other plant personnel. A lack of social interaction can exacerbate the effects of fatigue on individuals' abilities to remain alert (Horne, 1988). Third, these deployment positions can be fixed posts where very little physical activity is

required, further promoting an atmosphere in which fatigue could transition into sleep. Fourth, many security duties are largely dependent on maintaining vigilance. Vigilance tasks are among the most susceptible to degradation from fatigue (Rosekind, 1997; Monk and Carrier, 2003). Finally, unlike operators, security forces lack automated backup systems that can prevent or mitigate the consequences of an error caused by fatigue.

Consistent with the requirements of the proposed rule, the final rule requirement differs from that in Order EA–03–038 by establishing more stringent work hour requirements for unplanned plant outages than for increased threat conditions. Order EA–03–038 currently does not impose collective work hour limits for unplanned plant outages. As discussed in the preceding paragraph, security duties are particularly susceptible to fatigue. Therefore, the NRC considers that the minimum day off requirement for security personnel should only be waived in cases in which (1) licensees would be unable to sufficiently plan for the increased security demands, and (2) the increased potential for fatigue-induced errors is outweighed by the need for a higher complement of security personnel on shift to maintain the common defense and security. In the case of unplanned plant outages, although licensees would be unable to sufficiently plan for the increased security demands that typically accompany plant outages, licensees can control the demands on the work hours of security personnel by controlling the outage activities (e.g., maintenance) that create the increased demand for security personnel. As a consequence, work hours that may compromise the FFD of security personnel, such as those that would be permitted in the absence of the minimum day off requirements of § 26.205(d)(5)(i), cannot be justified. The economic benefit gained by licensees cannot justify the increased potential for fatigue-induced errors.

Section 26.205(d)(5)(ii) provides an exception from the minimum day off requirements for security personnel for the first 60 days of an unplanned security system outage or an increased threat condition. This requirement replaces proposed § 26.199(f)(2)(iii), which would have provided an exception to the collective work hour limits for security personnel for the first 8 weeks of an unplanned security system outage or an increased threat condition. The exception allowed by § 26.205(d)(5)(ii) is consistent with compensatory measures required by Order EA–03–038. However, Order EA–03–038 provides an exception from the collective work hour limits in the compensatory measures for these conditions for a period of up to 120 days. Section 26.205(d)(5)(ii) establishes a more stringent exception period.

Unplanned security system outages and increased threat conditions require extensive increases in security force labor in terms of compensatory measures. These increases can make it very difficult to maintain work hour controls during these periods, especially because licensees are unable to plan in advance for these circumstances. Although the increased work hours increase the potential for cumulative fatigue, other fatigue management requirements, including the work hours controls in § 26.205(d)(1) and (d)(2), provide reasonable assurance of guard readiness during the exception period. Therefore, the benefit to plant security of ensuring adequate staffing during such unplanned conditions outweighs the potential for excessive worker fatigue.

Staffing to a level necessary to meet the minimum day off requirements of § 26.205(d)(3) during unplanned security system outages or increased threat conditions would not be practical because it would require licensees to maintain security staffing in numbers that would be excessive for the vast majority of circumstances. Limiting periods of extended work hours for security personnel to 60 days aligns the exception period for security personnel with the exception period for other personnel subject to the work hour requirements, simplifying the rule and its implementation. Further, the cost to licensees of the compensatory measures required to address security system outages is significant, and most security systems are modular. Therefore, an unplanned security system outage is unlikely to exceed 60 days. Outages of this duration have been uncommon. Therefore, reducing the exclusion period from 120 days to 60 days is not likely to have a practical impact on licensees.

The Department of Homeland Security has refined its threat system to compartmentalize increases in threat conditions for individual business sectors and regions of the country. In addition, since the inception of the system, the threat level has not been increased for any period that exceeded 6 weeks. An event that would cause NRC-regulated sites to maintain increased protective measures for a period of more than 60 days would likely mean a significant domestic attack had occurred. In this event, § 26.207(c) [Common defense and security] provides a means for extending the proposed 60-day exception period, as discussed with respect to that provision.

Proposed § 26.199(f)(2)(iv) would have clarified the instances in which security personnel would be subject to a collective work hour limit for certain instances in which multiple plant conditions exist. The NRC has not retained this provision for the final rule because § 26.205(d)(ii), in conjunction with the definition of increased threat condition as described in § 26.5, adequately addresses the applicability of the work hour requirements for circumstances in which multiple plant conditions (e.g., a unit outage and increased threat condition) occur simultaneously. Specifically, § 26.205(d)(ii) states that during the first 60 days of an unplanned security system outage or increased threat condition, licensees need not meet the requirements of either § 26.205(d)(3) or (d)(5)(i). As a consequence, should an unplanned security system outage or increased threat condition occur at any time during a unit outage, security personnel subject to the work hour requirements would not be required to meet the minimum day off requirements of § 26.205(d)(3) or (d)(5)(i) during the first 60 days of the unplanned security system outage or increased threat condition.

Proposed § 26.199(f)(2)(iv) would have also clarified the applicability of the collective work hour controls to instances in which a threat level increases and then decreases. In the final rule, the NRC has defined an increased threat condition in § 26.5 as ''an increase in protective measure level, relative to the lowest level applicable to the site during the previous 60 days, as promulgated by an NRC advisory.'' Accordingly, any time a threat level changes, whether by increasing or decreasing, the determination of whether a site is in an increased threat condition, for purposes of applying the work hour requirements of Subpart I, is made by comparing the current threat level with the lowest level applicable to the site during the previous 60 days.

Proposed § 26.199(f)(2)(v) would have clarified the applicability of the collective work hour limits for security personnel during multiple consecutive and concurrent plant conditions. The NRC has not retained this provision for the final rule because the requirements in § 26.205(d)(5) and (d)(7), in conjunction with the definition of increased threat condition as described in § 26.5, adequately define the requirements applicable to multiple

consecutive and concurrent plant conditions. In the case of multiple consecutive increases in threat conditions, § 26.205(d)(ii) would permit a 60-day exception from the minimum day off requirements, with the 60 days beginning with each increase. As described in the preceding paragraph, should the threat level decrease, the determination of which work hour requirements are applicable (i.e., whether the increased threat level exception applies) depends upon a comparison of the current threat level to the lowest level applicable in the previous 60 days.

Proposed § 26.199(f)(2)(vi) would have established requirements controlling the exception period from the collective work hour controls when a threat condition decreases during an unplanned security system outage or increased threat condition. In these circumstances, the proposed rule would have established the beginning of the exception period based upon the date upon which the current threat condition was last entered as a result of a threat condition increase. The NRC has not retained this provision for the final rule because the requirement in § 26.205(d)(5) in conjunction with the definition of increased threat condition as described in § 26.5, adequately define the requirements. For example, if the threat level increases at the beginning of week 1, increases again at the beginning of week 3, and then decreases in week 5 to the level of week 1, the beginning of the maximum 60-day exception period would be the beginning of week 1 because the definition of increased threat condition is based upon an increase from the lowest level of protective measures in the past 60 days. The requirements ensure that the duration of the exception period is no longer than necessary based upon the current threat level, thereby providing licensees with the flexibility to respond to increased threat conditions while minimizing the potential for cumulative fatigue of security personnel. As a consequence, § 26.205(d)(5), in conjunction with the definition of increased threat condition in § 26.5, establishes requirements applicable to changes in threat conditions that are consistent with the work hour controls order EA–03–038 requires.

Section 26.205(d)(6) permits licensees to extend the 60-day exception periods in § 26.205(d)(4) and (d)(5) for each individual in 7-day increments for each non-overlapping 7-day period in which the individual has worked not more than 48 hours during the unit or security system outage or increased threat condition. For example, during weeks 5 and 6 of a 10-week outage, an individual may work 42-hour work weeks because of reduced demand for his or her skills during those weeks of the outage. That individual would then be eligible to work an additional 2 weeks beyond the 60-day exception period under the minimum day off requirements applicable to the first 60 days of an outage. The NRC added this provision to the final rule partly in response to public comment on the proposed rule that the exception for outage periods should be extended to 10 weeks. As described with respect to § 26.205(d)(4), the NRC does not believe it is appropriate to extend the outage exception period to 10 weeks without restriction because of the increased potential for cumulative fatigue when individuals work at the limits established by § 26.205(d)(4) for extended periods of time. However, during public meetings on the proposed rule, stakeholders also commented that during extended outages individuals do not always work an outage schedule for the entire outage but may have periods of reduced activity that provide opportunity for individuals to recover from cumulative fatigue. The break requirements exception allowed by § 26.205(d)(6) acknowledges this circumstance. The provision accommodates longer outages without increasing the risk of worker fatigue by allowing licensees to extend the outage exception, and therefore the reduced requirements applicable to outages, by taking credit for these periods of reduced work hours. As a result, this requirement also provides licensees the flexibility of planning outages longer than the normal 60-day exception period by incorporating periods of reduced work hours appropriate to maintaining worker FFD over an extended duration outage. In addition, this provision also applies to increased threat conditions and provides a mechanism for a limited extension of the reduced requirements applicable to scheduling individuals performing security functions during increased threat conditions.

Proposed § 26.199(f)(3) would have permitted the collective work hours of any job duty group specified in proposed § 26.199(a) to exceed an average of 48 hours per week in one averaging period if all of the conditions specified in § 26.199(f)(3)(i) through (f)(3)(iii) of the proposed rule were met. The criteria in proposed § 26.199(f)(3)(i) through (f)(3)(iii) would have permitted licensees to control work hours to a higher collective work hour limit under certain occasional, short-term exigent circumstances. The NRC has not retained this provision for the final rule because the requirements in § 26.205(d)(3) and (d)(6), and § 26.207 adequately define the requirements applicable to these circumstances.

The objective of proposed § 26.199(f)(3) would have been to establish a regulatory framework that accommodated circumstances beyond the reasonable control of licensees, while ensuring that licensees continue to provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety. The requirements of the final rule provide licensees the flexibility to accommodate these circumstances in a manner that is consistent with reasonable assurance of worker FFD. Section 26.205(d)(3) establishes minimum day off requirements that accommodate variation in workload because it does not require a minimum number of days off each week but requires licensees to ensure that individuals have an average number of days off over the duration of a shift cycle of up to 6 weeks. As a consequence, individuals are able to work up to 72 hours in a week, to the extent that they are still able to meet the minimum days off requirement for the shift cycle. For example, individuals on 12-hour shifts can work 72 hours per week for 2 weeks, and still have enough days off to work an average of 45 hours per week for the remaining 4 weeks of a 6-week cycle. Section 26.205(d)(3) also accommodates circumstances that may require increased work hours for more extended periods of time. Again, as an example, § 26.205(d)(3)(iii) requires an average of 2.5 days off per week for individuals performing the job duties specified in § 26.4(a)(1) through (a)(4). Individuals can meet this requirement while working an average of 54 hours per week. This limit is comparable to the limit that would have been required by § 26.199(f)(3)(ii) of the proposed rule, which would have restricted the exception allowed by § 26.199(f)(3) to a group collective work hour average of not more than 54 hours per person per week. Section 26.205(d)(6) can also accommodate limited unplanned extensions of an outage beyond the 60-day exception period, provided individuals have periods of reduced work hours that qualify for the 7-day extensions. Such circumstances may arise if unexpected complications in an outage task occur that cause the work to be deferred until later in the outage,

leaving the assigned work crew with a reduced period of activity.

The NRC also notes that the work hour limits of Subpart I are only applicable to a limited scope of personnel and therefore not all exigent circumstances would necessarily involve individuals or duties subject to these controls. In addition, should the circumstances require increased work hours by individuals who perform the duties specified in § 26.5(a)(1) through (a)(5), the provisions of § 26.207 address waivers of the work hour requirements when necessary to prevent or mitigate conditions adverse to safety and provide exceptions from the requirements when necessary to ensure common defense and security and allow adequate staffing during declared plant emergencies.

Proposed § 26.199(f)(4) would have prohibited licensees from repeatedly permitting the collective work hours of any job duty group to exceed an average of 48 hours per person per week. The final rule does not retain this requirement because the NRC has deleted collective work hour control requirements from the final rule. As a consequence, a limit on repeatedly exceeding the collective work hour limit is not necessary for the final rule.

Proposed § 26.199(f)(5) would have permitted licensees to exceed any collective work hour limit of proposed § 26.199(f) if the licensee submitted and obtained advance approval of a written request to the NRC that included the information in proposed § 26.199(f)(5)(i) through (f)(5)(iii). The primary objective of this provision was to provide a regulatory framework for addressing unique and infrequent circumstances, such as steam generator replacements or other extended outages, that would be difficult to manage within the collective work hour controls of § 26.199(f) of the proposed rule. As described with respect to § 26.205(d)(6), § 26.205(d)(6) provides a mechanism in the final rule for licensees to establish work hour schedules for extended outages without the need for NRC approval of a written request and therefore allows licensees to directly and more simply address the circumstances that would have otherwise been handled through the process that proposed § 26.199(f)(5) would have required.

Proposed § 26.199(g) [Successive plant outages] would have established requirements for the control of work hours during unit and security system outages that follow a preceding outage by less than 2 weeks. The objective of the proposed requirements would have been to limit the potential for cumulative fatigue that could result from working successive outages in close succession. The final rule does not retain these requirements.

A comment on the proposed rule noted that several companies own and operate reactors at multiple sites and it is common for these companies to develop outage work groups and deploy these work groups to outages in close succession at their sites. Another comment noted that recruiting qualified supplemental workers to support outages is challenging for the entire commercial reactor industry and that for many supplemental workers the availability of overtime is a key factor in where they decide to work. This comment further stated that the industry has already experienced cases where individuals have left during an outage for employment that offered more overtime.

In determining to eliminate the requirements pertaining to successive plant outages the NRC concluded that although reduced work hours between successive outages would reduce the potential for cumulative fatigue, the NRC expects that in many cases transient workers would have days off between outages as they travel between nuclear power plant sites or wait for the beginning of the next outage. As a result, a rule requirement for reduced work hours between successive outages would provide no or limited additional benefit in these circumstances. The NRC also considered the limited applicability of the requirement, i.e., the requirement would have been limited to instances in which individuals worked successive outages for the same licensee. As a result, the requirement would have provided a benefit for only a limited scope of individuals in these circumstances. The NRC also considered the increased challenge licensees would face in retaining crews of supplemental workers between outages if these workers were required to take a full 2 weeks off between outages. The NRC further considered that licensees could have alternatively complied with the requirement by employing supplemental workers for a 2 week period at the conclusion of an initial outage or the beginning of a successive outage at the levels applicable to an operating plant. The NRC acknowledges that such a practice would likely extend outages and the reduced work hours could cause some individuals to seek alternative employment. In addition, the NRC considered the potential for the successive outage requirements to adversely affect outage schedules. Specifically, if a planned outage must be extended due to unforeseen complications, the schedule for subsequent outages could be affected if the outage extension affects the ability of individuals to have 2 weeks of reduced work hours before the subsequent outage.

Given the limited scope of individuals that would benefit from the requirements in proposed § 26.199(g) and the potential for substantial adverse impacts on licensee's ability to plan and conduct outages, the NRC has not retained these requirements in the final rule. However, the NRC notes that the final rule includes other provisions that will reduce the potential for cumulative fatigue from successive outages, including more stringent work hour controls, requirements for a process through which individuals may self-declare if they believe they are not fit for duty because of fatigue, and requirements for training in fatigue management.

Section 26.205(e) [Reviews] has been added to require licensees to periodically self-assess their performance with respect to controlling the work hours of those individuals who perform the job duties specified in proposed § 26.4(a). This section replaces with substantive changes the requirements in § 26.199(j) of the proposed rule. The NRC revised the review requirements to eliminate reviews related to the collective work hour limits that were deleted from the final rule and to add a review requirement for the implementation of the requirements in § 26.205(d)(3).

Work hour controls in proposed § 26.205(d) would provide licensees with substantial flexibility in controlling work hours. Accordingly, periodic self-assessments are needed for the licensee to maintain reasonable assurance that they are implementing the specific work hour control provisions of § 26.205(d) consistent with the general performance objective in § 26.23(e). In addition, it is necessary for the self-assessments to be scheduled in a manner that ensures corrective action, if necessary.

Outages and increased threat conditions increase the risk of human error as a result of higher workload, the performance of more complex and infrequent tasks, and the pressure to meet schedular goals. Therefore, it is particularly important to include those periods of time in any assessment of the effectiveness of a licensee's work hour controls. Accordingly, licensees are required to conduct a review once per calendar year. If any plant or security system outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee shall include in the review an

evaluation of the control of work hours during the outages or increased threat conditions. Licensees shall complete the review within 30 days of the end of the review period.

Section 26.205(e)(1) requires licensees to review the actual work hours and performance of individuals who are subject to this section for consistency with the requirements of § 26.205(c), so that licensees can determine if they are scheduling individuals with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts. This review is consistent with the performance-based approach in § 26.205(c).

Section 26.205(e)(1)(i) requires the licensees to assess individuals whose actual hours worked during the review period exceeded an average of 54 hours per week in any shift cycle while the individuals' work hours are subject to the requirements of § 26.205(d)(3). Individuals that average more than 54 hours over a shift cycle have a substantial number of extended work days, or have received minimal days off, or both. Although the objective of the minimum day off requirements of § 26.205(d)(3) is a maximum average work week of 48 hours, the requirements do not prevent individuals from exceeding an average of 54 hours per week. The requirement is necessary to ensure that licensees fully evaluate the work hours and performance of these individuals. Several studies have indicated a tendency for individuals to underestimate their levels of fatigue (Wylie, et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988). This tendency may cause an individual to fail to recognize that his or her ability to perform is degraded. The final rule requires licensees to independently evaluate the performance of these individuals to determine whether their abilities to safely and competently perform their duties had actually been compromised.

Section 26.205(e)(1)(ii) requires that licensee assessments include individuals who were granted more than one waiver during the review period. This provision requires licensees to assess the work hours and performance of these individuals to ensure that licensees adequately evaluate whether an individual's abilities to safely and competently perform their duties had actually been compromised while working under a waiver. This requirement is necessary to ensure that licensees' use of waivers did not result in degraded worker fitness-for-duty.

Section 26.205(e)(1)(iii) requires that the licensee assessments include individuals who were assessed for fatigue in accordance with § 26.211 during the review period. This section requires licensees to evaluate whether these individuals' abilities to safely and competently perform their duties had actually been compromised. An individual who has been assessed for fatigue may be working above his or her tolerance for overtime, and it would be necessary for licensees to fully evaluate the individual's overall performance. The requirement is necessary to ensure that licensee fatigue assessments are consistent with worker performance and are providing an effective basis for licensee fatigue management decisions.

Section 26.205(e)(2) requires licensees to review each individual's hours worked and the waivers under which work was performed to assess staffing adequacy for all of the jobs that are subject to the work hour controls of § 26.205. The minimum day off requirements of § 26.205(d)(3) through (d)(5) provide assurance that licensees are managing cumulative fatigue at a gross level, and an indication of whether staffing is adequate to support the objectives of the rule. However, there is a potential that individuals with specialized skills may work a disproportionate number of hours and, consequently, may be more susceptible to fatigue than others. Accordingly, § 26.205(e)(2) requires licensees to review work hours and waivers of the work hour controls to provide assurance that fatigue is properly managed for all jobs.

Section 26.205(e)(3) requires licensees to document the methods used to conduct their reviews and the results of the reviews. The NRC will use the documentation during site inspections as a means of assuring compliance with the regulations. The methods and results of the reviews are indicative of a licensee's performance in managing the fatigue of its workers who are subject to the requirements of this section. Irregularities in the review process may indicate a programmatic weakness that might trigger further inspection activities. The NRC considers the additional recordkeeping burden for documenting this information to be outweighed by the NRC's need to ensure that licensees are complying with the proposed requirements of this section and maintaining effective fatigue management programs.

Section 26.205(e)(4) requires licensees to record, trend, and correct, under the licensee's corrective action program, any problems identified in maintaining control of work hours consistent with the specific requirements and performance objectives of Part 26. Accordingly, licensees are required to maintain the documentation that is necessary for NRC reviews of licensees' compliance with the work hour controls within the licensees' existing corrective action programs. The requirement is in keeping with the existing requirements in 10 CFR Part 50 Appendix B, Criterion XVII, ''Quality Assurance Records,'' and Criterion XVI, ''Corrective Action.'' The NRC will use the documentation during site inspections as a means of assuring compliance with the regulations. The corrective actions and trending would be indicative of a licensee's performance in managing the fatigue of its workers who are subject to the requirements of this part. Irregularities in the corrective action process may indicate a programmatic weakness that might trigger further inspection activities. The NRC considers the additional recordkeeping burden for documenting this information under the existing corrective action program to be outweighed by the NRC's need to ensure that licensees are complying with the requirements and maintaining effective fatigue management programs.

Section 26.207 Waivers and Exceptions

Section 26.207 permits licensees to authorize waivers from the work hour requirements in § 26.205(d)(1) through (d)(5)(i) for conditions that meet the two criteria specified in this section. Section 26.207 contains the revised requirements in proposed § 26.199(d)(3) and 26.199(h) and (i) of the proposed rule. The final rule consolidates these requirements into a single section to improve the organization of Subpart I. Although the provisions are renumbered, the NRC made only limited changes to the requirements for the final rule.

Section 26.207(a) permits licensees to grant a waiver of the work hour controls in § 26.205(d)(1) through (d)(5)(i). Exceeding the individual work hour limits is justified for limited circumstances in which compliance with the work hour requirements could have immediate adverse consequences for the protection of public health and safety or the common defense and security. Limited use of waivers is also consistent with the Commission's position stated in the NRC's Policy on Worker Fatigue. However, as specified in § 26.207(a)(2), which contains the requirements in proposed § 26.199(d)(3)(ii), the NRC expects a licensee to grant waivers only to address circumstances that it cannot reasonably control.

Section 26.207(a)(1)(i) requires an operations shift manager to determine that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager to determine that the waiver is necessary to maintain site security, or a site senior-level manager with requisite signature authority to make either determination. This section establishes one of two criteria in the final rule for granting a waiver from the individual work hours requirements. This section replaces proposed § 26.199(d)(3)(i)(A), with limited editorial revisions.

The NRC's Policy on Worker Fatigue recognized that ''very unusual circumstances may arise requiring deviation from the above [work hour] guidelines.'' In SECY–01–0113, the NRC noted that the frequency of guideline deviations at a substantial proportion of sites appeared to be inconsistent with the intent of the policy and that some licensees abused the authority to grant deviations from the work hour guidelines. Section 26.207(a)(1)(i) more clearly articulates the NRC's expectations with respect to exceeding the work hour limits; licensees must limit the granting of waivers from the work hour limits to circumstances in which such a waiver is necessary to prevent or mitigate a condition adverse to safety or to maintain the security of the plant. The criterion in the final rule limits waivers to conditions that are infrequent while still permitting waivers that are necessary for safety or security. For example, § 26.207(a)(1)(i) permits a licensee to grant a waiver from a work hour requirement if necessary to prevent a condition adverse to safety, if compliance with the work hour requirement will cause the licensee to violate other NRC requirements, such as the minimum onsite staffing requirements in 10 CFR 50.54(m), or if a delay in the recovery of failed plant equipment that is necessary for maintaining plant safety will occur. Similarly, the NRC considers it appropriate to grant a waiver from the work hour requirements if necessary to prevent a condition adverse to safety or if compliance with the work hour requirements would cause a forced reactor shutdown, power reduction, or other similar action, as a result of exceeding a time limit for a technical specification limiting condition for operation (LCO). LCOs require nuclear power plant licensees to take certain actions to maintain the plant in a safe condition under various conditions, including malfunctions of key safety systems.

The criterion for granting waivers in § 26.207(a)(1)(i) was the subject of considerable stakeholder comment and discussion during the public meetings described in the preamble to the proposed rule. Industry representatives stated that the criterion is overly restrictive because it would prohibit the granting of waivers for conditions that could be cost beneficial to the licensee without a substantive decrease in safety. However, the potential for worker fatigue in conditions that require a waiver is substantial (Baker, et al., 1994; Dawson and Reid, 1997; Stephens, 1995; Strohl, 1999). Therefore, the NRC does not believe that licensees can reasonably justify the performance of risk-significant functions by individuals who have worked hours in excess of the limits on the basis that granting the waiver will not have an adverse impact on safety or security. The preamble to the proposed rule details the NRC's decision not to incorporate industry's comment on this provision.

Section 26.207(a)(1)(i) further requires that an operations shift manager or a senior-level site manager with requisite signature authority must make the determination that a waiver is necessary to mitigate or prevent a condition adverse to safety. Similarly, the final rule requires that a security shift manager, or a senior-level site manager with requisite signature authority, must make the determination that a waiver is necessary to maintain the security of the facility. Operations shift managers and security shift managers have the requisite knowledge and qualifications to make the respective safety or security determinations and making such determinations is consistent with the scope of duties currently performed by individuals in these positions. The NRC considered industry stakeholder comments during the public meetings described in the preamble to the proposed rule, expressing concern that limiting the authority to approve waivers to operations shift managers and security shift managers could contribute to overburdening individuals in these positions and prevent distributing the administrative burden of granting a waiver to other qualified individuals. The NRC also considered other stakeholder comments concerning the need to ensure that the individuals making these determinations are not unduly influenced by schedule pressures. The NRC noted that some licensees had delegated the authority to authorize deviations to organizational levels that appeared to be inconsistent with the guidelines in the NRC's Policy on Worker Fatigue, which recommend that the plant manager or plant manager designee authorize deviations from the guidelines. Accordingly, § 26.207(a)(1)(i) permits senior site managers with the signature authority of operations shift supervisors to make the safety determinations that are required to grant waivers and senior site managers with the signature authority of security shift supervisors to make the security determinations required to grant waivers.

Section 26.207(a)(1)(ii) establishes the second of two criteria for granting a waiver from the individual work hour controls of § 26.205(d)(1) through (d)(5)(i). This section contains, with revision, the requirements in § 26.199(d)(3)(i)(B) of the proposed rule. Section 26.207(a)(1)(ii) requires that a supervisor, who is qualified to direct the work to be performed by the individual to whom the waiver will be granted and is trained in accordance with the requirements of §§ 26.29 [Training] and 26.203(c) [Training and examinations], must assess the individual face to face and be reasonably sure that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver is sought. These determinations require knowledge of the specific skills that are necessary to perform the work and the conditions under which the work will be performed in order to assess the potential for fatigue to adversely affect the ability of an individual to safely and competently perform the work. This knowledge is generally limited to individuals who are qualified to direct the work. The training required by §§ 26.29 and 26.203(c) provides the KAs that are essential for a supervisor to make valid assessments in this regard. Among other FFD topics, the training addresses the contributors to worker fatigue and decreased alertness in the workplace, the potential adverse effects of fatigue on job performance, and the effective use of fatigue countermeasures. Accordingly, the training is necessary for individuals to perform these assessments.

The NRC revised the proposed rule to account for the situation in which no supervisor qualified to direct the work is on site. To address this circumstance, § 26.207(a)(1)(ii) of the final rule states that a supervisor who is qualified to provide oversight of the work to be performed by the individual can make the assessment if he or she is trained in accordance with the requirements of §§ 26.29 and 26.203(c). Although this individual may be less familiar with the details of how the work is to be performed, the exception prevents the substantial burden of a licensee requiring a supervisor who is qualified

to direct the work to report to the site to perform the assessment, as well as preventing the potential fatigue of the supervisor if called in during the night.

Section 26.207(a)(1)(ii) further requires that supervisors must perform the assessment face to face with the individual to which the waiver will apply. This requirement ensures that the supervisor who is performing the assessment has the opportunity to observe the individual's appearance and behavior and note any indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech). The supervisor can also interact with the individual to assess his or her ability to continue to safely and competently perform his or her duties during the period for which the waiver will be granted.

Section 26.207(a)(1)(ii) also requires that the supervisory assessment must address, at a minimum, the potential for acute and cumulative fatigue, considering the individual's work history for at least the past 14 days, and the potential for circadian degradations in alertness and performance, considering the time of day for which the waiver will be granted. The potential for acute fatigue can be practically assessed by estimating the total number of continuous hours that the individual will have worked by the end of the work period for which the waiver is being considered. The potential for cumulative fatigue can be practically assessed by reviewing the individual's work schedule during the past 14 days to determine whether (1) the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods, (2) the available sleep periods occurred during the night or at other times when sleep quality may be degraded, and (3) the potential exists for transitions between shifts (e.g., from days to nights) to have interfered with the individual's ability to obtain adequate rest. The potential for circadian degradations in alertness and performance can be practically assessed by considering the time of day or night during which the work would be performed, as well as the times of day of the individual's recent shift schedules. Section 26.207(a)(1)(ii) in effect requires supervisors to address the three work schedule factors (i.e., shift timing, shift duration, and speed of rotation) that are generally considered to be the largest determinants of worker fatigue (Akerstedt, 2004; McCallum, et al., 2003; Mallis, et al., 2002; Folkard and Monk, 1980; Rosa, 1995; Rosa, et al., 1996). In determining the scope of the assessment, the NRC also considered the need for licensees to be able to focus the assessment on information that is readily available and could be verified.

Section 26.207(a)(1)(ii) further requires that the supervisory assessment for granting a waiver address the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions and whether it is necessary to establish controls and conditions under which the individual is permitted to perform work. This requirement is consistent with the NRC's Policy on Worker Fatigue, which states that ''the paramount consideration in such authorizations shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely.'' However, § 26.207(a)(1)(ii) requires the supervisor to identify any risk-significant functions that may be compromised by worker fatigue, thereby focusing the assessment on worker activities that have the greatest impact on the protection of the public, considering the types of skills and abilities that are most sensitive to fatigue-related degradations.

Section 26.207(a)(1)(ii) also requires the supervisor to identify any additional controls and conditions that he or she considers necessary to grant the individual a waiver from a work hour control. For example, applicable controls and conditions may include, but are not limited to (1) peer review and approval of assigned job tasks, (2) assignment of job tasks that are non-repetitive in nature, (3) assignment of job tasks that allow the individual to be physically active, and (4) provisions for additional rest breaks. The requirement to consider establishing controls and conditions is necessary to ensure that licensees take steps to mitigate fatigue from an extended work period and reduce the likelihood of fatigue-related errors adversely affecting public health and safety or the common defense and security.

Section 26.207(a)(2) requires licensees, to the extent practical, to grant waivers only in circumstances that could not have been reasonably controlled. This section contains the requirement presented in § 26.199(d)(3)(ii) of the proposed rule. This requirement is necessary because conditions for meeting the waiver criteria that are specified in § 26.207(a)(1) could routinely result from inadequate staffing or work planning. Licensees have authorized deviations from their technical specification limits on work hours for such reasons in the past. However, because of the significant adverse effects of worker fatigue, as detailed in Section IV.D, waivers should be used infrequently and only when necessary to protect the public. Licensees should take all reasonable care to ensure the use of waivers is minimized. Therefore, § 26.207(a)(2) prohibits the use of waivers in lieu of adequate staffing or proper work planning, for example, but would permit the use of waivers for circumstances that the licensee could not have reasonably controlled, which may include, but are not limited to, equipment failures or a sudden increase in the personnel attrition rate.

Section 26.207(a)(3) requires that the face-to-face supervisory assessment required by § 26.207(a)(1)(ii) be performed sufficiently close in time to the period during which the individual will be performing work under the waiver to ensure that the assessment will provide a valid indication of the potential for worker fatigue during the extended work period. This section contains the requirements presented in § 26.199(d)(3)(iii) of the proposed rule. This requirement is needed because worker alertness and the ability to perform can change markedly over several hours (Baker, et al., 1990; Dawson and Reid, 1997; Frobert, 1997; Folkard and Monk, 1980; Rosa, 1995). These changes can be particularly dramatic if fatigue from sustained wakefulness coincides with circadian periods of decreased alertness (Baker, et al., 1990; Gander, et al., 1998; Rosekind, 1997; Folkard and Tucker, 2003; Carrier and Monk, 2000). Therefore, the final rule requires licensees to conduct supervisory assessments within a time period that provides reasonable assurance that the individual's condition will not substantively change before work is performed under the waiver.

Section 26.207(a)(3) also establishes a period of 4 hours before the individual begins working under the waiver as the period within which the supervisory assessment must be performed. In establishing a maximum time period the NRC considered several factors. Conducting the assessment as close in time as practical to the period during which the individual will perform work under the waiver will provide the greatest assurance of a valid assessment. However, conducting the assessment immediately before the individual will begin performing work under the waiver could, in some circumstances, cause the timing of assessments to conflict with the conduct of shift turnovers and other practical administrative and operational constraints. Additionally, assessments for granting waivers from the longer term individual limits (e.g., the maximum number of work hours in 7

days) would be less sensitive to the specific timing of the assessment. However, certain licensees have periodically authorized blanket deviations from technical specification work hour limits days and weeks in advance of the actual performance of the work. A maximum limit of 4 hours would address the need for an enforceable requirement that would provide reasonable assurance of valid assessments and would take into account the relevant technical and practical considerations. An added benefit of this requirement is that it would prevent the simultaneous granting of blanket waivers for large groups of individuals that do not take into account each individual's level of fatigue.

Section 26.207(a)(4) requires licensees to document the bases for granting waivers from the individual work hour controls of § 26.205(d). This section contains the requirement presented in § 26.199(d)(3)(iv) of the proposed rule. This section requires licensees to document the circumstances that necessitate the waiver, a statement of the scope of work and time period for which the waiver is approved, and the bases for the determinations required by § 26.207(a)(1). This documentation is necessary to support NRC inspections of compliance with requirements for granting waivers from the work hour limits as well as for the licensee self-assessments of the effectiveness of implementing work hour controls that would be required under § 26.205(e).

Section 26.207(b) [Force-on-force tactical exercises] of the final rule relieves licensees from the requirements of § 26.205(d)(3) by allowing them to exclude shifts worked by security personnel during the actual conduct of NRC-evaluated force-on-force tactical exercises when calculating the individual's number of days off. This provision is an addition to the requirements of the proposed rule and is similar to a slightly different exception contained in Order EA–03–08 that applied to group work hour controls. The NRC believes this provision is appropriate in order to provide licensees flexibility in accommodating the NRC-evaluated tactical exercises, which are not under a licensee's full control. For example, it allows licensees to use security personnel on their normally scheduled days off to support the conduct of the exercise without violating the rule. The exception in Order EA–03–08 also applied to other force-on-force tactical exercises (i.e., any not evaluated by the NRC), but the NRC believes this is not an appropriate exception for the minimum days off requirement because these exercises can be fully planned and scheduled by licensees in advance in a manner that complies with the requirements. Nevertheless, the more limited exception should provide adequate flexibility to licensees given that (1) the final rule removes all restrictions on group work hour controls for security personnel, and (2) the exception applies to all security personnel working during affected shifts (including staff that do not participate in the exercise) even though the minimum days off requirement applies to security personnel on an individual basis. In contrast, the group work hour controls applied to security personnel collectively. During the limited exception period for these triennial (every 3 years) NRC-evaluated exercises, the requirements in § 26.205(d)(1) and (d)(2) provide reasonable assurance that fatigue does not impair the ability of these individuals to safely and competently perform their duties.

Section 26.207(c) [Common defense and security] provides a licensee relief from the work hour control requirements of § 26.205(d) upon written notification from the NRC, for the purpose of assuring the common defense and security for a period the NRC defines. This section contains the requirements presented in § 26.199(h) of the proposed rule. The exception granted by this section provides necessary relief from the requirements of the work hour controls in cases of emergencies that are not otherwise covered in this section, including war, in which the increased risk from fatigue-induced errors would be outweighed by the need to maintain the common defense and security. This section also indicates that the NRC would provide such relief in writing.

Section 26.207(d) [Plant emergencies] adds the potential to temporarily waive the requirements of § 26.205(c) and (d) during declared emergencies, as defined in the licensee's emergency plan. This section contains the requirements presented in § 26.199(i) of the proposed rule. Plant emergencies are extraordinary circumstances that may be most effectively addressed through staff augmentation that can only be practically achieved through the use of work hours in excess of the limits of § 26.205(c) and (d). The objective of the temporary exemption is to ensure that the control of work hours and management of worker fatigue do not impede a licensee's ability to use whatever staff resources may be necessary to respond to a plant emergency and ensure that the plant reaches and maintains a safe and secure status. At the conclusion of the declared emergency, the rule would require licensees to again comply with the work hour controls.

Section 26.209 Self-Declarations

Section 26.209(a) retains, with limited editorial changes, the requirements presented in § 26.199(e) of the proposed rule. Section 26.209(a) requires licensees to take immediate action in response to a self-declaration (as discussed with respect to § 26.203(b)(1)) by an individual who is working under, or being considered for, a waiver from the work hour controls in § 26.205(d)(1) through (d)(5)(i). Licensees are required to immediately stop the individual from performing any duties listed in § 26.4(a) unless the individual is required to continue performing those duties under other requirements of 10 CFR Chapter I, such as the minimum control room staffing requirements in 10 CFR 50.54(m). If other requirements make it necessary for the individual to continue working, this section requires the licensee to immediately take action to relieve the individual. For example, the licensee should immediately begin a call-in procedure for another individual to fill the required position and remove the individual from duties as soon as relief becomes available.

The final rule retains this requirement of the proposed rule because correct performance of the duties specified in § 26.4(a) is critical to maintaining public health and safety and the common defense and security. In addition, there is a significantly increased potential for fatigue-related errors when individuals work more than the maximum work hours or obtain less rest than the minimum rest requirements of § 26.205(d)(1) through (d)(5)(i). Individuals working extended hours under a waiver will have a clear and legitimate basis for a self-declaration of being unfit for duty because of fatigue. Further, by self-declaring fatigue, the individual will effectively provide an assessment of his or her ability to continue to safely and competently perform these critical duties. Several studies indicate a tendency for individuals to underestimate their level of fatigue (Wylie et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988). Therefore, it is very likely that an individual who makes a self-declaration of fatigue is potentially more impaired than he or she realizes.

Section 26.209(a) does not require that licensees immediately relieve an individual who self-declares when it is necessary for the individual to continue performing his or her duties under other requirements of 10 CFR Chapter I. The

failure to meet minimum staffing or similar requirements will, in the majority of cases, have a greater potential to adversely affect public health and safety and the common defense and security than permitting a fatigued individual to continue performing his or her duties for a limited period of time. Further, in these circumstances, licensees can implement any fatigue mitigation strategies they deem necessary while the individual remains on duty. Fatigue mitigation measures in these circumstances include, but are not limited to, controls on the type of work that the individual may perform until he or she is relieved (e.g., physical or mental, tedious or stimulating, individual or group, risk-significant or not) and an increased level of supervision (continuous or intermittent) and other oversight (e.g., peer checks, independent verifications, quality assurance reviews, and operability checks).

Section 26.209(b) establishes the requirements for returning an individual to duty following a self-declaration under the conditions described in § 26.209(a). These provisions allow the individual to be reassigned to duties that are not subject to work hour requirements, if the individual is fit for such duties, and requires that the individual have a break of at least 10 hours before returning to duties that are subject to the work hour requirements of Subpart I.

Section 26.209(b)(1) permits licensees to reassign an individual who has made a self-declaration of fatigue to perform other duties than those specified in § 26.4(a). This section contains with limited editorial revisions the requirements presented in § 26.199(e)(1) of the proposed rule. The final rule includes this flexibility because, although an individual may not be fit to perform the activities specified in § 26.4(a), he or she may be able to safely and competently perform other duties. Other duties can include, but are not limited to, tasks that require skills that are less susceptible to degradation from fatigue or do not have the potential to adversely affect public health and safety or the common defense and security if the individual commits fatigue-related errors. The final rule permits licensees to reassign individuals who make a self-declaration of fatigue to other duties, if the results of a fatigue assessment (as required under § 26.211) indicate that he or she is fit to perform them, because permitting the individual to remain at work and continue performing such duties will not have the potential to adversely impact public health and safety or the common defense and security.

Section 26.209(b)(2) requires licensees to permit or require an individual who has made a self-declaration to take a rest break of at least 10 hours before the individual returns to performing any duties listed in § 26.4(a). This section contains, with limited editorial revisions, the requirements presented in § 26.199(e)(2) of the proposed rule. The final rule includes this requirement to ensure that individuals who have self-declared are given an opportunity to sleep before they are permitted to resume performing any duties that have the potential to adversely affect public health and safety or the common defense and security. Sleep is widely considered the only non-pharmacological means of reducing fatigue. As discussed with respect to § 26.205(d)(2)(i), a 10-hour rest break generally allows individuals to obtain the 7–8 hours of sleep that is recommended by most experts for maintaining human performance (National Sleep Foundation, 2001; Dinges et al., 1997; Belenky et al., 2003; Akerstedt, 2003; Monk et al., 2000; Rosekind et al., 1997; Rosa, 1995).

Although one sleep period of 7–8 hours may be insufficient to ensure full recovery from excessive fatigue, nothing in the final rule precludes an individual in this circumstance from making a second self-declaration of fatigue if the individual believes that he or she remains unable to safely and competently perform his or her duties following the rest break. Section I.B of NRC RIS 2002–07 addressed the applicability of the protections of 10 CFR 50.7, [Employee protection] to workers who self-declare that they are unfit for duty as a result of fatigue.

Section 26.211 Fatigue Assessments

Section 26.211 requires licensees to conduct fatigue assessments under several conditions and contains, with limited editorial changes, the requirements presented in proposed § 26.201. The numbering and content of the paragraphs in § 26.211 remain consistent with that of proposed § 26.201. These conditions, specified in § 26.211(a)(1) through (a)(4), include for cause, after a self-declaration, after an event that requires post-event drug and alcohol testing, and as a followup to returning an individual to work after a self-declaration. The assessments are necessary to determine whether individuals who are observed to be in a condition creating a reasonable suspicion of impaired individual alertness or have indicated that they are not fit for duty because of fatigue can, in fact, safely and competently perform their duties. Further, in situations in which a plant event requires drug or alcohol testing as specified in § 26.31(c) [Conditions for testing], this section requires the licensee to conduct a fatigue assessment to determine whether fatigue contributed to the event.

Work hour requirements are necessary, but not sufficient, to manage worker fatigue effectively. Worker fatigue, and its effects on worker alertness and performance, can result from many causes in addition to work hours (e.g., stress, sleep disorders, daily living obligations) (Rosa, 1995; Presser, 2000). Further, individuals differ substantially in their ability to work for extended periods without performance degradation from fatigue (Gander, 1998; Jansen et al., 2003; Van Dongen et al., 2004a; Van Dongen et al., 2004b). The work hour requirements of § 26.205 provide only partial assurance that individuals are not fatigued. Therefore, fatigue assessments are essential.

Appropriately assessing fatigue is also important because workers who are experiencing either acute or cumulative fatigue may not be able to perform their duties safely and competently, as discussed in Section IV.D. A large body of research demonstrates the negative effects of fatigue on individuals' abilities to perform. The literature includes studies comparing the effects of fatigue with those of alcohol intoxication. The effects of both conditions can be expressed in the form of performance decrements. Studies have correlated hours of wakefulness with equivalent blood alcohol concentrations showing that the performance decrements resulting from fatigue are at least as severe as the performance decrements observed when individuals consume the legal limit of alcohol (Dawson and Reid, 1997; Falleti et al., 2003). At the extreme, workers who have acute fatigue show symptoms that are similar to those of intoxication. Speech is less precise, attention may be lacking, and normal body movements and posture may be absent. Therefore, it is just as important for a worker to be assessed to determine if he or she is unduly impaired from fatigue as it is for the worker to be evaluated to determine whether he or she is impaired from consuming alcohol.

The objective of the assessments required by § 26.211(a)(1) through (a)(4) is for licensees to address instances of worker fatigue appropriately, including those that are not prevented by the work hour requirements, regardless of the number of hours that the subject individual has worked or rested. As discussed with respect to § 26.211(c),

these assessments provide the basis for subsequent management actions for fatigue management (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). Therefore, fatigue assessments are important for effective fatigue management because they provide the basis for any short-term corrective actions that may be necessary to ensure that individuals are able to safely and competently perform their duties and any long-term corrective actions that may be necessary to address individual or programmatic issues contributing to recurring instances of fatigue.

Section 26.211(a)(1) specifies that licensees must perform a fatigue assessment, in addition to any other testing that is required under §§ 26.31(c) and 26.77, if a worker is observed to be in a condition of impaired alertness and there is a reasonable suspicion that he or she may not be fit to safely and competently perform his or her duties. The objective of the requirement is to ensure that fatigue is considered, in addition to drugs or alcohol, as a cause for impaired alertness. As noted in SECY–01–0113, approximately 80 percent of all for-cause FFD tests conducted annually yield negative results for drugs and alcohol. A fatigue assessment will help to determine if fatigue was the cause for the perceived impairment when testing does not support drugs or alcohol as the probable cause.

Common indications of impaired alertness include yawning, red eyes, prolonged or excessive blinking, rubbing of the face with the hands, and gross body movements to maintain alertness. Individuals may take substantially longer to complete routine tasks, exhibit difficultly processing written or oral communications, and may become less talkative. At the extreme, workers who are experiencing acute fatigue have symptoms that are similar to those of intoxication. Individuals who are fatigued are more likely to complain of illness, pain, or discomfort. In addition to decreased vigor, fatigued individuals may be more irritable, engage in inappropriate humor, exhibit less conservative decisionmaking, and persevere in using ineffective problem solutions (Horne, 1988; Harrison and Horne, 2000; Dinges et al., 1997; Pilcher and Huffcutt, 1996; Belenky et al., 2003; Monk, 2003).

Section 26.211(a)(1) does not require licensees to conduct a fatigue assessment if indications of impaired individual alertness are observed during an individual's break period. The NRC considered a comment from the IBEW at a September 14, 2004, public meeting expressing concern with for-cause assessments for work performed outside of the protected area (PA). Although whether a worker is inside the PA is not a criterion for being subject to Part 26 requirements, the NRC recognizes that napping is an effective means for reducing worker fatigue. Therefore, § 26.211(a)(1) excludes napping during a break period as a condition for which the final provision requires a for-cause fatigue assessment.

Section 26.211(a)(1) also permits licensees to conduct a fatigue assessment, without drug and alcohol testing, if the observed condition is impaired alertness with no other indication of possible substance abuse. In developing the requirement related to for-cause fatigue assessments, the NRC considered stakeholder comments during the public meetings described in the preamble to the proposed rule. Stakeholders expressed concern that testing for drugs and alcohol, in addition to fatigue, when the only apparent cause of impairment was decreased alertness, would cause stigma, burden, and reluctance to raise FFD concerns that may result in for-cause testing. Accordingly, the requirement permits licensees to assess only fatigue if there are no indications of possible substance abuse.

Section 26.211(a)(1) also permits licensees to conduct drug and alcohol testing, without a fatigue assessment, when the licensee has reason to believe that the observed condition is not caused by fatigue. The NRC considered stakeholder comments at the public meetings described in the preamble to the proposed rule that a requirement to perform a fatigue assessment when the licensee has a reasonable basis for believing that the condition is from causes other than fatigue is an undue burden. In many cases, an observed condition may clearly relate to drugs or alcohol only (such as the smell of alcohol on an individual), and in such cases, a fatigue assessment will have no benefit.

Section 26.211(a)(2) requires licensees to conduct a fatigue assessment if an individual makes a self-declaration that he or she is not fit to safely and competently perform his or her duties because of fatigue, except if the licensee permits or requires the individual to take a rest break of at least 10 hours. Self-declarations provide assurance that instances of worker fatigue, including those that are not prevented by the work hour requirements in § 26.205, are appropriately addressed, regardless of the number of hours the individual has worked or rested. Former § 26.27(b)(1) required that ''impaired workers, or those whose fitness may be questionable, shall be removed from activities within the scope of this part, and may be returned only after determined to be fit to safely and competently perform activities within the scope of this part.'' A statement by an individual to his or her supervisor that he or she is not fit to safely and competently perform his or her duties because of fatigue is an indication that the individual's FFD is questionable, and that an assessment, or a rest break of at least 10 hours, is necessary before the individual may be returned to duty. Therefore, in circumstances in which an individual requests to be relieved of duties because of fatigue and the individual is relieved of duties for at least 10 hours, the final rule does not require the licensee to conduct another fatigue assessment before permitting the individual to return to duty, consistent with current industry practice. Providing a 10-hour break is consistent with § 26.205(d)(2)(i), which establishes required break times between work periods, and is generally considered sufficient to address most acute fatigue conditions.

As discussed with respect to § 26.211(c), a fatigue assessment provides a basis for a licensee to determine whether the individual is able to safely and competently perform his or her duties and what, if any, subsequent management actions for fatigue management are necessary (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). As discussed with respect to § 26.203(b)(1)(ii), licensees are required to establish controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit because of fatigue.

In developing the final requirement for fatigue assessments of individuals who have self-declared, the NRC considered research on subjective assessments of alertness. Self-declarations are generally based on an individual's subjective evaluation of his or her alertness. Studies have indicated that individuals often misjudge their own fatigue, typically by underestimating their level of fatigue and propensity for uncontrolled sleep episodes. This effect is widely recognized by scientists who study sleep and fatigue. Rosekind, et al. (1997) noted that ''An important phenomenon, highly relevant to operational environments, is that there is a discrepancy between subjective reports of sleepiness/alertness and physiological measures. In general, individuals will report higher levels of

alertness than indicated by physiological measures.'' As a consequence, individuals who self-declare will tend to be more impaired than they realize. An exception to this tendency has been noted by Dinges, et al. (1988) who noted that naps can benefit the performance of those experiencing sleep loss, without that benefit being apparent in subjective measures. Therefore, it is not only important to assess self-declarations as an indicator that an individual may not be able to safely and competently perform his or her duties, but also to consider factors in addition to a self-declaration as part of the fatigue assessment.

Section 26.211(a)(2) also specifies that licensees must perform fatigue assessments for self-declarations made to an individual's supervisor. The NRC considered stakeholder comments at public meetings that the final rule should be clear with respect to the behavior that constitutes a self-declaration. For example, stakeholders expressed concern that an individual's off-hand remark to a co-worker that he or she is groggy would be considered a self-declaration under the final rule and, therefore, require a fatigue assessment in conditions that could be satisfactorily addressed through less formal processes. The NRC's objective is not to supplant these normal processes for licensee workforce management, but to ensure that formal declarations of fatigue are appropriately evaluated and addressed. Therefore, the requirement specifies that fatigue assessments must be conducted for self-declarations concerning an individual's ability to ''safely and competently perform his or her duties'' and require that the self-declaration must be made to the individual's supervisor. However, as discussed with respect to § 26.211(a)(1), a fatigue assessment must be performed in response to an observed condition of impaired alertness. If, in the preceding example, the groggy individual remains on duty and is observed to exhibit impaired alertness, a fatigue assessment is required for cause in accordance with § 26.211(a)(1).

Section 26.211(a)(3) specifies that licensees must perform a fatigue assessment after an event that requires drug or alcohol testing, as required in § 26.31(c)(3). Section 26.31(c)(3)(i) through (c)(3)(iii) specifies the events and conditions requiring post-event drug and alcohol testing. A fatigue assessment is also necessary in these circumstances to determine whether worker fatigue contributed to the event and, if so, to identify the need for any corrective actions to prevent similar future events. The assessment will also provide the basis for subsequent management actions for fatigue management, as required by § 26.211(c) (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). Further, the fatigue assessment will provide insights concerning the effectiveness of the licensee's fatigue management program.

Consistent with § 26.31(d)(5)(ii), the requirement specifies that licensees may not delay necessary medical treatment in order to conduct a fatigue assessment, if the event involved physical harm to the individual. The NRC considers the immediate medical needs of the individual to be paramount. In these circumstances, it is reasonable to presume that the individual has been removed from duty and consequently the individual's level of fatigue is irrelevant to the immediate protection of public health and safety or the common defense and security.

Section 26.211(a)(4) requires licensees to perform a followup fatigue assessment if an individual is returned to work after a break of fewer than 10 hours following a fatigue assessment that was performed for cause or in response to a self-declaration. Although sleep periods of less than 8 hours (e.g., naps) can mitigate some effects of fatigue, such sleep periods are typically insufficient to provide complete recovery from fatigue (McCallum, et al., 2003; Dinges, et al., 1997; Totterdell, et al., 1995). As a consequence, the objective of this provision is to ensure that, in circumstances of sleep periods of less than 8 hours (e.g., if a licensee provides an individual an opportunity for a nap rather than a 10-hour break), the short rest break has provided sufficient rest to mitigate the individual's fatigue and that the individual is not still groggy from sleep inertia. Sleep inertia is the grogginess that an individual experiences in the transition from sleep to wakefulness that can temporarily affect an individual's ability to safely and competently perform his or her duties (Bruck and Pisani, 1999; Sallinen, et al., 1998). Further, the assessment ensures that the individual is capable of performing his or her duties safely and competently during the upcoming work period. It also provides the information necessary for the licensee to determine whether any controls or conditions must be implemented during the work period (Priest, 2000; Baker, et al., 1990; Sallinen, 1998; Kruger, 2002).

Section 26.211(b) requires that either a supervisor or a staff member of the FFD program, who is trained in accordance with the requirements of §§ 26.29 and 26.203(c), must conduct any fatigue assessment that is required under § 26.211. Under § 26.211(c), fatigue assessments provide the basis for subsequent actions for fatigue management (e.g., relieving an individual of duties or requiring additional fatigue mitigation actions). In addition, the NRC recognizes that fatigue assessments may be used by some licensees as a basis for imposing sanctions on individuals. Therefore, the authority to perform fatigue assessments should be limited to supervisors or staff members of the FFD program. The training required by §§ 26.29 and 26.203(c) provides the KAs that are essential to a supervisor's or FFD program staff member's ability to make valid assessments in this regard. Among other FFD program topics, the training addresses (1) the contributors to worker fatigue and decreased alertness in the workplace, (2) symptoms of worker fatigue, (3) indications and risk factors for common sleep disorders, and (4) the effective use of fatigue countermeasures. Section 26.29(b) [Policy] also requires individuals to demonstrate successful completion of the training by passing a comprehensive examination that addresses the KAs.

Section 26.211(b) further requires that supervisors or FFD program staff members must perform the fatigue assessment face to face with the subject individual. This requirement ensures that the individual performing the assessment has the opportunity to (1) observe the subject individual's appearance and behavior to note indications of fatigue (e.g., decreased facial tone, rubbing of eyes, slowed speech), (2) interact with the individual to understand the individual's self-assessment of his or her ability to safely and competently perform his or her duties, and (3) understand any factors in addition to the individual's work schedule that may have contributed to fatigue.

Section 26.211(b)(1) prohibits individuals who observe another individual exhibiting indications of impaired alertness from performing the for-cause fatigue assessment of that individual. Without this prohibition, a single supervisor could potentially both observe a worker exhibiting indications of impairment from fatigue and also conduct the for-cause assessment of that worker. In accordance with § 26.211(c), fatigue assessments provide the basis for subsequent management actions for fatigue management. In addition, some licensees may use fatigue assessments as a basis for imposing sanctions on individuals, if, for example, a licensee believes that an individual has been

negligent in maintaining his or her FFD. Therefore, in the case of fatigue assessments that are conducted for cause, an independent third party shall perform the fatigue assessment to provide reasonable assurance of an objective assessment.

Section 26.211(b)(2) prohibits individuals from performing a post-event fatigue assessment in those circumstances specified in § 26.211(b)(2)(i) through (b)(2)(iii), in which a conflict of interest may be present. An individual who has a conflict of interest may not provide an objective assessment of the subject individual's fatigue. This requirement provides assurance of an objective fatigue assessment by prohibiting individuals from performing the assessment who were directly responsible for performing the work or assessing the individuals who were involved in the event.

Section 26.211(b)(2)(i) prohibits individuals from performing a post-event fatigue assessment if they performed or directed the work activities during which the event occurred. A supervisor who performed some of the work activities during which the event occurred may benefit from either positive or negative results from a fatigue assessment of another individual, depending on the circumstances. Similarly, a supervisor who directed the work activities of an individual may avoid an adverse action against himself or herself for the actions of a fatigued individual under his or her supervision if the supervisor erroneously assessed the individual as not fatigued. Therefore, the final rule prohibits these individuals from performing fatigue assessments under the specified conditions.

Section 26.211(b)(2)(ii) prohibits individuals from performing a post-event fatigue assessment if they performed a fatigue assessment of the individuals who were performing or directing the work activities during which the event occurred within 24 hours before the event occurred. These individuals may have a conflict of interest. For example, if an individual previously self-declared fatigue, but a fatigue assessment determined he or she was fit to continue work and an event subsequently occurred that required the subject individual to be assessed again, then the supervisor who performed the first assessment may avoid adverse action for the previous determination by performing the post-event fatigue assessment and erroneously determining that the individual was not fatigued. The final rule prohibits these individuals from performing fatigue assessments under the specified conditions.

Section 26.211(b)(2)(iii) prohibits individuals from performing a post-event fatigue assessment if they evaluated or approved a waiver of the limits specified in § 26.205(d)(1) through (d)(5)(i) for any of the individuals who were performing or directing the work activities during which the event occurred if the event occurred while such individuals were performing work under that waiver. This provision limits the potential for bias in assessments that can result from prior involvement in assessing the individual or responsibility for the work activities associated with the event.

Section 26.211(c) requires that fatigue assessments must provide the information necessary for management decisions and actions in response to the circumstance that initiated the assessment. This information is necessary to determine the subject individual's ability to safely and competently perform his or her duties, as well as any controls or conditions that must be implemented. Section 26.211(c) provides assurance that fatigue assessments include sufficient and appropriate information to support a valid assessment of the individual relative to fatigue and therefore an appropriate basis for management decisions and actions. The criteria listed in § 26.211(c)(1)(i) through (c)(1)(iii) specify the minimum considerations for fatigue assessments.

In determining the scope of the assessments, the NRC considered the need for licensees to be able to focus the assessment on information that is readily available and verifiable. Section 26.211(c) requires the assessment to address the three work schedule factors described in § 26.211(c)(1) through (c)(3), which are generally considered to be the largest determinants of worker fatigue (Akerstedt, 2003, 2004; McCallum, et al., 2003; Mallis, et al., 2002; Folkard and Monk, 1980; Rosa, 1995; Rosa, et al., 1996), as follows.

Section 26.211(c)(1)(i) specifies the first criterion that fatigue assessments will address, acute fatigue. Acute fatigue directly affects an individual's ability to safely and competently perform his or her duties, as discussed in Section IV.D. Licensees will assess the potential for acute fatigue by estimating, at a minimum, the total number of continuous hours the individual has been awake, as well as considering other individual factors or information provided by the individual (such as his or her ability to obtain rest during break periods).

Section 26.211(c)(1)(ii) specifies the second criterion that fatigue assessments will address, cumulative fatigue. Cumulative fatigue also directly affects an individual's ability to safely and competently perform his or her duties, as discussed in Section IV.D. Licensees will assess the potential for cumulative fatigue by reviewing, at a minimum, (1) the individual's work schedule during the past 14 days to assess whether the individual had adequate opportunity to obtain sufficient rest, considering the length and sequencing of break periods, (2) whether the available sleep periods occurred during the night or at other times when sleep quality may be degraded, (3) the potential for transitions between shifts (e.g., from days to nights) to have interfered with the ability of the individual to obtain adequate rest, and (4) other individual factors or information provided by the individual (such as any personal issues that may impact his or her ability to obtain adequate sleep). For cumulative fatigue, the sleep medicine scientific establishment uses the concept of a ''sleep debt,'' which is analogous to a bank account becoming overdrawn, and is a measure of how much an individual's sleep is being cumulatively reduced from his or her everyday sleep need. Many individuals build up a slight sleep debt during the working week, dissipating it by ''catch-up'' sleep on weekends (National Sleep Foundation, 2000; Monk, et al., 2001). Therefore, in evaluating cumulative fatigue, how much of a ''sleep debt'' the worker has accrued in the preceding week needs to be evaluated. Dinges and colleagues (1997) noted a five- to seven-fold increase in the percentage of subjects noting a significant ''illness, infection, pain, discomfort, worry or problem'' in their daily logs as they progressed from baseline through the 7 nights of restricted sleep. In addition to the expected decrements in vigor over the restricted sleep days, subjects' ratings indicated increases in confusion-bewilderment, tension-anxiety, and total mood disturbance.

Symptoms of cumulative fatigue are in some ways similar to those of acute fatigue, but in other ways quite different. The term ''burnout'' has been used to describe workers experiencing cumulative fatigue. Similar to burnout from other sources, burnout from cumulative fatigue is often characterized by a lack of initiative and/or creativity, with the individual just ''going through the motions like a zombie'' without being actively engaged or involved in the job he or she is being asked to

perform. Harrison and Horne (2000) advanced the view that the more creative thought processes are those most likely to be impaired by the individual receiving insufficient amounts of the ''core'' sleep needed for cognitive restitution. They note ''[sleep deprivation] presents particular difficulties for decisionmaking involving the unexpected, innovation, revising plans, competing distraction and effective communication.''

Section 26.211(c)(1)(iii) specifies the third criterion that fatigue assessments will address, circadian variations in alertness and performance. Section IV.D discusses the impact of such variations on an individual's ability to safely and competently perform his or her duties. Licensees can assess the potential for circadian degradations in alertness and performance by considering the time of day or night during which the work was or will be performed and whether the time period coincides with a circadian variation through in the individual's level of alertness.

Section 26.211(c)(2) requires that individuals must provide complete and accurate information that may be required by the licensee to address the factors listed in § 26.20(c)(1) (i.e., acute fatigue, cumulative fatigue, and circadian variations in alertness and performance). Although work hours are an important determinant of worker fatigue, many other factors can affect worker fatigue, not all of which may be readily apparent to a licensee. As a consequence, individuals and licensees share the responsibility for effective assessment and management of fatigue which depends upon complete and accurate communication between the individual and the licensee concerning matters that may influence an individual's level of fatigue. For example, licensees may be able to estimate the total number of continuous hours that an individual has been awake through review of the individual's work schedule and assumptions regarding typical waking times for individuals on that schedule. However, individuals can provide information to better approximate the number of hours they have been continuously awake and facilitate a more accurate assessment of acute fatigue. Additionally, individuals may be able to provide information about their general level of work- and non-work-related activities, as well as opportunities for rest during the period addressed in the fatigue assessment.

Licensees can practically assess the potential for cumulative fatigue by reviewing the individual's work schedule during the past 14 days to identify schedule features that typically influence whether an individual has had adequate opportunity to obtain sufficient rest. However, individuals differ substantially in their ability to adapt to various schedules (Monk and Folkard, 1985). Therefore, individuals can provide general information related to the quality and quantity of sleep that they actually obtained during this period, which substantively improves the licensee's assessment of the potential for cumulative fatigue.

Licensees can practically assess the potential for circadian degradations in alertness and performance by considering the time of day or night during which the work is or will be performed and whether the time period coincides with a circadian trough in alertness for the individual. However, individuals differ in the extent and rate at which they adapt to work during periods in which they would otherwise be asleep (Folkard and Tucker, 2003; Carrier and Monk, 2000) and can provide information (e.g., the timing of their sleep periods) that can better inform a licensee's assessment of the potential for circadian degradations in alertness.

Section 26.211(c)(2) also limits licensees' inquiries to only obtaining information from the subject individual that is necessary to assess the factors listed in § 26.211(c)(1). The fatigue assessment will provide a valid basis for licensee decisions and actions for fatigue management without undue invasion of an individual's privacy. For example, inquiries limited to the amount, quality, and timing of sleep and general activity level of the individual can support an accurate fatigue assessment without the need for an individual to divulge personal details about the reasons for missed sleep or abnormal timings for sleep. Consistent with § 26.37 [Protection of information], licensees are required to keep any information from the individual's self-disclosures confidential.

Section 26.211(d) prohibits licensees from concluding that fatigue had not or will not degrade the individual's ability to safely and competently perform his or her duties solely on the basis that the individual's work hours have not exceeded any of the limits specified in § 26.205(d)(1) or that the individual has had the minimum rest breaks required in § 26.205(d)(2) or the minimum days off required in 26.205(d)(3) through (d)(5). The work hour controls of § 26.205(d)(1) and (d)(2) provide reasonable measures to prevent fatigue resulting from excessive work hours. However, these controls address only work hours and work schedules, and as a consequence, compliance with these controls may not prevent an individual from experiencing fatigue from one or more of the many other factors that can cause fatigue, some of which may not be readily apparent to an employer. Workload and the type of work an individual performs, home stresses, sleep disorders, and differences in an individual's ability to work extended hours or adapt to certain schedules can all substantively affect worker fatigue (Rosa, 1995; Totterdell, et al., 1995; Knauth and Hornberger, 2003). Although the NRC considered the findings from studies of work hours and worker fatigue in developing the work hours requirements of § 26.205(d)(1) through (d)(5), it is neither practical nor possible to establish limits that will prevent fatigue for all individuals. Therefore, the final rule requires licensees to consider factors in addition to work hours and rest breaks when determining whether an individual is fit to safely and competently perform duties.

Section 26.211(e) requires that, following a fatigue assessment, the licensee must decide whether the individual may perform duties without a rest break, and, if so, whether controls and conditions must be established under which the individual may perform those duties. Examples of controls and conditions include, but are not limited to (1) a rest break, (2) peer review and approval of assigned job tasks, (3) assignment of job tasks that are non-repetitive in nature, (4) assignment of job tasks that are simple in nature, and (5) assignment to duties that are not important to the protection of public health and safety or common defense and security. Section 26.211(e) also requires licensees to ensure that any controls and conditions that they determine to be necessary to return an individual to duty will be implemented.

Section 26.211(f) requires that licensees document the results of any fatigue assessments that were performed, the circumstances that necessitated the fatigue assessments, and any controls and conditions that were implemented. The documentation is necessary for NRC inspectors to evaluate the fatigue assessment component of licensees' FFD programs and for the licensee to conduct the reviews required under § 26.205(e). The information that the final rule requires licensees to document will indicate how well a licensee's fatigue mitigation program at a site is performing.

Section 26.211(g) requires that licensees prepare an annual summary for each nuclear power plant site of instances of fatigue assessments that were conducted during the previous

calendar year for any individual identified in § 26.4(a) through (c). The NRC revised the reporting provisions in § 26.197(e)(3) of the proposed rule to eliminate the requirement to include information regarding fatigue assessments in an annual report to the NRC. However, the NRC concluded that the fatigue assessment information that would have been required in the annual report should be documented in an annual summary available on site for NRC inspection. Specifically, § 26.211(g)(1) requires that the summary include the conditions under which each fatigue assessment was conducted (i.e., whether the assessment was conducted for cause, for a self-declaration, after an event, or as a followup, as described in § 26.211(a)(1) through (a)(4)). As a result, the annual reports will indicate the means by which licensees are identifying potential instances of worker impairment from fatigue, including whether these instances are identified through plant events. Section 26.211(g)(2) requires that the annual summaries include a statement for each fatigue assessment of whether or not the assessed individual was working on outage activities at the time of the self-declaration or condition resulting in the fatigue assessment. The annual summaries will therefore show the incidence of fatigue assessments during known periods of increased work hours (i.e., outage periods) relative to other times during the reporting period. Section 26.211(g)(3) requires that the annual summary indicate for each fatigue assessment the category of duties that the individual was performing, if the individual was performing the duties described in § 26.4(a)(1) through (a)(5) at the time of the self-declaration or condition resulting in the fatigue assessment. Accordingly, the annual summaries will show the relative incidence of fatigue assessments for each category of duties subject to the work hour requirements of § 26.205 in addition to the incidence of fatigue assessments for individuals subject to the FFD requirements of Part 26 but not subject to the work hour controls of § 26.205. Section 26.211(g)(4) requires that the annual summaries include for each fatigue assessment the management actions, if any, resulting from each fatigue assessment. The annual summaries will therefore show the incidence of fatigue assessments that warranted management actions, and the nature of those actions.

Subpart J—[Reserved]

As a result of reorganization of the proposed rule, the provisions contained in Subpart J of the proposed rule have been moved to Subpart N of the final rule. This section is currently reserved.

Subpart K—FFD Programs for Construction

Section 26.401 General

Section 26.401(a) provides that a licensee or other entity specified in § 26.3(c) may, at its discretion, establish, implement, and maintain an FFD program that meets the requirements of Subpart K for those individuals who are specified in § 26.4(f). Alternatively, if an FFD program for those individuals that meets the requirements of Subpart K is not established, those individuals must be subject to an FFD program that meets the requirements of Subparts A [Administrative Provisions] through H [Determining Fitness-for-Duty Policy Violations and Determining Fitness], N [Recordkeeping and Reporting Requirements], and O [Inspections, Violations, and Penalties] of Part 26. The NRC recognizes that some new plants will be constructed near existing nuclear power plants, and it may be more efficient for the licensees of those plants to extend their existing FFD programs to cover the individuals specified in § 26.4(f). Therefore, this section of the final rule provides licensees and other entities flexibility to implement either the Subpart K program or a program meeting all of the requirements of Subparts A through H, N, and O. Subparts A through H, N, and O include all elements of the FFD program that apply to operating nuclear power plant licensees, except fatigue management requirements. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs. It also meets Goal 6 to improve clarity in the organization and language of the rule.

This section of the final rule differs in several respects from those sections of the former rule and the proposed rule that established the general applicability requirements for FFD programs during construction. The former rule did not specify the construction activities that would be subject to the FFD program. Consequently, it applied to all workers performing any construction activities, whether or not the SSCs under construction could have an impact on public health and safety or the common defense and security. In addition, it did not provide a choice between applying the FFD program in § 26.2(c) of the former rule or a complete Part 26 program to the new reactor construction workforce (although the former § 26.2(c) could have been interpreted as requiring a complete Part 26 program). The proposed rule also did not specify the individuals to whom the program would apply, thus making it applicable to the entire new reactor construction workforce. The proposed rule also did not provide the option that is included in § 26.401(a) of the final rule. The final rule provides greater flexibility to licensees and other entities than either the former rule or the proposed rule by giving them an option concerning the type of FFD program to apply. It also clarifies and narrows the scope of the group to which Subpart K applies. This is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The former rule in § 26.2(c) imposed FFD requirements on construction permit holders ''with a plant under active construction'' but did not define that term. The proposed rule in § 26.3(e) would have required an FFD program for construction following NRC authorization to construct, and the Part 52 final rule made these changes to the former § 26.2(c). However, the NRC recognizes that there may be a period of time that elapses between the authorization to construct and the commencement of specific construction activities that have the potential to affect public health and safety and the common defense and security when the nuclear power plant begins operations. Therefore, the final rule clarifies that an FFD program for construction is not required until a licensee or other entity begins ''fabricating, erecting, integrating, and testing safety- and security-related SSCs, and the installation of their foundations, including the placement of concrete.''

In addition, the FFD program for construction in the final rule applies only to construction activities that are performed at the location where the new plant will be constructed and operated. The NRC added this phrase to the definition of construction activities in § 26.5 of the final rule to clarify that any fabrication, integration, or testing of safety- or security-related SSCs that is not performed within or near the licensee's or other entity's owner-controlled area in which the new plant will be operated would not be subject to Subpart K. For example, fabricating, integrating, and testing safety- or security-related SSCs at a vendor's or manufacturer's facility that is located in another city, state, or country would not be subject to Subpart K, whereas producing (i.e., ''fabricating'') the concrete to be used for the foundation of the reactor building in a facility located on the site where the nuclear power plant will be constructed and operated would be subject to Subpart K

(although the construction of the cement mixing facility would not). The NRC anticipates that the focus of the Subpart K program on construction activities performed at the location where the new plant will be constructed and operated will lead licensees and other entities to ensure that the program covers all those individuals who perform construction activities within the footprint of the new power reactor (e.g., the exterior boundary of the reactor building once it is completed) as well as the nearby areas where safety- and security-related SSCs will be installed and operated when the plant begins operations.

The NRC considered whether the FFD program for construction should also cover individuals who construct safety- and security-related SSCs at a vendor's or manufacturer's facility that is geographically remote from the location where the new plant will be operated. Because of the modular design of new reactors, many of the safety-related SSCs that will be relied on to protect public health and safety will be fabricated by vendor personnel at remote locations and transported to the site for installation and integration. Similarly, the small, complete nuclear reactors that may be constructed by manufacturing licensees under Part 52 will also be constructed at remote locations and transported to the site for installation and integration. However, because of the complexity of the technical and regulatory issues raised by imposing FFD requirements on these entities, the staff has decided to defer adopting requirements for reactor manufacturing facilities, which were included in the proposed rule, and has declined to impose a Subpart K program on modular fabrication facilities located at a distance from the site where the nuclear power plant will be constructed and operated at this time. Although the Part 52 final rule added manufacturing licensees to the scope of Part 26, this final rule removes holders of manufacturing licenses from regulation under Part 26.

The former rule and the proposed rule also did not limit the applicability of the FFD program to individuals who are constructing only safety- or security-related SSCs. However, the NRC recognizes that there will be other construction work being performed at the location where a new plant will be constructed and operated that will not have the potential to affect public health and safety or the common defense and security when the nuclear power plant begins operations, such as constructing a building that will be used only for training or administration purposes. The NRC does not intend that individuals who are performing these other construction activities must be subject to the FFD program. Therefore, the final rule also limits the scope of the requirements to cover only those individuals who are constructing (i.e., fabricating, erecting, integrating, testing, and installing foundations of) these specific SSCs. Thus, as one example of a safety-related SSC, the rule requires individuals who are constructing the containment structure that surrounds the reactor to be subject to an FFD program because the containment is relied on to mitigate the consequences of accidents that could result in potential offsite exposure. Similarly, individuals who are constructing security-related SSCs, such as the central and secondary alarm stations, physical barriers, communications systems, guard towers, surveillance and detection systems, or installing locks and illumination systems, that will be necessary to implement the physical security and safeguards contingency plans that are required under 10 CFR Part 73 also are subject to an FFD program for construction.

Section 26.401(b) provides that licensees and other entities who intend to implement an FFD program under Subpart K shall submit a description of the FFD program and its implementation as part of the license, permit, or limited work authorization application. The former rule and the proposed rule did not contain a reference to a limited work authorization application, because the requirements in 10 CFR parts 50 and 52 pertaining to limited work authorization had not yet been developed. The reference to a limited work authorization application in § 26.401(b) is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Licensees and other entities who intend to implement an FFD program for construction that meets all of the requirements of Subparts A through H, N, and O are not required under Part 26 to submit a description of their FFD program and its implementation because the details of the program are specified by 10 CFR Part 26, Subparts A through H, N, and O.

Submittal of a description of the FFD program and its implementation was not required by § 26.2(c) of the former rule or § 26.3(e) of the proposed rule, but is a logical and necessary component of Subpart K because of the flexibility that Subpart K provides in § 26.401(a) and (d). The description of the FFD program and its implementation will provide the information that the NRC needs to enable it to review as a part of the license, permit, or limited work authorization application the particular FFD requirements that are selected for implementation by licensees and other entities. Subpart K provides licensees and other entities substantial flexibility in the design of the program to accommodate local circumstances and the logistical challenges associated with construction. The NRC believes this flexibility is necessary because it cannot reasonably anticipate all of the circumstances that may affect implementation of an FFD program for construction (e.g., proximity to a licensee testing facility, proximity to a population center that offers alternative collection sites, stability in the composition of the workforce at a specific site, variations in the need for an FFD program during different construction stages based on the potential risks imposed by the construction activities at each stage) and, therefore, could not develop prescriptive requirements that would be appropriate for all potential circumstances. However, because Subpart K is not prescriptive and includes several new concepts (e.g., the fitness monitoring program, permission to use specimens other than urine for drug testing), the NRC believes that it is necessary to verify that a licensee or other entity has understood the intent of the Subpart K provisions and will implement a program that meets that intent, including ensuring that any procedures used for testing specimens other than urine for drugs will be scientifically sound and legally defensible.

Requiring a Part 50 applicant to submit a description of its FFD program for construction and its implementation is also consistent with the Part 52 license application requirements. In the Part 52 rulemaking, the NRC implemented the Commission's SRM–SECY–02–0067, dated September 11, 2002, in which the Commission disapproved the use of ITAAC for operational programs such as FFD as long as combined license applicants provide descriptions of the operational programs in their applications:

> [A]n ITAAC for a program should not be necessary if the program and its implementation are fully described in the application and found to be acceptable by the NRC at the COL stage. The burden is on the applicant to provide the necessary and sufficient programmatic information for approval of the COL without ITAAC.

This requirement to include descriptions of operational programs in combined license applications was reiterated in the Commission's SRM–SECY–04–0032, ''Programmatic

Information Needed for Approval of a Combined License Application Without Inspections, Tests, Analyses, and Acceptance Criteria,'' dated May 14, 2004:

> In this context, ''fully described'' should be understood to mean that the program is clearly and sufficiently described in terms of the scope and level of detail to allow a reasonable assurance finding of acceptability. Required programs should always be described at a functional level and at an increased level of detail where implementation choices could materially and negatively affect the program effectiveness and acceptability.

Accordingly, Part 52 requires a combined license applicant to include a description of its FFD program and its implementation, including the FFD program to be implemented during construction. Similarly, § 26.401(b) requires license, permit, or LWA applicants under Part 50 to submit a description of their FFD programs during construction and their implementation. The NRC believes that prior review of the description of the FFD program for construction and its implementation will be more efficient than inspecting FFD programs for construction because it will significantly reduce the inspection resources necessary to ensure proper program implementation once construction has begun. In addition, delaying an evaluation of the program until an inspection can be scheduled, which may occur after construction has begun, could mean that an ineffective FFD program may be in place during early construction, when important tasks are being performed and errors resulting in faults could not be easily detected and corrected (e.g., the pouring of concrete). Finally, the emphasis on performance objectives in Subpart K, compared to the specific, prescriptive requirements in the remainder of the rule, means that the Subpart K requirements will be difficult to enforce without prior NRC knowledge of a licensee's FFD program secured through the description of the FFD program and its implementation.

Consistent with the Part 52 final rule, the NRC expects a Part 50 applicant's FFD program for construction and its implementation to be ''fully described,'' as explained by the Commission in SRM–SECY–04–0032. The applicant should provide a description of the FFD policy and procedures prepared by licensees or other entities, including, but not limited to, procedures for implementing either random testing or fitness monitoring and for performing drug and alcohol testing, and identification of the personnel covered by the FFD program. This requirement meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.401(c) provides that nothing prohibits the licensees and other entities listed in § 26.3(c) from subjecting the individuals described in § 26.4(f) to an FFD program that meets all of the requirements of Part 26, or program elements that meet all of the applicable requirements of Part 26. This provision provides flexibility to licensees and other entities to cover all individuals with an FFD program that includes all the requirements of Part 26 or to adopt certain FFD requirements for individuals described in § 26.4(f) from Subpart K and certain FFD requirements from other subparts of Part 26, as long as the latter meet all of the applicable requirements of Part 26. In either case, workers conducting preliminary work that does not involve building any safety-or security-related SSCs of a facility are not required to be subject to an FFD program. This section allows licensees and other entities, if they so choose, to include fatigue management requirements under Subpart I in their FFD programs for reactor construction. It also allows licensees to mingle elements of the requirements of Subpart K and program elements under Subparts A through H, N, and O, as long as the elements selected from Subparts A through H, N, and O meet all of the requirements in Part 26 for that element. Because neither the former rule nor the proposed rule included this provision, the final rule provides greater flexibility than either the former rule or the proposed rule. This section achieves Goals 3 and 5 of the rulemaking to improve the effectiveness and efficiency of FFD programs and to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.403 Written Policy and Procedures

Section 26.403 addresses the requirements related to the FFD policy for personnel listed in § 26.4(f) and the requirements related to the procedures for such FFD programs. These requirements are presented in separate sections to ensure that the requirements related to FFD policy and procedures are easy to locate within this section. This is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.403(a) requires FFD programs under Subpart K to ensure that a clear, concise, written FFD policy statement is provided to individuals who are subject to the program. Section 26.403(a) specifies that the policy statement must be written in sufficient detail to provide affected individuals with information on the program's expectations of them and the consequences that may result from a lack of adherence to the policy. Because Subpart K does not require licensees and other entities to provide site-specific FFD training to individuals, the FFD policy statement will be the primary means for communicating information with respect to, for example, the sanctions that are applied for confirmed positive, adulterated, substituted, or invalid test results, the types of specimens and cutoff levels used in drug or alcohol testing, or the time periods within which an individual who has been selected for random testing must report to the collection site, if the program includes random testing. Because of the likely large numbers and transient nature of construction workers involved in new reactor plant construction, requiring each of them to be provided with a copy of the FFD policy statement is the most effective and efficient means of ensuring that each individual listed under § 26.4(f) is informed of the contents of the policy. A clear and concise FFD policy statement that is provided to individuals subject to the program will promote their awareness of the site-specific FFD policy to which they are subject. This section satisfies Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, as well as Goal 7 to protect the privacy and other rights (including due process) of individuals who are subject to the rule.

If a licensee or other entity chooses, under § 26.401(d), to adopt FFD elements from Subparts A through H, N, and O of Part 26, the requirements established by those elements will need to be documented in the FFD policy and procedures, and in the FFD program plan. Also, notice will need to be provided to the relevant workers falling under the scope of the program, as required by this section of the rule.

The final rule differs in several other respects from the former rule and the proposed rule. The former rule contained a simple cross-reference to the section of the former rule pertaining to the requirement to adopt an FFD policy and procedures in writing and did not describe or circumscribe the requirement. Thus, the policy and procedures requirement for FFD programs applicable to only the reactor construction workforce was the same as

the requirement for other FFD programs. In contrast, the proposed rule did not contain any explicit cross-reference to the requirement pertaining to FFD program and procedures. However, the program and procedures section could be interpreted to apply to FFD programs applicable to the reactor construction workforce. The final rule both clarifies and adds flexibility to the requirement for an FFD policy statement and FFD procedures for FFD programs for construction by explaining the limited nature of the Subpart K FFD policy and procedures and indicating that they need to be provided only to those persons subject to the Subpart K FFD program. This is consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.403(b) requires FFD programs under Subpart K to develop, implement, and maintain written procedures that address the topics specified in section (b)(1) through (b)(3). However, the procedures must address a more limited set of topics than specified in § 26.27 [Written policy and procedures], the section of Part 26 that deals with policy and procedures for FFD programs generally. Thus, the final rule reduces the scope of the FFD procedures that are required for FFD programs applicable to the individuals listed in § 26.4(f), compared to the scope of the former rule and the proposed rule. This section implements Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.403(b)(1) requires the written procedures to address the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy of the individual who provides a specimen, procedures for protecting the integrity of the specimen, and procedures for ensuring that the test results are valid and attributable to the correct individual.

Section 26.403(b)(2) requires the procedures to describe the immediate and followup actions that must be taken if an individual is determined to have: (1) Been involved in the use, sale, or possession of illegal drugs; (2) consumed alcohol to excess before or while constructing safety-or security-related SSCs, as determined by a test that accurately measures BAC; (3) attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means; (4) refused to provide a specimen for testing; or (5) had legal action taken relating to drug or alcohol use.

Section 26.403(b)(3) requires the procedures to describe the process to be followed if an individual's behavior raises a concern regarding the possible use, sale, or possession of illegal drugs on or off site; the possible possession or consumption of alcohol while constructing safety-or security-related SSCs; or impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her duties.

The NRC considers the procedures specified in § 26.403(b)(1) to (b)(3) to be the minimum set of procedures necessary to implement an effective FFD program meeting the requirements of Subpart K. Those sections clarify the requirements in the former rule and the proposed rule for FFD policy and procedures by explaining what is meant by the requirements and limiting them to the listed topics. The section satisfies Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 of the rulemaking to improve clarity in the organization and language of the rule. As specified in § 26.401(c), licensees and other entities are free to adopt procedures for other aspects of their FFD programs that are applicable to the individuals listed in § 26.4(f).

Section 26.405 Drug and Alcohol Testing

The former rule required reactor construction permit holders to implement a chemical testing program, including random tests. The proposed rule made the requirement more explicit, by requiring the implementation of a drug and alcohol testing program, including random testing, during construction. The final rule requires pre-assignment, for-cause, post-accident, and followup testing, as discussed with respect to § 26.405(c), but does not require random testing of all individuals who are constructing safety- or security-related SSCs, as discussed with respect to § 26.405(b), if a licensee or other entity implements a fitness monitoring program, as discussed with respect to § 26.406.

The NRC concludes that there is a strong empirical basis for requiring drug and alcohol testing for construction. SAMHSA conducts annual surveys that investigate the prevalence, patterns, and consequences of alcohol and illegal drug use and abuse in the general U.S. civilian population. Its National Household Survey on Drug Abuse (NHSDA) covering the years 2000–2001, for example, indicated that over 23 percent of male construction workers aged 18–24 and over 11 percent of those 25 and older admitted to the use of an illicit drug within the month previous to the survey, while over 75 percent of the 18–24 age group and almost 55 percent of the over 25 group admitted to binge drinking or heavy use of alcohol at least once during the prior month. Because of the relatively small number of female construction workers, the data pertain only to male construction workers. A study based on the results of the SAMHSA NHSDA conducted in 1994 and in 1997 showed that in 1994 15.6 percent of full-time construction workers, ages 18–49, reported current illicit drug use and 17.6 percent reported heavy alcohol use, while in 1997 14.1 percent and 12.4 percent reported such drug and alcohol use, respectively. The report of the 2000 SAMHSA NHSDA stated that ''workers in the construction and mining industries reported the highest rates'' of heavy alcohol use, illicit drug use, dependence on or abuse of alcohol, and dependence on or abuse of illicit drugs among full time workers aged 18 through 49 in the U.S. labor force. SMHSA's 2004 National Survey on Drug Use and Health indicated that from 2002–2004, past month illicit drug use among full-time construction and extraction workers aged 18 to 64 was 15.1 percent, and past month heavy alcohol use among this same group was 17.8 percent, which was the highest level among surveyed occupational groups. Also, construction industry groups, such as the Construction Safety and Drug Abuse Executive Roundtable, also have concluded that ''drug abuse continues to be widespread in the construction industry,'' affecting up to 25 percent of the workforce. Finally, data collected annually through the FFD program performance reports and evaluated by the NRC show a consistent pattern of substantially higher incidence of detections of drugs and/or alcohol in the population of short-term contractors, which includes construction workers who seek employment or are employed during outages, who are given pre-access, random, for-cause, and post-event drug and alcohol tests by the FFD programs of reactor licensees, compared to long-term permanent employees at reactors.

To clarify that the drug and alcohol testing requirements under Subpart K are not intended to incorporate all of the requirements in Subparts C [Granting and Maintaining Authorization], E [Collecting Specimens for Testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services] of Part 26, but at the same time to ensure that the drug and alcohol

testing requirements of Subpart K are clear, the final rule clarifies the proposed rule by substantially expanding the description of the program requirements in § 26.405. This section meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(a) requires Subpart K FFD programs to provide a means to deter and detect substance abuse. The FFD programs must include drug and alcohol testing that complies with the requirements of § 26.405. The final rule clarifies that if a licensee or other entity complies with the requirements of § 26.405 with respect to drug and alcohol testing, it is not required to meet the drug and alcohol testing requirements in the balance of Part 26.

Section 26.405(b) specifies that if the licensee or other entity elects to impose random testing for drugs and alcohol on individuals who are constructing safety- or security-related SSCs, the random testing must meet the requirements specified in § 26.405(b)(1) through (b)(4). Random testing must—

(1) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected.

(2) Require individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program policy.

(3) Ensure that all individuals in the population that is subject to testing on a given day have an equal probability of being selected and tested.

(4) Provide that an individual completing a test is immediately eligible for another unannounced test.

The random testing requirements in Subpart K are considerably more flexible than the random testing requirements in § 26.31 [Drug and alcohol testing]. These requirements represent those elements of the random testing requirements under § 26.31 that the NRC has concluded are necessary and appropriate for random testing of individuals identified in § 26.4(f). They are intended to ensure randomness of selection for testing but also take into account the potentially difficult logistical problems associated with testing at such large and diverse locations. Licensees and other entities who adopt random testing will need, in particular, to develop a system for tracking individuals who are subject to the random testing program to identify when they are physically present and therefore available and eligible for testing. Licensees and other entities may also need to develop programs to ensure that subcontractors who operate independently also implement random testing programs, and it will be necessary for licensees and other entities to conduct audits of subcontractor programs. Section 26.405 provides licensees and other entities flexibility to design their random testing programs to address those problems. For example, the final rule in Subpart K does not specify that random testing must take place at times including weekends, backshifts, and holidays, and at various times during a shift because the construction schedule may not in all cases include work during those periods. The final rule also provides flexibility for licensees and other entities to determine the number of random tests to be performed annually and the probability that a member of the population that is subject to the FFD program will be selected for random testing. Because of the likely fluctuations in the numbers of reactor construction workers over the course of a year, the NRC cannot specify that the number of random tests performed annually must be equal to at least 50 percent of the population that is subject to the FFD program, as it does under § 26.31. Finally, Subpart K provides licensees and other entities with the flexibility to adopt a fitness monitoring program under § 26.406 to detect and deter substances abuse, rather than conducting random testing of individuals identified in § 26.4(f).

Section 26.405(c) specifies that the individuals who are constructing safety- and security-related SSCs shall be subject to drug and alcohol testing under the following four conditions: (1) Before assignment to construct safety-or security-related SSCs; (2) When the licensee or other entity has adequate cause, arising either in response to an individual's observed behavior or physical condition indicating possible substance abuse or after the licensee or other entity has received credible information that an individual is engaging in substance abuse, as defined in § 26.5; (3) Following an accident in which the individual was involved. Post-accident testing should be conducted as soon as practical after an event involving a human error that was committed by an individual specified in § 26.4(f), where the human error may have caused or contributed to the accident. The licensee or other entity is not required to test individuals who were affected by the event but whose actions likely did not cause or contribute to the event. Post-accident testing may involve more than one individual, and should be conducted if the event resulted in either: (i) A significant illness or personal injury to the individual to be tested or another individual, which within 4 hours after the event is recordable under the U.S. Department of Labor standards contained in 29 CFR 1904.7, and subsequent amendments, and results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury as diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; or (ii) Significant damage to any safety-related SSC of a facility that is required by the Commission's rules and regulations to be described in the site safety analysis report or preliminary or final safety analysis report. Finally, (4) followup testing should be conducted as part of a followup plan to verify an individual's continued abstinence from substance abuse.

The conditions that can lead to drug and alcohol testing of an individual specified in § 26.405(c)(1) through (c)(4) parallel generally the conditions listed in § 26.31(c)(1) through (c)(4), with changes to reflect the different reasons for testing individuals identified in § 26.4(f) under Subpart K and testing individuals at an operating nuclear reactor under Part 26. Thus, pre-assignment testing is limited to those individuals who will construct safety-or security-related SSCs. Because the NRC has concluded that there is no basis to distinguish between for-cause testing under Subpart K and for-cause testing under Part 26 generally, the final rule in Subpart K and § 26.31(c)(2) provide the same basis for for-cause testing. Similarly, § 26.405(c)(3)(i) requires post-accident testing for exactly the same significant illness and personal injury situations as required under § 26.31(c)(3)(i). However, the Subpart K post-accident testing requirement that is triggered by property damage is limited to damage to any safety-or security-related SSC of a facility. The NRC recognizes that in the context of reactor plant construction, damage incidents can occur in a number of contexts that are not related to the impairment or potential sabotage bases for FFD programs under Subpart K (e.g., vehicle accidents, injuries to persons not working on safety-or security-related

SSCs). Followup testing under § 26.405(c)(4) is defined exactly the same as followup testing under § 26.31(c)(4). In the NRC's view, the purpose of the testing, to verify an individual's continued abstinence from substance abuse, is exactly the same in both cases. These requirements meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(d) specifies that, at a minimum, FFD programs under Subpart K shall test specimens for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol at the cutoff levels specified in this part for testing the respective specimens, or comparable cutoff level, if alternate specimens, such as oral fluids, are used for drug screening. The list of substances for which testing must be conducted under Subpart K exactly parallels the list in § 26.31(d)(1). The NRC considers this the minimum set of substances that an effective and adequate FFD program must include for both construction and operation. However, this section does not prohibit Subpart K programs from testing for additional drugs, consistent with the permission in § 26.31(d)(1)(i)(A) for licensees and other entities who are implementing an FFD program for operating plants to test for additional drugs.

The NRC is not prohibiting drug testing of specimens other than urine under Subpart K because it recognizes that there may be circumstances during construction where waiting for the results of urine drug tests could unacceptably delay the assignment of individuals to construct safety-or security-related SSCs. For example, for some construction activities or in some locations, licensees and other entities may rely on craftspersons from a local union hall and may not know in advance which specific individuals will be assigned to work on a particular day. If the union local does not offer pre-employment testing to its members, a licensee or other entity may elect to conduct an oral fluids drug screen, for example, that provides very rapid results, as long as the collection procedures and testing of oral fluids meet the criteria established in § 26.405(e) by protecting the donor's privacy and the integrity of the specimen, and stringent quality controls are implemented to ensure that test results are valid and attributable to the correct individual. The NRC does not permit testing of oral fluids for drugs in FFD programs for other licensees and entities who are subject to Part 26 because the window of detection for marijuana use when testing for oral fluids is very short compared to the window of detection for marijuana use when testing urine specimens, and the NRC has a higher expectation that individuals will be trustworthy and reliable, as demonstrated by the avoidance of substance abuse, for the categories of individuals who are subject to Part 26 under the licensees' and entities' FFD program for operating plants. However, the NRC believes that oral fluids drug test results would be adequate to demonstrate that an individual who will be constructing safety- and security-related SSCs is not impaired that day from recent marijuana use or the other substances for which testing is required under § 26.405(d). Permitting testing of alternate specimens under FFD programs for construction is consistent with Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs. This permission is also consistent with § 26.2(c) of the former rule and § 26.3(e)(2) of the proposed rule that required drug and alcohol testing during construction, but did not specify the specimens to be tested.

Section 26.405(d) also requires that urine specimens collected for drug testing must be subject to validity testing. Although § 26.405(d) specifies that urine specimens collected for drug testing must be subject to validity testing and does not further elaborate on the validity testing requirement, the NRC considers the regulatory detail found in § 26.31 to provide useful guidance to licensees and other entities on the agency's expectations. However, Subpart K also provides flexibility to licensees and other entities with respect to this requirement by not specifying that they are required to meet the standards of § 26.31. This section limits the requirement for validity testing to urine specimens because the final rule does not prohibit the use of specimens other than urine for drug testing under Subpart K and scientifically sound and legally defensible means of testing the validity of other types of specimens are not yet available for some alternate specimens. The requirements in this section meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(e) specifies that the specimen collection and drug and alcohol testing procedures of FFD programs under this subpart must protect the donor's privacy and the integrity of the specimen and implement stringent quality controls to ensure that test results are valid and attributable to the correct individual. At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility in accordance with the specimen collection and alcohol testing requirements of 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944; August 9, 2001), and subsequent amendments. This section of the final rule is intended to provide licensees and other entities with additional flexibility about the locations where specimen collections and alcohol testing may be carried out and to help ensure that licensees will not be required, before construction can begin, to build specimen collection and alcohol testing facilities at sites that are distant from a current licensee's specimen collection facilities for drug and alcohol testing. This provision is consistent with the former and proposed rules, which also did not require the construction of specimen collection and alcohol testing facilities. This requirement meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.405(f) specifies that testing of urine specimens for drugs and validity, except validity screening and initial drug and validity tests that may be performed by licensee testing facilities, must be performed in a laboratory that is certified by HHS for that purpose, consistent with its standards and procedures for certification. This section requires that urine specimens collected for drug testing must be subject to initial validity and drug testing by the laboratory because means to attempt to adulterate or substitute a urine specimen are readily available, but does not apply these requirements to drug testing of other specimens for two reasons: (1) Some HHS-certified laboratories may not have the capability to perform tests of alternate specimens, such as oral fluids, or validity testing of alternate specimens, and (2) means for attempting to adulterate or substitute some alternative specimens (e.g., oral fluids) are not readily available. However, any initial drug test performed by a licensee or other entity subject to Subpart K, including tests of alternate specimens, must use an immunoassay that meets

the requirements of the Food and Drug Administration for commercial distribution. Urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by an HHS-certified laboratory, except for invalid specimens that cannot be tested. Alternate specimens that yield positive drug test results must be subject to confirmatory testing by a laboratory that meets quality control requirements that are at least as stringent as the requirements those laboratories are required to meet for HHS-certification, such as the accreditation process of the American College of Pathologists. These requirements constitute the general administrative procedures that the NRC considers necessary for drug testing. Licensees and other entities would be allowed to conduct initial testing of urine or alternate specimens at a licensee testing facility, provided that the licensee testing facility staff members possess the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for testing are implemented. However, in parallel with § 26.31, Subpart K requires licensees and other entities to use only HHS-certified laboratories to perform drug testing of urine specimens, except if a licensee testing facility performs initial tests. This requirement is consistent with the former and proposed rules, which also required the use of only HHS-certified laboratories for testing urine specimens for drugs.

Section 26.405(g) requires FFD programs under Subpart K to provide for an MRO review of positive, adulterated, substituted, and invalid drug and validity test results from confirmatory testing to determine whether the donor has violated the FFD policy, before reporting the results to the individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under § 26.419. This requirement in Subpart K parallels the requirement in § 26.169 [Reporting results] of the final rule. This requirement is an integral component of all Federally-mandated drug and alcohol testing programs, and required by the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs. It is fully consistent with the former and proposed rules, which also followed the HHS Guidelines. This requirement meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.406 Fitness Monitoring

Section 26.406(a) of Subpart K specifies that the requirements in § 26.406 apply only if a licensee or other entity does not elect to subject the individuals specified in § 26.4(f) to random testing for drugs and alcohol under § 26.405(b). The NRC considers fitness monitoring of the individuals who are constructing safety- and security-related SSCs, as specified in § 26.406, to be a means of detecting and deterring substance abuse that can function as effectively as random testing, given the logistical and other issues associated with random testing. Daily monitoring of individuals by trained personnel provides a constant source of information about their fitness, in contrast to the sporadic information provided by random testing during construction. Fitness monitoring can immediately detect situations where for-cause testing is required as well as provide a degree of deterrence comparable to the deterrence provided by the potential for a random test. Subpart K gives a licensee or other entity the flexibility to adopt either random testing under § 26.405(b), or fitness monitoring under § 26.406, or to implement both if the licensee or other entity chooses. Neither the former rule nor the proposed rule explicitly required fitness monitoring. However, both listed the performance objective standards section as one of the specific rule sections that an FFD program applicable to individuals involved with the construction of a new reactor plant was required to satisfy. Attainment of the performance objectives clearly implied that licensees and other entities would undertake a program to deter substance abuse and detect impairment. Section 26.406(b) described below contains a similar performance objective. The requirement for fitness monitoring in § 26.406, if a licensee or other entity does not implement random testing of individuals who construct safety- and security-related SSCs, meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.406(b) establishes the performance objective for a fitness monitoring program. It requires licensees and other entities to implement a program to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs, use or possession of alcohol while constructing safety-or security-related SSCs, and impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security. Both the former rule and the proposed rule included a cross-reference to the performance objectives standard. Thus, § 26.406(b) of the final rule extends and clarifies the former and proposed rules.

Section 26.406(c) requires licensees and other entities to establish procedures that fitness monitors shall follow in response to the indications and actions specified in § 26.406(b) and to train the monitors to implement the program. Section 26.406(d) provides licensees and other entities with significant flexibility in determining the number of individuals required to monitor fitness and the procedures they are required to follow, commensurate with the potential risk. Development of fitness monitoring procedures and training of monitors in those procedures as well as the licensee's or other entity's requirements for program implementation will ensure that fitness monitors know what is meant by the requirement and are informed about the procedures for implementing this requirement.

Section 26.406(d) requires licensees and other entities to ensure that the fitness of individuals who are constructing safety- and security-related SSCs is monitored effectively, commensurate with the potential risk to public health and safety and the common defense and security imposed by the construction activity. To achieve this objective, the rule requires licensees and other entities to consider the number and placement of monitors required, the necessary ratio of monitors to individuals specified in § 26.4(f), and the frequency with which the individuals shall be monitored while performing each construction activity. The NRC does not expect that the individuals designated as fitness monitors will be dedicated solely to the task of fitness monitoring. Licensees and other entities may assign fitness monitoring responsibilities to first-line supervisors, security personnel, and others who are performing other activities for the licensee or other entity while monitoring the fitness of individuals who are constructing safety- and security-related SSCs. In determining the number of such monitors licensees and other entities may need to consider how to ensure that equipment, walls, and other temporary or permanent barriers do not interfere with the monitors' abilities to maintain visual contact with individuals performing the construction activity and whether monitoring will be conducted

continuously until completion of the construction activity, continuously only at critical points during a construction activity, once at the beginning of a shift and again after a lunch break, or at a frequency of every few hours on an irregular schedule. Licensees and other entities thus have considerable flexibility in designing their fitness monitoring program. However, they must ensure that the program meets the performance objective stated in § 26.406(b). This requirement is consistent with the requirement in the former rule that FFD programs pertaining to licensees actively constructing nuclear power plants satisfy former § 26.10(b), calling for measures for the early detection of persons who are not fit to perform activities within the scope of Part 26.

Section 26.407 Behavioral Observation

Section 26.407 provides that individuals in § 26.4(f) shall be subject to behavioral observation while they are constructing safety- and security-related SSCs at the location where a nuclear power plant is under construction and will be operated. However, if these individuals are subject to a fitness monitoring program under § 26.406, they are not required to be subject to behavioral observation under § 26.407. Thus, this section provides licensees and other entities with the flexibility of subjecting the individuals specified in § 26.4(f) to either fitness monitoring under § 26.406 or to a combination of random drug and alcohol testing under § 26.405(b) and behavioral observation under § 26.407.

Behavioral observation is an important component of an FFD program because it increases the likelihood that the licensees and other entities who are subject to the rule detect and appropriately address impairment and other adverse behaviors. The individuals listed under § 26.4(e) will be trained in behavioral observation, because § 26.4(e) specifies that they shall be subject to an FFD program that meets all of the requirements of Part 26, except Subparts I and K, and such a program includes behavioral observation training. The individuals who will perform the behavioral observation are specified under § 26.4(e) as including any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to perform the following activities at the location where the nuclear power plant will be constructed and operated: (1) Serves as a security officer under NRC requirements; (2) performs quality assurance activities, as specified in Appendix B to Part 50; (3) based on a designation under § 26.406 by a licensee or other entity, monitors the fitness of the individuals specified in § 26.4(f) (and thus has also received fitness monitoring training); (4) determines that inspections, tests, and analyses, or parts thereof, required under 10 CFR Part 52 have been successfully completed; (5) supervises or manages the construction of safety-or security-related SSCs; or (6) directs, as defined in § 26.5, or implements the licensee's or other entity's access authorization program. Because of their important oversight responsibilities, these individuals will be subject to an FFD program that meets the requirements for Subparts A through H, N, and O of Subpart 26. In addition to behavioral observation training, they will be subject to random testing at the 50 percent annual rate and a suitable inquiry/employment history check.

Neither the former rule nor the proposed rule explicitly required behavioral observation. However, both listed the performance objective standards section as one of the specific rule sections that an FFD program applicable to individuals involved with the construction of a new reactor plant was required to satisfy, and attainment of the performance objectives clearly implied the use of behavioral observation. The final rule clarifies the requirement and adds flexibility. This requirement is consistent with the requirement in the former rule that FFD programs pertaining to licensees actively constructing nuclear power plants satisfy former § 26.10(b), calling for measures for the early detection of persons who are not fit to perform activities within the scope of Part 26. Section 26.407 meets Goal 3, to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.409 Sanctions

Section 26.409 requires FFD programs under Subpart K to establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4(f) from being assigned to or performing the duties specified in that section until the licensee or other entity determines that the individual's behavior does not pose a threat to public health and safety or the common defense and security. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

The former rule provided for flexibility in the development and application of sanctions by specifying only that an FFD program applicable to individuals involved in the construction of a new reactor plant should make provision for the imposition of sanctions but did not otherwise specify the level or type of sanctions to be applied. The proposed rule, in § 26.3(e)(3), included an identical provision, also without specifying the level or type of sanctions to be included in the FFD program. By adding explicit criteria for the types of FFD policy violations to which sanctions shall be applied, the final rule clarifies the sanctions provision of the former and proposed rules. This provision in the final rule adds flexibility because it does not require FFD programs under Subpart K to implement the minimum requirements for sanctions in § 26.75 [Sanctions] or to apply the specific procedures for conducting a determination of fitness in § 26.189. Subpart K also allows licensees and other entities the flexibility to assign individuals who violate the FFD policy under Subpart K to other duties at the site not covered by the FFD program, depending on the licensee's assessment of the violation and the other duties involved.

Section 26.411 Protection of Information

Section 26.411(a) requires FFD programs that collect personal information about an individual for the purpose of complying with Subpart K to establish and maintain a system of files and procedures to protect the personal information. It also requires FFD programs to maintain and use such records with the highest regard for individual privacy. This requirement exactly parallels the requirement in § 26.37 [Protection of information] of the final rule pertaining to protection of information under Part 26 generally. The NRC does not believe that any lesser standard of protection can be justified for personal information collected under Subpart K than is required for personal information collected under Part 26 generally. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, Goal 6 to improve clarity in the organization and language of the rule, and Goal 7 to protect the privacy of individuals.

The final Subpart K rule parallels the requirements in the former rule and in the proposed rule. Both included a requirement that FFD programs applicable to individuals involved with the construction of a new reactor plant make provisions for the protection of information. Section 26.411(a) provides

additional detail about the level of protection (the highest regard for individual privacy) required of FFD programs that maintain and use records of personal information. Thus, this final rule provides additional clarity, compared to the former rule or the proposed rule, that the program should achieve the necessary protection through a system of files and procedures.

Section 26.411(b) requires licensees and other entities to obtain a signed consent that authorizes the disclosure of the personal information collected and maintained under Subpart K before disclosing the personal information, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.413 [Review process]. These persons include the subject individual or his or her representative, when the individual has designated the representative in writing for specified FFD matters; assigned MROs and MRO staff; NRC representatives; appropriate law enforcement officials under court order; a licensee's or other entity's representatives who have a need to access the information to perform assigned duties, including determinations of fitness, audits of FFD programs, and human resources functions; the presiding officer in a judicial or administrative proceeding that the subject individual initiates; and other persons pursuant to court order. The NRC did not include a reference to § 26.37(b)(7) because it refers to persons deciding matters under another section of Part 26 that Subpart K does not include. Instead, this section adds a new reference to persons deciding matters under review in § 26.413. The requirement to obtain permission to release the personal information to individuals who are not specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.413 is necessary because licensees have misinterpreted the former requirement as prohibiting them from releasing the personal information under any circumstances. In some instances, such failures to release information have inappropriately inhibited an individual's ability to obtain information that was necessary for a review or appeal of the licensee's determination that the individual had violated the FFD policy. Therefore, the final rule includes the explicit permission for licensees and other entities to release personal information when an individual consents to the release, in writing. This requirement precisely parallels the requirement in § 26.37, except for the differences noted, because the NRC does not believe that any different procedures for handling personal information can be justified for personal information collected under Subpart K than are required for personal information collected under Part 26 generally.

Section 26.413 Review Process

Section 26.413 requires FFD programs under Subpart K to establish and implement procedures for the review of a determination that an individual listed in § 26.4(f) has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy. This requirement parallels the one in § 26.39(a) of the final rule. Because the NRC recognizes that much of the construction workforce will be transient and rapidly changing, it is leaving licensees and other entities the flexibility to adopt the additional review procedures found in § 26.39(b) through (e), but is not mandating their adoption by including them in the review process requirements in § 26.413. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs and Goal 6 to improve clarity in the organization and language of the rule.

The final rule is more explicit than the former rule, which specified only that the FFD program for the reactor construction workforce should make provisions for appeals procedures. The proposed rule in § 26.3(e)(3) similarly required FFD program for construction to make provisions for procedures for the objective and impartial review of authorization decisions. This final rule more clearly requires FFD programs under Subpart K to establish and implement procedures and more clearly specifies that the procedures are for the review of the facts related to the determination that an individual has violated the FFD policy. However, the basic requirement in this final rule is the same as that in the former rule and the proposed rule. The requirement for an objective and impartial review establishes the same criteria for the review as did the proposed rule, which also mandated an impartial and objective review.

Section 26.415 Audits

Section 26.415 establishes audit requirements for Subpart K FFD programs. Section 26.415(a) requires licensees and other entities to ensure that audits are performed to assure the continuing effectiveness of the FFD program, including FFD program elements that C/Vs provide, and the FFD programs of C/Vs that are accepted by the licensee or other entity. This requirement parallels the audit requirement in § 26.41(a) of the final rule. The agency has not identified any circumstances relating to the reactor construction workforce that would support different auditing requirements for Subpart K FFD programs than for FFD programs under the other subparts of Part 26. The criterion to be applied for each audit program is that it must assure the continuing effectiveness of the FFD program. Although the former rule did not contain a requirement for audits of the FFD programs for construction, the proposed rule referred explicitly to § 26.41 [Audits and corrective action] as one of the requirements to be complied with by licensees authorized to construct a nuclear power plant. Thus, § 26.415 extends and clarifies the requirement in the proposed rule, meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, and satisfies Goal 6 to improve clarity in the organization and language of the rule.

Section 26.415(b) requires each licensee and other entity who implements an FFD program under Subpart K to ensure that these programs are audited at a frequency that ensures their continuing effectiveness and that corrective actions are taken to resolve any problems identified. The section also provides that licensees and entities may conduct joint audits, or accept audits of C/Vs conducted by others, so long as the audit addresses the relevant services of the C/V. The NRC expects that in determining the frequency of audits, licensees and other entities will consider the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and lessons learned. The requirement is intended to promote performance-based rather than compliance-based audit activities. By allowing joint audits, the final rule creates additional flexibility for Subpart K FFD programs.

Section 26.415(c) provides that licensees and other entities who implement FFD programs under Subpart K need not audit the HHS-certified laboratories or specimen collection and alcohol testing services that meet the requirements of 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944, August 9, 2001) upon which licensees and other entities may rely to meet the drug and alcohol testing requirements of Subpart K. Because the

DOT conducts audits of collection sites that the agency's grantees use, the NRC has concluded that audits of those sites when they are used by NRC licensees and other entities are unnecessary.

Section 26.417 Recordkeeping and Reporting

Section 26.417(a) of the final rule provides that FFD programs shall ensure that records pertaining to the administration of the program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the administration of the program. This recordkeeping provision provides more extensive detail than the equivalent recordkeeping sections of the former rule or the proposed rule, both of which provided only that the FFD program for the reactor construction workforce should make provisions for recordkeeping. This final rule provides notice that records may be stored and archived electronically, which clarifies the requirement and provides flexibility to licensees and other entities. This rule also incorporates standard language pertaining to the availability of records for NRC inspection purposes and for any legal proceedings resulting from the administration of the program. These provisions are inherent to the NRC's recordkeeping requirements. While adding clarity, they do not significantly change the recordkeeping requirement from that in the former or proposed rule. Both the former rule and the proposed rule contained an explicit requirement for recordkeeping by the FFD program applicable to reactor construction workers. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Section 26.417(b) requires licensees and other entities that implement FFD programs under Subpart K to make the reports described in § 26.417(b)(1) and (b)(2). Section 26.417(b)(1) requires reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to Subpart K. This provision also specifies that these events must be reported under Subpart K, rather than under the provisions of 10 CFR 73.71 [Reporting of safeguards events]. Section 26.417(b)(2) requires annual program performance reports for the FFD program. The former rule contained detailed reporting requirements similar to those in the final rule. In addition, the NRC considers the reporting of acts that cast doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals subject to Subpart K, as well as annual program performance reports, to be clearly logical and necessary components of the program and outgrowths of the recordkeeping requirements.

Section 26.419 Suitability and Fitness Evaluations

Section 26.419 requires licensees and other entities who implement FFD programs under Subpart K to develop, implement, and maintain procedures for evaluating whether to assign individuals to the duties specified in § 26.4(f). These procedures must provide reasonable assurance that such individuals are fit to safely and competently perform their duties and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse. This section provides flexibility for Subpart K programs to develop procedures for determining suitability. The requirement that licensees and other entities develop, implement, and maintain procedures for evaluating whether to assign individuals to the duties specified in § 26.4(f) is necessary to enable licensees and other entities to implement Subpart K. These procedures will allow licensees, other entities, and the individuals who are subject to the FFD program to know who the Subpart K requirements cover. This section meets Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs, and Goal 6 to improve clarity in the organization and language of the rule.

Although neither the former rule nor the proposed rule contained an explicit requirement for suitability and fitness evaluations, each contained a cross-reference to the general performance objectives sections of their respective rules (§ 26.10 of the former rule and § 26.23 of the proposed rule). Section 26.10 required the FFD programs applicable to reactor construction workers to provide reasonable assurance that personnel would perform their tasks in a reliable and trustworthy manner and that they are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way would affect their ability to safely and competently perform their duties. Section 26.23 of the proposed rule used language similar to that in this final rule, requiring FFD programs to provide reasonable assurance that individuals who are subject to Part 26 are trustworthy and reliable, as demonstrated by the avoidance of substance abuse, and to provide reasonable assurance that individuals who are subject to Part 26 are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely impairs their ability to safely and competently perform their duties.

Subpart L—[Reserved]

Subpart M—[Reserved]

Subpart N—Recordkeeping and Reporting Requirements

As a result of the reorganization of the proposed rule, the NRC has moved the provisions from Subpart J of the proposed rule to a new Subpart N of the final rule. The final rule includes minor clarifications of the language of the proposed rule that are discussed with respect to those sections. The NRC has also made more substantive changes to the proposed rule in § 26.711(c) and (d). Otherwise, the provisions in this subpart have been adopted as proposed without change.

Section 26.709 Applicability

The NRC has added § 26.709 to the final rule to specify the licensees and other entities to whom the requirements of this subpart apply.

Section 26.711 General Provisions

The NRC has added § 26.711 to the final rule to define general requirements related to recordkeeping and reporting under Part 26.

Section 26.711(a) of the final rule establishes a requirement that licensees and other entities must maintain records and submit certain reports to the NRC, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. In addition, this section requires that licensees and other entities retain the records required under this part for either the periods that are specified in Subpart N or for the life of the facility's license, certificate, or other regulatory approval, if no records retention requirement is specified. This general records retention requirement clarifies the language of the rule and is a standard administrative provision that is used in all other parts of 10 CFR that contain substantive requirements applicable to licensees and applicants, such as 10 CFR 50.71(c).

The NRC has added § 26.711(b) to the final rule to permit records to be stored and archived electronically if the method used to create the electronic records (1) provides an accurate representation of the original records, (2) prevents the alteration of any archived information and/or data once it has been committed to storage, and (3) allows easy retrieval and re-creation of the original records. This provision recognizes that most records are now stored electronically and must be protected to ensure the integrity of the data. The requirements are consistent with related requirements in the access authorization orders issued to nuclear power plant licensees dated January 7, 2003. Therefore, these requirements meet Goal 4 of this rulemaking to improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56 [Personal access authorization requirements for nuclear power plants], as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

In the final rule, the NRC has added a new provision in § 26.711(c). This provision requires licensees and other entities to inform individuals of the right to review and correct the records maintained about the individual under this part and imposes a requirement on licensees and other entities to ensure that the information they maintain and share with other licensees and entities is correct and complete. The NRC added this provision to provide further assurance that individuals who are subject to an FFD program under this part are not unjustly or inaccurately portrayed as having violated FFD requirements in any written documentation that licensees and other entities rely on when making authorization decisions. This provision meets Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26. This provision is also meets Goal 4 of this rulemaking to improve consistency between this rule and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

The NRC has also added § 26.711(d) to the final rule to require licensees and other entities to ensure that only correct and complete information about individuals is retained and shared. This provision specifies that licensees and other entities shall correct or augment shared information contained in the records if this information changes or new information is developed. Also, if the changed or new information has implications for adversely affecting an individual's eligibility for authorization, the final rule requires that the licensee or other entity who discovers the incorrect information or developed new information shall inform the reviewing official of the updated information. The NRC has added this provision to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26. This provision also meets Goal 4 of this rulemaking to improve consistency between this rule and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003.

Section 26.713 Recordkeeping Requirements for Licensees and Other Entities

Section 26.713 of the final rule amends former § 26.71 [Recordkeeping requirements]. Former § 26.71(d), which established requirements for FFD program performance reports, is retained in § 26.717 [Fitness-for-duty program performance data], a separate section that focuses only on those reports. Section 26.713 retains but amends former § 26.71(a) through (c) and adds other requirements that are interspersed throughout the former rule. The NRC has made these changes to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule by grouping recordkeeping requirements that apply to licensees and other entities in one section.

Section 26.713(a) of the final rule requires licensees and other entities to retain certain records related to authorization decisionmaking for at least 5 years after an individual's authorization has been terminated or denied, or until the completion of all related legal proceedings, whichever is later. The agency has added the requirement to retain records until the completion of all related legal proceedings at the suggestion of stakeholders during the public meetings discussed in Section I.D. The stakeholders noted that some legal proceedings involving records of the type specified in the paragraph have continued longer than the 5 years that the former rule required these records to be retained and that adding a requirement in the final rule to retain the records until all legal proceedings are complete protects an individual's right to due process under the rule. This provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.713(a)(1) amends former § 26.71(a). Former § 26.71(a) required licensees to retain records of the inquiries that licensees conduct in granting unescorted access to an individual for 5 years following the termination of such access authorizations. The final rule updates the terminology used in the former paragraph for consistency with the revised language used throughout the rule. For example, the paragraph refers to ''self-disclosures,'' ''employment histories,'' ''suitable inquiries,'' and ''granting authorization,'' but retains the intent of the former paragraph. The NRC has made the changes in terminology for the reasons discussed with respect to §§ 26.61 [Self-disclosure and employment history] and 26.63 [Suitable inquiry]. In addition, the agency has updated the former cross-reference to § 26.27(a) to reflect the new organization of the rule.

Section 26.713(a)(2) amends former § 26.71(b). Former § 26.71(b) required licensees to retain records that are related to positive drug test results that the MRO has confirmed. The final rule revises the former requirement by mandating that licensees and other entities retain records related to any violation of the FFD policy, which includes confirmed positive drug and alcohol test results. This change ensures that licensees and other entities who may be considering granting authorization to an individual who has previously violated any aspect of an FFD policy can obtain these records for review as part of the authorization decisionmaking process specified in § 26.69 [Authorization with potentially disqualifying fitness-for-duty information].

The NRC has added § 26.713(a)(3) to the final rule to require licensees and other entities to retain records that are related to the granting and termination of an individual's authorization. This provision ensures that licensees and other entities who may be considering granting authorization to an individual under Subpart C [Granting and Maintaining Authorization] can determine which category of authorization requirements in Subpart C applies to the individual, based upon the length of time that has elapsed since the termination of the individual's last period of authorization and whether it was terminated favorably. The new section discusses the categories of authorization requirements with respect to §§ 26.55 [Initial authorization], 26.57

[Authorization update], 26.59 [Authorization reinstatement], and 26.69.

The NRC has added § 26.713(a)(4) to the final rule to require licensees and other entities to retain records that are related to any determination of fitness that was conducted under § 26.189 [Determination of fitness]. The final rule, with respect to the proposed rule, clarifies that the records to be retained include any recommendations for treatment and followup testing plans. This provision ensures that licensees and other entities who may be considering granting authorization to an individual who has previously undergone a determination of fitness can obtain these records for review as part of the authorization decisionmaking process specified in § 26.69. In addition, if an individual who is subject to followup testing and a treatment plan transfers to another FFD program, the reviewing official and SAE of the receiving FFD program, which takes responsibility for implementing the testing and treatment plans, are required to have access to this information under § 26.69(e).

Section 26.713(b)(1) and (b)(2) of the final rule requires licensees and other entities to retain records related to FFD training, examinations, audits, audit findings, and corrective actions for at least 3 years, or until the completion of all related legal proceedings, whichever is later. These paragraphs retain the 3-year recordkeeping requirements of the former rule in §§ 26.21(b) and 26.22(c) for training records, and § 26.80(c) for audit findings and corrective action records.

Section 26.713(c) of the final rule amends former § 26.71(c). Former § 26.71(c) required licensees to retain records related to any individual who was made ineligible for authorization for 3 years or longer under former § 26.27 [Management actions and sanctions to be imposed] until the Commission terminates each license under which the records were created. However, the final rule requires licensees and other entities to retain records concerning 5-year and permanent denials of authorization for 40 years or until, upon application, the NRC determines that the records are no longer needed. The requirement to retain records related to 5-year denials of authorization is consistent with the more stringent sanctions established in § 26.75(c), (d), and (e)(2), in which the NRC has eliminated the sanction of a 3-year denial of authorization, as discussed with respect to those paragraphs. The 40-year retention requirement is based on the longest expected working life of an individual, rather than on the period of the license. The termination of a license by the Commission does not mean that individuals whose authorizations were denied for 5 years or permanently denied under the licensee' FFD program would necessarily leave the industry. Requiring retention of the records pertaining to those individuals ensures that the records of the 5-year and permanent denials are available, should the individual seek authorization from another licensee or other entity. This amendment is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26 and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.713(d) of the final rule replaces the recordkeeping requirement in former § 26.20 [Written policy and procedures]. This paragraph requires licensees and other entities to retain superseded FFD policies and procedures for at least 5 years, or until completion of all legal proceedings related to an FFD violation that may have occurred under the policy and procedures, whichever is later. The NRC has increased the required period for retaining superseded materials from 3 to 5 years to ensure that the materials are available if subsequent licensees and other entities require the information in making a determination of fitness. The requirement to retain the policy and procedures related to any matter under legal challenge until the matter is resolved ensures that the materials remain available if an individual, the NRC, a licensee, or another entity who is subject to this rule require access to them in a legal or regulatory proceeding. This provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.713(e) of the final rule amends the requirement in former § 26.23(a) pertaining to the retention of written agreements for the provision of FFD program services. This provision requires licensees and other entities to retain the written agreement for the life of the agreement (as in the former rule), or until completion of all legal proceedings related to an FFD violation that involved the services, whichever is later. This requirement ensures that the materials remain available should an individual, the NRC, a licensee, or another entity who is subject to the rule require access to them in a legal or regulatory proceeding. This amendment is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.713(f) to the final rule to require licensees and other entities to retain records related to the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under § 26.31(b)(1)(i), for the length of the individual's employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later. This requirement is consistent with the last phrase of former Section 2.6(c) in Appendix A to Part 26, which required licensee testing facilities to retain personnel files that include ''appropriate data to support determinations of honesty and integrity conducted in accordance with Section 2.3 of this appendix.'' The required period during which these records must be maintained is based on the NRC's need to have access to the records for inspection purposes and the potential need for the records to remain available if an individual, the NRC, a licensee, or another entity who is subject to this rule requires access to them in a legal or regulatory proceeding. However, the final rule establishes a new limit on the period during which the records must be retained in order to reduce the burden associated with storing such records indefinitely. This new provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.713(g) to the final rule to require licensees and other entities to retain records of the certification, provided by a qualified forensic toxicologist, as required under § 26.31(d)(1)(i) and (d)(3)(iii)(C), of the scientific and technical suitability of any assays and cutoff levels used for drug testing that this part does not address. This provision requires the licensee or other entity to retain these records for the period of time during which the FFD program continues to test for drugs for which this part does not require testing, uses more stringent cutoff levels than those specified in this part, or until the completion of all related legal proceedings, whichever is later. This new requirement ensures that the NRC has access to the records for inspection purposes and that the

records remain available if an individual, the NRC, a licensee, or another entity who is subject to this rule requires access to them in a legal or regulatory proceeding. This provision is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

Section 26.715 Recordkeeping Requirements for Collection Sites, Licensee Testing Facilities, and Laboratories Certified by The Department of Health and Human Services

The NRC has added § 26.715 to the final rule to group together in one section the recordkeeping requirements that apply to collection sites, licensee testing facilities, and HHS-certified laboratories.

Section 26.715(a) of the final rule retains the requirement in former Section 2.7(n) in Appendix A to Part 26. This provision mandates that collection sites, HHS-certified laboratories and licensee testing facilities must maintain documentation of all aspects of the testing process for at least two years. The final rule includes collection sites within this provision because licensee testing facilities and collection sites may not be co-located, as was typically the case when the former rule was first published. This section retains the provision in former Section 2.7(n) that the two-year period may be extended upon written notification by the NRC or any licensee or other entity for whom services are being provided. The final rule also adds a requirement to retain the documentation until completion of all legal proceedings related to an FFD violation to ensure that the records remain available if an individual, the NRC, a licensee, or another entity who is subject to this rule requires access to them in a legal or regulatory proceeding. This change is consistent with Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26, and Goal 3 to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.715(b)(1) through (b)(14) to the final rule to list in a single paragraph the documents that collection sites, licensee testing facilities, and HHS-certified laboratories must retain. Specifically, those documents include personnel files of individuals who are no longer working at a collection site, licensee testing facility, or HHS-certified laboratory; on chain-of-custody documents; quality assurance/quality control records; superseded procedures; all test data; test reports; records on performance testing; records on testing errors or unsatisfactory performance, and the investigation and correction of the errors or unsatisfactory performance; performance records on certification inspections; records on preventative maintenance; records on negative test results based on scientific insufficiency; computer-generated data, printed or electronic copies of computer-generated data; records of individuals accessing secured areas in licensee testing facilities and HHS-certified laboratories; and records of EBT maintenance, inspection, and calibration. This listing of records to be retained comes from provisions of the former rule in §§ 26.20 and 26.71(a) and Sections 2.7(a)(1), 2.7(f)(2), 2.7(g)(8), 2.7(n), 2.7(o)(1), 2.7(o)(3), 2.8(e)(4), 2.9(g), and 3.1 of Appendix A to Part 26. The final rule groups them together in a single paragraph to make them easier to locate within the rule, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

Section 26.717 Fitness-for-Duty Program Performance Data

The NRC has added § 26.717 to the final rule to amend the requirements in former § 26.71(d) for collecting, compiling, and submitting FFD program performance data to reduce the burden on licensees and other entities and to make the reporting time consistent with the NRC's need for the information. Specifically, this paragraph requires licensees and other entities to submit program performance data to the NRC every 12 months, rather than every 6 months. The NRC has made the additional conforming changes described below to former § 26.71 for consistency with other revisions to the rule.

Section 26.717(a) of the final rule retains the requirement in former § 26.71(d) that each FFD program subject to Part 26 must collect and compile FFD performance data.

Section 26.717(b)(1) through (b)(9) of the final rule amends the second sentence of former § 26.71(d). The provision specifies the FFD program performance data that a licensee or other entity must report, including the random testing rate, the drugs for which testing is conducted and their cutoff levels, workforce populations tested, numbers of tests administered and results, conditions under which the tests were performed, substances identified, number of subversion attempts by type, summary of management actions; and the information required under § 26.203(e)(1) and (e)(2). With respect to the proposed rule, the final rule clarifies § 26.717(b)(2) to be consistent with the changes the NRC has made to procedures for dilute specimens, as discussed with regard to § 26.163(a)(2). This paragraph is identical to the requirements of the former provision with two exceptions: (1) the final rule requires reporting the number of subversion attempts by type, and (2) does not require a list of events reported during the reporting period.

Concerning the first exception, the final rule adds a requirement for licensees and other entities to report the number of subversion attempts by type. This new requirement is necessary to enable the NRC to monitor the ongoing integrity and effectiveness of FFD programs in detecting subversion attempts, consistent with the NRC's heightened concern with this issue, as discussed with respect to §§ 26.31(d)(3)(i) and 26.75(b). Although this information is available to NRC inspection personnel at each site, it would be costly and an inefficient use of resources for inspectors to aggregate and report it annually. Under the former rule, licensees typically reported subversion attempts they detected under the requirement to summarize ''events reported'' in former § 26.71(d). Therefore, the NRC expects that the reporting requirement imposes minimal additional burden. The agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Second, the final rule eliminates the former requirement to include the number of events reported to the NRC during the reporting period. The NRC eliminated the former reporting requirement because it has access to this information through other avenues and reporting it twice is unnecessary. Eliminating this requirement meets Goal 5 of the rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

The final rule also adds a requirement in § 26.717(b)(9) that the FFD program performance data must include the information required under § 26.203(e)(1) and (e)(2), which includes (1) a summary of all instances during the past calendar year when certain work hour controls were waived, and (2) a summary of corrective actions taken, resulting from the analysis of the data collected under § 26.203(e), respectively.

Section 26.717(c) of the final rule amends the portions of former § 26.71(d)

that required licensees and other entities to analyze the FFD program performance data semiannually. Instead, this provision requires licensees and other entities to analyze FFD program performance data annually and retains the requirement that actions must be taken to correct program weaknesses. NRC experience in reviewing FFD program performance reports since it first promulgated the rule has shown that reporting twice per year is unnecessary to ensure the continuing effectiveness of FFD programs. Therefore, the final rule relaxes the semiannual analysis and reporting requirement, consistent with Goal 5 of the rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements. Furthermore, the provision requires licensees and other entities to retain for 3 years records of the data, analysis, and corrective actions taken, which is the same as the former requirement in § 26.71(d). However, the rule adds a requirement to retain the documentation until completion of any legal proceedings related to an FFD violation to ensure that the records remain available if an individual, the NRC, a licensee, or another entity who is subject to this rule requires access to them in a legal or regulatory proceeding. The agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.717(d) of the final rule retains the last sentence of former § 26.71(d). The former provision required any licensee who temporarily suspends an individual's authorization or takes administrative actions on the basis of an initial positive marijuana or cocaine drug test result (under the provisions of former § 26.24(d)) to report the results in the annual summary by processing stage (i.e., initial testing at the licensee testing facility, testing at the HHS-certified laboratory, MRO determination). The final rule continues to require that the report include the number of administrative actions taken against individuals for the reporting period. However, the agency has eliminated the term ''temporarily suspend'' from the provision and replaced it with the term ''administratively withdraw authorization,'' in response to stakeholder requests at the public meetings discussed in Section I.D. The stakeholders noted that an individual is either authorized to perform job duties under Part 26 or not, and that the concept of suspending an individual's authorization is conceptually inconsistent. The NRC concurred with this observation and, therefore, has eliminated the inaccurate phrase from the final rule. The agency made this change to meet Goal 6 of the rulemaking relating to improving clarity in the language of the rule.

Section 26.717(e) of the final rule amends portions of former § 26.71(d). It requires licensees and other entities to submit the annual summary to the NRC by March 1 of the following year, rather than the former requirement to provide a semiannual summary within 60 days of the end of each six-month reporting period. The agency made this change for consistency with the requirement in § 26.717(c) to submit the report annually, as discussed with respect to that paragraph, and to meet Goal 5 of the rulemaking to improve Part 26 by eliminating or modifying unnecessary requirements.

Section 26.717(f) of the final rule retains the requirement in former § 26.71(d) that program performance data may be submitted in a consolidated report as long as the data are reported separately for each site.

The NRC has added § 26.717(g) to the final rule to require that C/Vs who maintain an approved drug and alcohol testing program must submit to the NRC the same program performance data that are required from licensees and other entities who are subject to the final rule, either directly or via the licensee or other entity to whom the C/V provides services, ensuring that duplicate reports are not provided to the NRC. This requirement is necessary because the final rule applies directly to C/Vs who maintain licensee-approved programs, rather than applying only to licensees under the former rule, as discussed with respect to § 26.3(d). The agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.719 Reporting Requirements

The NRC has added § 26.719 to the final rule to replace former § 26.73 and combines it with former Section 2.8(e)(4), (e)(5), and (e)(6) in Appendix A to Part 26. The final rule groups into one section reporting requirements that are interspersed throughout the former rule to meet Goal 6 of this rulemaking to improve clarity in the organization and language of the rule.

The NRC added § 26.719(a) to the final rule to introduce the section, consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. This provision specifies the categories of significant events that licensees and other entities must report to the NRC (i.e., significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing). The second sentence of the paragraph retains the requirement in former § 26.73(c) that significant events must be reported under this section, rather than under the provisions of 10 CFR 73.71 [Reporting of safeguards events].

Section 26.719(b) of the final rule reorganizes and amends former § 26.73(a)(1), (a)(2), and (b), consistent with Goal 6 of this rulemaking to improve clarity in the organization and language of the rule. Paragraph 26.719(b) retains the requirement in former § 26.73(b) that notifications of events must be made to the NRC Operations Center within 24 hours of their discovery. However, the final rule presents this requirement at the beginning of the paragraph to clarify that it applies to all of the events that are listed in the paragraph.

Section 26.719(b)(1) amends former § 26.73(a)(1). The former provision required licensees to report the sale, use, or possession of illegal drugs within a protected area. The final rule adds a requirement for licensees and other entities also to report the consumption or presence of alcohol in a protected area. This change is consistent with the NRC's increased concern with the adverse effects of alcohol abuse on safe performance, as discussed with respect to § 26.75(e). The agency has made the change for consistency with the performance objective in § 26.23(d), which is to provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol, as discussed with respect to that paragraph. This change also meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs, as the consumption or presence of alcohol in a protected area constitutes a significant programmatic failure in achieving this performance objective.

Section 26.719(b)(2) amends former § 26.73(a)(2). Former § 26.73(a)(2) required licensees to report any acts by licensed operators and supervisory personnel involving the sale, use, or possession of a controlled substance; resulting in confirmed positive test results for such persons; involving the use of alcohol within the protected area; or resulting in a determination of unfitness for scheduled work because of the consumption of alcohol. The final rule expands the former reporting requirement to include SSNM transporter personnel and FFD program personnel. The NRC has made this

change to ensure that it is informed of events involving these individuals because of the important roles they play in assuring public health and safety and the common defense and security, in the former case, and the integrity of the FFD program, in the latter. The agency's change meets Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.719(b)(2)(i) retains former § 26.73(a)(2)(i). The provision requires licensees and other entities to report any acts by the subject individuals that involve the use, sale, or possession of a controlled substance.

Section 26.719(b)(2)(ii) combines and amends former § 26.73(a)(2)(ii) and (a)(2)(iv). The former section required licensees and other entities to report any confirmed positive test results for such persons and any acts by the subject individuals that result in a determination of unfitness for scheduled work because of the consumption of alcohol, respectively. The final rule amends the former requirements by mandating that licensees and other entities report any acts by the subject individuals that result in a determination that the individual has violated the licensee's or other entity's FFD policy (including subversion as defined in § 26.5 [Definitions]). This change is consistent with two other changes to the rule: (1) the addition of validity testing requirements to the final rule, as discussed with respect to § 26.31(d)(3)(i), and (2) the addition of new requirements in Subpart D [Management Actions and Sanctions to be Imposed] that impose the same sanctions for confirmed positive alcohol test results as those required for confirmed positive drug test results, as discussed with respect to § 26.75(e). Therefore, the final rule requires licensees and other entities to report confirmed positive drug test results, any other acts to subvert or attempt to subvert the testing process, and confirmed positive alcohol test results for these individuals.

Section 26.719(b)(2)(iii) amends former § 26.73(a)(2)(iii). The former provision required licensees and other entities to report any events involving the consumption of alcohol within the protected area by the subject individuals. The final rule adds the requirement to report any acts involving the consumption of alcohol while performing the duties that require these individuals to be subject to this part. This change is consistent with the addition of SSNM transporters and FFD program personnel to this paragraph, as discussed with respect to § 26.719(b)(2), because transporter and FFD program personnel typically do not work within a protected area. However, the NRC maintains an interest in the consumption of alcohol by the individuals listed in § 26.719(b)(2) while they are performing the duties specified in § 26.4 at any location.

Section 26.719(b)(3) establishes a new requirement for licensees and other entities to report any intentional act that casts doubt on the integrity of the FFD program. Because of the wide array of possible acts that could fit this definition and be of concern to the NRC, the final rule does not specify the acts that licensees and other entities must report. However, such intentional acts may include, but are not limited to:

(1) Notifying individuals, outside of the FFD program's normal notification procedures, that they will be selected for random or followup testing on a particular date or at a specific time so that the individuals have sufficient time available to attempt to mask drug use by, for example, obtaining a substitute urine specimen or an adulterant, drinking large amounts of liquid in order to provide a dilute urine specimen, or leaving the site to avoid testing;

(2) Attempting to divert or tamper with urine specimens that are being prepared for transfer to a licensee testing facility or HHS-certified laboratory by stealing the specimens, substituting specimens in the package, or altering the specimens' custody-and-control documentation;

(3) Attempting to tamper with testing instruments so that they provide false negative test results;

(4) Collusion by collection site personnel, an MRO, or MRO staff with an individual who is subject to testing to alter the individual's test results; and

(5) Attempts by information technology personnel to alter the software that the FFD program uses to randomly select individuals for testing to ensure that specific individuals are not selected.

The intentional acts that this final rule requires licensees and other entities to report could involve any aspect of the operations of the FFD program and the testing process.

The final rule adds this reporting requirement because of other changes to the final rule that permit licensees and other entities to rely on other Part 26 programs to a much greater extent than under the former requirement. The final rule permits licensees and other entities to rely on testing performed by another Part 26 program, FFD training, other programs' suitable inquiries and determinations of fitness, and audits. Therefore, intentional acts that cast doubt on the integrity of one FFD program may also indirectly affect the integrity and effectiveness of other FFD programs. The NRC requires reporting of these acts in order to monitor their impacts and ensure that other FFD programs that may be affected are informed of the problem so that they can take corrective actions, if necessary. The agency has made this change to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The NRC has added § 26.719(b)(4) to the final rule to require licensees and other entities to report any programmatic failure, degradation, or discovered vulnerability of an FFD program that may permit undetected drug or alcohol use or abuse by individuals within a protected area, or by individuals who are assigned to perform the duties that require them to be subject to the FFD program. In Item 10.1 of NUREG–1385, ''Fitness for Duty in the Nuclear Power Industry: Responses to Implementation Questions,'' the NRC emphasized that it expects licensees to exercise prudent judgment in determining whether to report unusual situations and that the significant events the licensees must report are not limited to the examples contained in the rule. However, the NRC understands that licensees have not reported many significant events that would be useful for formulating public policy or that the NRC should respond to in a timely fashion because licensee management decided not to do so unless the rule specifically required this reporting. Therefore, this final rule adds § 26.719(b)(4) to clarify that significant events and programmatic failures are not limited to those listed in § 26.719(b), but include any programmatic failures or weaknesses that potentially could permit substance abuse to be undetected. The agency has made this change to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

Section 26.719(c) of the final rule reorganizes and amends former requirements for reporting errors in drug and alcohol testing, consistent with Goal 6 of the rulemaking to improve clarity in the organizational of the rule. The final rule retains the former requirements for licensees and other entities to investigate and take corrective actions for drug and alcohol testing errors in §§ 26.137(f) and 26.167(g) for licensee testing facilities and HHS-certified laboratories, respectively, but moves the reporting requirements to this section.

Section 26.719(c)(1) updates the portion of former § 2.8(e)(4) in Appendix A to Part 26 that mandated that licensees and other entities must report within 30 days of completing an investigation any testing errors or unsatisfactory performance in performance testing at either a licensee testing facility or an HHS-certified laboratory. This section amends the former requirement by specifying that the report of the incident must describe the corrective actions taken or planned. Although licensees and other entities have consistently described corrective actions in such reports, the agency has added this new requirement to meet Goal 6 of the rulemaking to improve clarity in the language of the rule.

In addition, this section adds cross-references to other sections of the final rule that define processes that may also result in the identification of errors, including the reviews required under § 26.39 [Review process for fitness-for-duty policy violations] and § 26.185 [Determining a fitness-for-duty policy violation]. In the original rule, the NRC intended that testing or process errors discovered in any part of the program, including these review processes, would be investigated as an unsatisfactory performance of a test. Thorough investigation and reporting of such test results will continue to assist the NRC, the licensees, HHS, and the HHS-certified laboratories in preventing future occurrences. Therefore, this change, consistent with Goal 6 of the rulemaking to improve clarity in the language of the rule, clarifies that the requirement to investigate, correct, and report errors is not limited only to errors identified through blind performance testing in licensee testing facilities and HHS-certified laboratories but also applies to errors identified through any means.

Section 26.719(c)(2) amends the portion of former Section 2.8(e)(5) in Appendix A to Part 26 that required licensees to promptly notify the NRC if a false positive error occurs on a blind performance test sample. This section replaces the former requirement that the report must be made ''promptly'' with one to report the false positive error within 24 hours of the discovery. The agency has made this change as a result of the public meetings discussed in Section I.D, during which the stakeholders noted that the term ''promptly'' is vague. Therefore, the final rule clarifies the former requirement by establishing a 24-hour time limit for the notification, consistent with Goal 6 of this rulemaking to improve clarity in the language of the rule.

The rule establishes a 24-hour time limit because false positive test results would cause licensees and other entities to impose sanctions on individuals who have not, in fact, abused drugs and/or attempted to subvert the testing process. HHS may decertify a laboratory as a result of false positive test results. The 24-hour time limit ensures that the NRC can quickly notify HHS of the problem so that HHS may initiate the applicable steps required under its guidelines for such circumstances. In addition, the NRC may use the information to inform other licensees and entities who rely on the same HHS-certified laboratory of the problem, so that they may determine whether to require the laboratory or a second laboratory to retest any specimens a licensee or other entity has submitted. The agency has established the 24-hour time limit to meet Goal 7 of the rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

The NRC has added § 26.719(c)(3) to the final rule to require licensees and other entities to report any false negative errors identified through quality assurance checks of validity screening tests within 24 hours of the discovery if the licensee or other entity uses these tests for validity screening at a licensee testing facility. This reporting requirement ensures that the NRC is aware of any testing failures, so that other Part 26 programs that rely on the tests may be informed of the error and stop using them until the cause of the error is identified and the problem is resolved. Continued use of unreliable tests may permit attempts to subvert the testing process to go undetected, with the result that individuals who have engaged in a subversion attempt may be granted or allowed to maintain authorization. The agency has added this requirement to meet Goal 3 of the rulemaking to improve the effectiveness and efficiency of FFD programs.

The final rule does not require licensees and other entities to report false positive errors identified through quality assurance checks of validity screening tests for two reasons. First, other provisions of the rule prohibit licensees and other entities from taking management actions or imposing sanctions on individuals on the basis of validity screening test results, as discussed with respect to § 26.75(h). Second, donors are protected from the adverse consequences of false positive validity screening test results because these specimens are forwarded to an HHS-certified laboratory for initial and confirmatory testing, if required, before a licensee or other entity is permitted to act, as discussed with respect to § 26.137(c). Therefore, reporting of false positive errors is unnecessary to protect the interests of either donors or the public.

The NRC has added § 26.719(d) to the final rule to require licensees and other entities to document, trend, and correct nonreportable FFD issues that identify programmatic weaknesses under the licensee's or other entity's corrective action program. The final rule includes this requirement because some licensees have not documented, trended, or corrected programmatic weaknesses, while others have created separate systems, with the result that corrective actions for FFD program weaknesses have not been timely or effective. Therefore, the final rule adds these requirements for consistency with Criterion XVI in Appendix B to 10 CFR Part 50 [Domestic licensing of production and utilization facilities] and to meet Goal 3 of this rulemaking to improve the effectiveness and efficiency of FFD programs.

This section also requires licensees and other entities to document, trend, and correct any programmatic weaknesses in a manner that protects individuals' privacy. For example, this section prohibits licensees and other entities from documenting a single confirmed positive, adulterated, substituted, or invalid drug test result in the corrective action program, because such documentation, along with other cues in the work environment, may permit any individual who has access to the corrective action system easily to identify the donor. However, under the final rule, the NRC expects licensees and other entities to document, trend, analyze, and take corrective actions for an increase in the rate of confirmed positive, adulterated, substituted, or invalid test results in the aggregate if the licensee or other entity determines that the increasing trend indicates programmatic weaknesses rather than improved effectiveness of the FFD program or some other factor. The agency has added the requirement to protect individuals' privacy within the corrective action program to meet Goal 7 of this rulemaking to protect the privacy and other rights (including due process) of individuals who are subject to Part 26.

Subpart O—Inspections, Violations, and Penalties

As a result of the reorganization of the proposed rule, the provisions contained in Subpart K of the proposed rule have been moved to Subpart O of the final rule. The NRC received no public comment on Subpart O, and the final

rule adopts the provisions in Subpart O as proposed without change.

The NRC added Subpart O to the final rule to combine into one subpart former §§ 26.70 [Inspections], 26.90 [Violations], and 26.91 [Criminal penalties], consistent with Goal 6 of the rulemaking to improve clarity in the organization of the rule, by grouping related sections into one subpart. Section 26.821 [Inspections] retains the requirements in former § 2626.70. Section 26.823 [Violations] retains the requirements in former § 2626.90. Section 26.825 [Criminal penalties] retains the requirements in former § 2626.91.

The NRC has deleted Appendix A to Part 26 ''Guidelines for Drug and Alcohol Testing Programs'' in its entirety and has incorporated its requirements into Subparts E [Collecting Specimens for Testing], F [Licensee Testing Facilities], and G [Laboratories Certified by the Department of Health and Human Services].

VII. Availability of Documents

The NRC is making the documents identified below available to interested persons through one or more of the following methods as indicated.

Public Document Room (PDR). The NRC Public Document Room is located at 11555 Rockville Pike, Rockville, Maryland.

Regulations.gov Web site (Web). The federal government's rulemaking portal is located at *http://www.regulations.gov/.*

NRC's Public Electronic Reading Room (EPDR). The NRC's electronic public reading room is located at *http://www.nrc.gov/reading-rm.html.*

The NRC staff contact. David Diec, Mail Stop O–12D3, Washington, DC 20555–0001, 301–415–2834.

Document	PDR	Web	EPDR	NRC staff
Part 26 Derivation and Distribution Tables	X		ML080570421	X
Comments received	X	NRC_2002_0002		X
Analysis of comments received (when available)	X		X	X
Regulatory Analysis	X		ML080580135	X

VIII. Criminal Penalties

For the purpose of Section 223 of the Atomic Energy Act (AEA), the Commission is amending 10 CFR Part 26 under one or more of Sections 161b, 161i, or 161o of the AEA. Willful violations of the rule are subject to criminal enforcement.

IX. Agreement State Compatibility

Under the ''Policy Statement on Adequacy and Compatibility of Agreement State Programs'' approved by the Commission on June 30, 1997, and published in the **Federal Register** on September 3, 1997 (62 FR 46517), this rule is classified as Compatibility Category ''NRC.'' Compatibility is not required for Category ''NRC'' regulations. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended (AEA), or the provisions of Title 10 of the Code of Federal Regulations. Although an Agreement State may not adopt program elements reserved to the NRC, it may wish to inform its licensees of certain requirements via a mechanism that is consistent with the particular States's administrative procedure laws but does not confer regulatory authority on the State.

X. Plain Language

The Presidential memorandum dated June 1, 1998, entitled ''Plain Language in Government Writing'' directed that the Government's writing be in plain language. This memorandum was published on June 10, 1998 (63 FR 31883). In complying with this directive, editorial changes have been made in these revisions to improve the organization and readability of the former language of the paragraphs being revised.

XI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104–113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. There are no consensus standards regarding the methods for performing drug and alcohol testing, fatigue assessments, or other aspects of FFD programs, that would apply to the requirements imposed by this rule, with the exception of short-term work hour limits for licensed operators, senior operators, and the shift technical advisor. The NRC notes the inclusion of these limits in a 1988 American Nuclear Society standard on administrative controls and quality assurance for the operational phase of nuclear power plants, ANSI/ANS–3.2–1998.

The NRC does not believe that this standard is sufficient, as it does not apply to other categories of workers who would be subject to the provisions of this rule, such as maintenance, health physics, chemistry, fire brigade, and security force personnel. Additionally, the standard is insufficient because it does not provide the comprehensive fatigue management approach that this rule does, and lacks provisions to mitigate long-term fatigue, provide a process for self-declarations of fatigue by workers, and provide for rest breaks.

Further, the standard does not adequately mitigate short-term fatigue, because it does not restrict deviations from the short-term limits to only those unique instances necessary for the safety and security of the plant. The standard only requires that exceptions be minimized and that they be approved by the plant manager or designee. The provisions in the standard are identical to those currently incorporated as requirements in some nuclear power plants' technical specifications. Section IV.D explains that enforcement of the technical specification requirements is complicated by the fact that the language is largely advisory, and key terms have not been defined, with the result that the requirements have been interpreted inconsistently.

For the reasons noted above, the ANS standard cannot be used in lieu of the provisions of this rule to meet the objective of comprehensive fatigue management.

XII. Finding of No Significant Environmental Impact: Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51, that this rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The basis for this determination reads as follows:

The final rule amends the NRC's requirements for FFD programs which are contained in 10 CFR Part 26 to address the following needs: (1) Update and enhance the consistency of 10 CFR Part 26 with advances in other relevant Federal rules and guidelines, including the HHS Guidelines and other Federal drug and alcohol testing programs (e.g., those required by DOT) that impose similar requirements on the private sector; (2) strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue; (3) improve the effectiveness and efficiency of FFD programs; (4) improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003; (5) improve 10 CFR Part 26 by eliminating or modifying unnecessary requirements; (6) improve clarity in the organization and language of the rule; and (7) protect the privacy rights and other rights (including due process) of individuals who are subject to 10 CFR Part 26.

It also grants, in part, a December 30, 1993, petition for rulemaking (PRM–26–1) from Virginia Electric and Power Company (now Dominion Virginia Power) which requested a relaxation in required audit frequencies, and a petition for rulemaking (PRM–26–2), dated December 28, 1999, from Barry Quigley, by establishing clear and enforceable requirements concerning the management of worker fatigue. In addition, the rule continues to apply to all personnel with unescorted access to the protected area of a nuclear power plant, consistent with the Commission's denial (SRM–SECY–04–0229) of an exemption request by IBEW Local 1245 dated March 13, 1990, and renewed on January 26 and December 6, 1993.

This rule does not significantly increase the probability or consequences of an accident. No changes have been made in the types or quantities of radiological effluents that may be released offsite, and there is no significant increase in public or occupational radiation exposure since there is no change to facility operations that could create a new or affect a previously analyzed accident or release path.

With regard to non-radiological impacts, no changes have been made to non-radiological plant effluents and there are no changes in activities that would adversely affect the environment. Therefore, there are no significant non-radiological impacts associated with this action.

The primary alternative to this action is the no action alternative. The no action alternative would result in continued inconsistencies between FFD and access authorization requirements, continued difficulties in implementation of the regulation due to the current organization of the rule, continued use of less current technologies and advances in testing and a continued lack of a comprehensive fatigue management program. The no action alternative would provide little or no safety, risk, or environmental benefit.

No outside agencies or persons were consulted, or outside sources used or relied upon, in the preparation of this environmental assessment. The NRC received no comments on this environmental assessment.

The determination of this environmental assessment is that there will be no significant environmental impact from this action.

XIII. Paperwork Reduction Act Statement

The final rule contains new or amended information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). These requirements were approved by the Office of Management and Budget, approval number 3150–0146.

The burden to the public for these information collections is estimated to average 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the information collection. Send comments on any aspect of these information collections, including suggestions for reducing the burden, to the Records and FOIA/Privacy Services Branch (T–5 F52), U.S. Nuclear Regulatory Commission, Washington DC 20555–0001, or by Internet electronic mail to *INFOCOLLECTS@NRC.GOV;* and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB–10202, (3150–0146), Office of Management and Budget, Washington, DC 20503.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

XIV. Regulatory Analysis

The NRC has prepared a final Regulatory Analysis on this regulation. The final regulatory analysis was prepared under the NRC's Regulatory Analysis Guidelines (RA Guidelines), NUREG/BR–0058, Revision 4, dated September 2004. The Regulatory Analysis consists of three parts. First, an aggregate analysis of the entire rule was performed. Second, a screening review for disaggregation was performed to identify any individual provisions that could impose costs disproportionate to the benefits attributable to each provision. Finally, a separate analysis of the rule's provisions addressing worker fatigue was performed. A description of each of these three elements is discussed below. Single copies may be obtained from the contact listed above under the **FOR FURTHER INFORMATION CONTACT** heading.

A. Aggregate Analysis

Consistent with the RA Guidelines, an aggregate analysis of the entire rulemaking was performed. The provisions of the rule relating to drug and alcohol testing (and other general FFD program requirements) are estimated to result in net present value savings to industry of $129 million–$204 million (using 7 percent and 3 percent real discount rates), consisting of $2 million in one-time costs and $10 million in annual net savings. The worker fatigue portions of the final rule are estimated to cost industry $439 million—$685 million net present value (using the 7 percent and 3 percent real discount rates, respectively), consisting of $12 million in one-time costs and $32 million in annual net costs. The net present value of the entire rule, including both the worker fatigue and drug and alcohol testing portions, is estimated to be a cost to industry of $310 million—$481 million (using 7 percent and 3 percent real discount rates), which consists of $14 million in one-time costs and $22 million in annual costs. In addition, the rule is estimated to be a cost to the NRC of $665,000—$1,025,000 net present value (using 7 percent and 3 percent real discount rates), consisting of $28,000 in one-time costs and $47,000 in annual net costs.

The NRC concludes that the costs of the rule are justified in view of the qualitative benefits evaluated in Section 4.1.2 of the Regulatory Analysis. The basic analysis measures the incremental impacts of the rule relative to a baseline that assumes full licensee compliance

with existing NRC requirements, including current regulations and any relevant orders or enforcement discretion. The aggregate analysis is contained in Section 4.1 of the regulatory analysis.

B. Screening Review for Disaggregation

The regulatory analysis also discusses the screening review for disaggregation performed by the staff. The analysis was performed consistent with Section 4.3.2 of the RA Guidelines to determine if there are provisions whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could obscure their impact, but also responds to the Commission's direction in SRM–01–0134 dated July 23, 2001, that, ''If there is a reasonable indication that a change imposes costs disproportionate to the safety benefit attributable to that change, as part of the final rule package the Commission will perform an analysis of that change in addition to the aggregate analysis of the entire rulemaking to determine whether this change should be aggregated with the other change for the purposes of the backfit analysis. That analysis will need to show that the individual change is integral to achieving the purpose of the rule, has costs that are justified in view of the benefits that would be provided or qualifies for one of the exceptions in 10 CFR § 50.109(a)(4).'' These results are described in Sections 4.1.4.1 and 4.4.2 of the regulatory analysis.

C. Dissaggregation of Worker Fatigue Provisions

Section 4.1.4.2 of the Regulatory Analysis summarizes the division of costs and savings of the fatigue management portions of the rule, in comparison with the rest of the rule. The worker fatigue portions of the rule are estimated to cost industry $439 million—$685 million net present value (using the 7 percent and 3 percent real discount rates, respectively), consisting of $12 million in one-time costs and $32 million in annual net costs. The NRC considers fatigue management to be an integral and necessary aspect of FFD. Fatigue was considered to be part of FFD under former § 26.10(a) and § 26.20(a)(2). However, the NRC included a summary of the costs associated with the fatigue management requirements in the aggregate as a courtesy to stakeholders in Section 4.1.4.2 of the Regulatory Analysis.

XV. Regulatory Flexibility Act Certification

As required by the Regulatory Flexibility Act, as amended, 5 U.S.C. 605(b), the Commission certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule affects only licensees authorized to operate nuclear power reactors; licensees authorized to possess, use, or transport formula quantities of SSNM; corporations who obtain certificates of compliance or approved compliance plans under Part 76 involving formula quantities of SSNM; combined license holders; holders of construction permits; combined license and construction permit holders and combined license and construction permit applicants with authorization to construct; and C/Vs who implement FFD programs or program elements, to the extent that licensees and other entities rely upon those C/V FFD programs or program elements to meet the requirements of Part 26. Those above do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act, or the Size Standards established by the Nuclear Regulatory Commission (10 CFR 2.810).

XVI. Backfit Analysis

The rule constitutes backfitting as defined in 10 CFR 50.109(a)(1). The NRC has performed a backfit analysis, as described in § 50.109(c) [which applies to power reactors], § 70.76(b) [which applies to formula quantity strategic special nuclear material licensees], and § 76.76(b) [which applies to gaseous diffusion plants], consistent with the NRC's Regulatory Analysis Guidelines (RA Guidelines) in NUREG/BR–0058, Revision 4, dated September 2004. The Backfit Analysis is included in the Regulatory Analysis.

A. Consideration of Fuel Fabrication Facilities and Gaseous Diffusion Plants

The backfit provision of 10 CFR 70.76 applies to currently licensed fuel fabrication facilities. Although gas centrifuge facilities are licensed under Part 70, these facilities have not been considered in the analysis because NRC has not granted authorization to possess formula quantities of SSNM at these facilities. These facilities have been considered in the aggregate backfit analysis. The planned mixed-oxide fuel fabrication facility also would be licensed under Part 70, but has not yet submitted a Part 26 program description. Therefore, the consideration of the costs to the mixed-oxide fuel fabrication facility in the regulatory analysis is sufficient for consideration of the impacts to that facility. Although the backfit provision of 10 CFR 76.76 applies to gaseous diffusion plants, there are no backfit impacts because the gaseous diffusion plants certified by the NRC are not currently authorized to possess formula quantities of strategic special nuclear material.

B. Aggregate Backfit Analysis

The NRC performed an aggregate backfit analysis of all backfits consistent with Section 4.3.2 of the RA Guidelines. Because the changes associated with the rule are interrelated and deal with a single subject area (FFD), the NRC followed its ordinary practice of assessing the backfitting implications in an aggregate manner, consistent with the RA Guidelines. The aggregate analysis is provided in Section 4.4.1 of the Part 26 Regulatory Analysis. The aggregate analysis also includes a list of all changes that constitute backfits, in Exhibits 4–14 and 4–15 of the analysis. Exhibit 4–16 of the analysis also includes a list of all changes that were evaluated for potential cost implications, but were determined to not constitute backfits, as well as a list of the reasons those changes were determined to not constitute backfits. In addition, the NRC prepared a supplemental backfit analysis for the requirements in Subpart K of Part 26. A summary of the results of the aggregate analysis follows.

The NRC determined the backfitting is justified under § 50.109(a)(3) and § 70.76(a)(3) because: (1) There is a substantial increase in the overall level of protection afforded for the public health and safety or the common defense and security to be derived from the backfitting; and (2) the costs of implementation and the annual costs are justified in view of this increase. The estimated cost of implementation would be $14 million and the annual net costs would be $42 million, resulting in a net present value cost of $582 million–$911 million (using 7 percent and 3 percent real discount rates, respectively).

In determining that the substantial increase standard is met, the NRC considered safety benefits qualitatively. In this qualitative consideration, the NRC determined that the FFD rule, considered in the aggregate, constitutes a substantial increase in protection to public health and safety by addressing the following six key areas that have been identified as posing recurring and, in some cases, significant problems with respect to the effectiveness, integrity, and efficiency of FFD programs at nuclear facilities.

1. Subversion of the detection/testing process;

2. Regulatory efficiency between 10 CFR Part 26 and other related Federal rules and guidelines;

3. Ineffective/unnecessary FFD requirements;

4. Ambiguous or imprecise regulatory language in 10 CFR Part 26;

5. Technical developments; and

6. FFD program integrity and protection of individual rights.

In addition to the six areas above, the NRC noted in its analysis a significant qualitative benefit in the management of worker fatigue for key personnel at nuclear power plants.

C. Screening Review for Disaggregation

The NRC also performed a screening review, consistent with Section 4.3.2 of the RA Guidelines, to determine if there are provisions constituting backfits whose costs are disproportionate to the benefits and whose inclusion in the aggregate analysis could obscure their impact. The NRC identified 17 backfits with reasonable indications that the costs associated with the backfit may be disproportional to the safety benefit attributable to the change. The NRC determined that all of the 17 backfits were necessary to meet the objectives of the rule. Therefore, the staff did not disaggregate any of those individual provisions and perform a separate backfit analysis for each provision. A detailed discussion of the screening review, including the reasons why each of the 17 backfits were determined to be necessary to meet the objectives of the rule is described in Section 4.4.2 of the Regulatory Analysis.

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''11/07/05 and 11/09/05 Notice Concerning Offsite Public Meetings to Present Purposes of Proposed Rule as Published in **Federal Register** Notice (70 FR 50442), Dated August 26, 2005 on 10 CFR Part 26, Fitness for Duty Programs,'' October, 26, 2005, ML052990048.

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Copies of publicly available reference items are available for inspection and/or copying for a fee in the NRC Public Document Room, One White Flint North, 11555 Rockville Pike, Room O-F21, Rockville, MD 20852–2738. Copyrighted materials may be viewed at the NRC Public Document Room, but may not be copied.

List of Subjects in 10 CFR Part 26

Alcohol abuse, Alcohol testing, Appeals, Chemical testing, Drug abuse, Drug testing, Employee assistance programs, Fitness for duty, Management actions, Nuclear power reactors, Protection of information, Reporting and recordkeeping requirements.

■ For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553; the NRC is revising 10 CFR Part 26.

■ 1. 10 CFR Part 26 is revised to read as follows:

PART 26—FITNESS FOR DUTY PROGRAMS

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Subpart O—Inspections, Violations, and Penalties

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§thnsp;26.823 Violations.
§thnsp;26.825 Criminal penalties.

Authority: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201, 2297f); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

Subpart A—Administrative Provisions

§ 26.1 Purpose.

This part prescribes requirements and standards for the establishment, implementation, and maintenance of fitness-for-duty (FFD) programs.

§ 26.3 Scope.

(a) Licensees who are authorized to operate a nuclear power reactor under 10 CFR 50.57, and holders of a combined license under 10 CFR Part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall comply with the requirements of this part, except for subpart K of this part. Licensees who receive their authorization to operate a nuclear power reactor under 10 CFR 50.57 after the date of publication of this final rule in the **Federal Register** and holders of a combined license under 10 CFR Part 52 after the Commission has made the finding under 10 CFR 52.103(g) shall implement the FFD program before the receipt of special nuclear material in the form of fuel assemblies.

(b) Licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under Part 70 of this chapter, and any corporation, firm, partnership, limited liability company, association, or other organization who obtains a certificate of compliance or an approved compliance plan under Part 76 of this chapter, only if the entity elects to engage in activities involving formula quantities of SSNM shall comply with the requirements of this part, except for subparts I and K of this part.

(c) Before the receipt of special nuclear material in the form of fuel assemblies, the following licensees and other entities shall comply with the requirements of this part, except for subpart I of this part; and, no later than the receipt of special nuclear material in the form of fuel assemblies, the following licensees and other entities shall comply with the requirements of this part:

(1) Combined license applicants (under Part 52 of this chapter) who have been issued a limited work authorization under § 50.10(e), if the limited work authorization authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related structures, systems, and components (SSCs) under the limited work authorization;

(2) Combined license holders (under Part 52 of this chapter) before the Commission has made the finding under § 52.103(g);

(3) Construction permit applicants (under Part 50 of this chapter) who have been issued a limited work authorization under § 50.10(e), if the limited work authorization authorizes the applicant to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the limited work authorization;

(4) Construction permit holders (under Part 50 of this chapter); and

(5) Early site permit holders who have been issued a limited work authorization under § 50.10(e), if the limited work authorization authorizes the early site permit holder to install the foundations, including the placement of concrete, for safety- and security-related SSCs under the limited work authorization.

(d) Contractor/vendors (C/Vs) who implement FFD programs or program elements, to the extent that the licensees and other entities specified in paragraphs (a) through (c) of this section rely on those C/V FFD programs or program elements to meet the requirements of this part, shall comply with the requirements of this part.

(e) This part does not apply to either spent fuel storage facility licensees or non-power reactor licensees who possess, use, or transport formula quantities of irradiated SSNM.

§ 26.4 FFD program applicability to categories of individuals.

(a) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and perform the following duties shall be subject to an FFD program that meets all of the requirements of this part, except subpart K of this part:

(1) Operating or onsite directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety;

(2) Performing health physics or chemistry duties required as a member of the onsite emergency response organization minimum shift complement;

(3) Performing the duties of a fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability;

(4) Performing maintenance or onsite directing of the maintenance of SSCs that a risk-informed evaluation process

has shown to be significant to public health and safety; and

(5) Performing security duties as an armed security force officer, alarm station operator, response team leader, or watchperson, hereinafter referred to as security personnel.

(b) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and who do not perform the duties described in paragraph (a) of this section shall be subject to an FFD program that meets all of the requirements of this part, except §§ 26.205 through 26.209 and subpart K of this part.

(c) All persons who are required by a licensee in § 26.3(a) and, as applicable, (c) to physically report to the licensee's Technical Support Center or Emergency Operations Facility by licensee emergency plans and procedures shall be subject to an FFD program that meets all of the requirement of this part, except §§ 26.205 through 26.209 and subpart K of this part.

(d) Any individual whose duties for the licensees and other entities in § 26.3(b) require him or her to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I and K of this part:

(1) All persons who are granted unescorted access to Category IA material;

(2) All persons who create or have access to procedures or records for safeguarding SSNM;

(3) All persons who measure Category IA material;

(4) All persons who transport or escort Category IA material; and

(5) All persons who guard Category IA material.

(e) When construction activities begin, any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to have the following types of access or perform the following activities at the location where the nuclear power plant will be constructed and operated shall be subject to an FFD program that meets all of the requirements of this part, except subparts I and K of this part:

(1) Serves as security personnel required by the NRC, until the licensees or other entities receive special nuclear material in the form of fuel assemblies, at which time individuals who serve as security personnel required by the NRC must meet the requirements applicable to security personnel in paragraph (a)(5) of this section;

(2) Performs quality assurance, quality control, or quality verification activities related to safety- or security-related construction activities;

(3) Based on a designation under § 26.406 by a licensee or other entity, monitors the fitness of the individuals specified in paragraph (f) of this section;

(4) Witnesses or determines inspections, tests, and analyses certification required under Part 52 of this chapter;

(5) Supervises or manages the construction of safety- or security-related SSCs; or

(6) Directs, as defined in § 26.5, or implements the access authorization program, including—

(i) Having access to the information used by the licensee or other entity to make access authorization determinations, including information stored in electronic format;

(ii) Making access authorization determinations;

(iii) Issuing entry-control picture badges in accordance with access authorization determinations;

(iv) Conducting background investigations or psychological assessments used by the licensee or other entity to make access authorization determinations, except that he or she shall be subject to behavioral observation only when he or she is present at the location where the nuclear power plant will be constructed and operated, and licensees and other entities may rely on a local hospital or other organization that meets the requirements of 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944; August 9, 2001) to collect his or her specimens for drug and alcohol testing;

(v) Adjudicating reviews or appeals of access authorization determinations;

(vi) Auditing the access authorization program; or

(vii) Performing any of the activities or having any of the duties listed in paragraph (e)(6) of this section for any C/V upon whom the licensee's or other entity's access authorization program will rely.

(f) Any individual who is constructing or directing the construction of safety- or security-related SSCs shall be subject to an FFD program that meets the requirements of subpart K of this part, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part, except for subparts I and K of this part.

(g) All FFD program personnel who are involved in the day-to-day operations of the program, as defined by the procedures of the licensees and other entities in § 26.3(a) through (c), and, as applicable, (d), and whose duties require them to have the following types of access or perform the following activities shall be subject to an FFD program that meets all of the requirements of this part, except subparts I and K of this part, and, at the licensee's or other entity's discretion, subpart C of this part:

(1) All persons who can link test results with the individual who was tested before an FFD policy violation determination is made, including, but not limited to the MRO;

(2) All persons who make determinations of fitness;

(3) All persons who make authorization decisions;

(4) All persons involved in selecting or notifying individuals for testing; and

(5) All persons involved in the collection or onsite testing of specimens.

(h) Individuals who have applied for authorization to have the types of access or perform the activities described in paragraphs (a) through (d) of this section shall be subject to §§ 26.31(c)(1), 26.35(b), 26.37, 26.39, and the applicable requirements of subparts C, and E through H of this part.

(i) The following individuals are not subject to an FFD program under this part:

(1) Individuals who are not employed by a licensee or other entity in this part, who do not routinely provide FFD program services to a licensee or other entity in this part, and whose normal workplace is not at the licensee's or other entity's facility, but who may be called on to provide an FFD program service, including, but not limited to, collecting specimens for drug and alcohol testing, performing behavioral observation, or providing input to a determination of fitness. Such individuals may include, but are not limited to, hospital, employee assistance program (EAP) or substance abuse treatment facility personnel, or other medical professionals;

(2) NRC employees, law enforcement personnel, or offsite emergency fire and medical response personnel while responding on site;

(3) SSNM transporter personnel who are subject to U.S. Department of Transportation drug and alcohol FFD programs that require random testing for drugs and alcohol; and

(4) The FFD program personnel of a program that is regulated by another Federal agency or State on which a licensee or other entity relies to meet the requirements of this part, as

permitted under §§ 26.4(j), 26.31(b)(2), and 26.405(e), if the FFD program personnel are not employed by the licensee or other entity and their normal workplace is not at the licensee's or other entity's facility.

(j) Individuals who are subject to this part and who are also subject to a program regulated by another Federal agency or State need be covered by only those elements of an FFD program that are not included in the Federal agency or State program, as long as all of the following conditions are met:

(1) The individuals are subject to pre-access (or pre-employment), random, for-cause, and post-event testing for the drugs and drug metabolites specified in § 26.31(d)(1) at or below the cutoff levels specified in § 26.163(a)(1) for initial drug testing and in § 26.163(b)(1) for confirmatory drug testing;

(2) The individuals are subject to pre-access (or pre-employment), random, for-cause, and post-event testing for alcohol at or below the cutoff levels specified in § 26.103(a) and breath specimens are subject to confirmatory testing, if required, with an EBT that meets the requirements specified in § 26.91;

(3) Urine specimens are tested for validity and the presence of drugs and drug metabolites at a laboratory certified by the Department of Health and Human Services (HHS);

(4) Training is provided to address the knowledge and abilities (KAs) listed in § 26.29(a)(1) through (a)(10); and

(5) Provisions are made to ensure that the testing agency or organization notifies the licensee or other entity granting authorization of any FFD policy violation.

§ 26.5 Definitions.

Acute fatigue means fatigue from causes (e.g., restricted sleep, sustained wakefulness, task demands) occurring within the past 24 hours.

Adulterated specimen means a urine specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent of urine or showing an abnormal concentration of an endogenous substance.

Alertness means the ability to remain awake and sustain attention.

Aliquot means a portion of a specimen that is used for testing. It is taken as a sample representing the whole specimen.

Analytical run means the process of testing a group of urine specimens for validity or for the presence of drugs and/or drug metabolites. For the purposes of defining the periods within which performance testing must be conducted by any licensee testing facility or HHS-certified laboratory that continuously processes specimens, an analytical run is defined as no more than an 8-hour period. For a facility that analyzes specimens in batches, an analytical run is defined as a group of specimens that are handled and tested together.

Authorization means that a licensee or other entity in § 26.3 has determined that an individual has met the requirements of this part to be granted or maintain the types of access or perform the duties specified in § 26.4(a) through (e), and, at the licensee's or other entity's discretion, § 26.4(f) or (g).

Best effort means documented actions that a licensee or other entity who is subject to subpart C of this part takes to obtain suitable inquiry and employment information in order to determine whether an individual may be granted authorization, when the primary source of information refuses or indicates an inability or unwillingness to provide the information within 3 business days of the request and the licensee or other entity relies on a secondary source to meet the requirement.

Blood alcohol concentration (BAC) means the mass of alcohol in a volume of blood.

Calibrator means a solution of known concentration which is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a cutoff concentration and/or a calibration curve over a range of interest.

Category IA material means SSNM that is directly usable in the manufacture of a nuclear explosive device, except if the material meets any of the following criteria:

(1) The dimensions are large enough (at least 2 meters in one dimension, greater than 1 meter in each of two dimensions, or greater than 25 centimeters in each of three dimensions) to preclude hiding the item on an individual;

(2) The total weight of an encapsulated item of SSNM is such that it cannot be carried inconspicuously by one person (i.e., at least 50 kilograms gross weight); or

(3) The quantity of SSNM (less than 0.05 formula kilograms) in each container requires protracted diversions to accumulate 5 formula kilograms.

Chain of custody means procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from the point of specimen collection to final disposition of the specimen and its aliquots. ''Chain of custody'' and ''custody and control'' are synonymous and may be used interchangeably.

Circadian variation in alertness and performance means the increases and decreases in alertness and cognitive/motor functioning caused by human physiological processes (e.g., body temperature, release of hormones) that vary on an approximately 24-hour cycle.

Collection site means a designated place where individuals present themselves for the purpose of providing a specimen of their urine, oral fluids, and/or breath to be analyzed for the presence of drugs or alcohol.

Collector means a person who is trained in the collection procedures of subpart E, instructs and assists a specimen donor at a collection site, and receives and makes an initial examination of the specimen(s) provided by the donor.

Commission means the U.S. Nuclear Regulatory Commission (NRC) or its duly authorized representatives.

Confirmatory drug or alcohol test means a second analytical procedure to identify the presence of alcohol or a specific drug or drug metabolite in a specimen. The purpose of a confirmatory test is to ensure the reliability and accuracy of an initial test result.

Confirmatory validity test means a second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Confirmed test result means a test result that demonstrates that an individual has used drugs and/or alcohol in violation of the requirements of this part or has attempted to subvert the testing process by submitting an adulterated or substituted urine specimen. For drugs, adulterants, and substituted specimens, a confirmed test result is determined by the Medical Review Officer (MRO), after discussion with the donor subsequent to the MRO's receipt of a positive confirmatory drug test result from the HHS-certified laboratory and/or a confirmatory substituted or adulterated validity test result from the HHS-certified laboratory for that donor. For alcohol, a confirmed test result is based on a positive confirmatory alcohol test result from an evidential breath testing device (EBT) without MRO review of the test result.

Constructing or construction activities mean, for the purposes of this part, the tasks involved in building a nuclear power plant that are performed at the location where the nuclear power plant will be constructed and operated. These

tasks include fabricating, erecting, integrating, and testing safety- and security-related SSCs, and the installation of their foundations, including the placement of concrete.

Contractor/vendor (C/V) means any company, or any individual not employed by a licensee or other entity specified in § 26.3(a) through (c), who is providing work or services to a licensee or other entity covered in § 26.3(a) through (c), either by contract, purchase order, oral agreement, or other arrangement.

Control means a sample used to monitor the status of an analysis to maintain its performance within predefined limits.

Cumulative fatigue means the increase in fatigue over consecutive sleep-wake periods resulting from inadequate rest.

Cutoff level means the concentration or decision criteria established for designating and reporting a test result as positive, of questionable validity (referring to validity screening or initial validity test results from a licensee testing facility), or adulterated, substituted, dilute, or invalid (referring to initial or confirmatory test results from an HHS-certified laboratory).

Dilute specimen means a urine specimen with creatinine and specific gravity concentrations that are lower than expected for human urine.

Directing means the exercise of control over a work activity by an individual who is directly involved in the execution of the work activity, and either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity.

Donor means the individual from whom a specimen is collected.

Eight (8)-hour shift schedule means a schedule that averages not more than 9 hours per workday over the entire shift cycle.

Employment action means a change in job responsibilities or removal from a job, or the employer-mandated implementation of a plan for substance abuse treatment in order to avoid a change in or removal from a job, because of the individual's use of drugs or alcohol.

Fatigue means the degradation in an individual's cognitive and motor functioning resulting from inadequate rest.

Formula quantity means SSNM in any combination in a quantity of 5000 grams or more computed by the formula, grams=(grams contained U–235)+2.5 (grams U–233+grams plutonium). This class of material is sometimes referred to as a Category I quantity of material.

HHS-certified laboratory means a laboratory that is certified to perform urine drug testing under the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (the HHS Guidelines), which were published in the **Federal Register** on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13, 1998 (63 FR 63483), and April 13, 2004 (69 FR 19643).

Illegal drug means, for the purposes of this regulation, any drug that is included in Schedules I to V of section 202 of the Controlled Substances Act [21 U.S.C. 812], but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

Increased threat condition means an increase in the protective measure level, relative to the lowest protective measure level applicable to the site during the previous 60 days, as promulgated by an NRC Advisory.

Initial drug test means a test to differentiate ''negative'' specimens from those that require confirmatory drug testing.

Initial validity test means a first test used to determine whether a specimen is adulterated, dilute, substituted, or invalid, and may require confirmatory validity testing.

Invalid result means the result reported by an HHS-certified laboratory for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, contains inconsistent physiological constituents, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

Legal action means a formal action taken by a law enforcement authority or court of law, including an arrest, an indictment, the filing of charges, a conviction, or the mandated implementation of a plan for substance abuse treatment in order to avoid a permanent record of an arrest or conviction, in response to any of the following activities:

(1) The use, sale, or possession of illegal drugs;

(2) The abuse of legal drugs or alcohol; or

(3) The refusal to take a drug or alcohol test.

Licensee testing facility means a drug and specimen validity testing facility that is operated by a licensee or other entity who is subject to this part to perform tests of urine specimens.

Limit of detection (LOD) means the lowest concentration of an analyte that an analytical procedure can reliably detect, which could be significantly lower than the established cutoff levels.

Limit of quantitation (LOQ) means the lowest concentration of an analyte at which the concentration of the analyte can be accurately determined under defined conditions.

Maintenance means, for the purposes of § 26.4(a)(4), the following onsite maintenance activities: Modification, surveillance, post-maintenance testing, and corrective and preventive maintenance.

Medical Review Officer (MRO) means a licensed physician who is responsible for receiving laboratory results generated by a Part 26 drug testing program and who has the appropriate medical training to properly interpret and evaluate an individual's drug and validity test results together with his or her medical history and any other relevant biomedical information.

Nominal means the limited flexibility that is permitted in meeting a scheduled due date for completing a recurrent activity that is required under this part, such as the nominal 12-month frequency required for FFD refresher training in § 26.29(c)(2) and the nominal 12-month frequency required for certain audits in § 26.41(c)(1). Completing a recurrent activity at a nominal frequency means that the activity may be completed within a period that is 25 percent longer or shorter than the period required in this part. The next scheduled due date would be no later than the current scheduled due date plus the required frequency for completing the activity.

Other entity means any corporation, firm, partnership, limited liability company, association, C/V, or other organization who is subject to this part under § 26.3(a) through (c), but is not licensed by the NRC.

Oxidizing adulterant means a substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drugs or drug metabolites, or a substance that affects the reagents in either the initial or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine/iodide, halogens, peroxidase, and peroxide.

Positive result means, for drug testing, the result reported by a licensee testing facility or HHS-certified laboratory when a specimen contains a drug or drug metabolite equal to or greater than the cutoff concentration. A result reported by an HHS-certified laboratory

that a specimen contains a drug or drug metabolite below the cutoff concentration is also a positive result when the laboratory has conducted the special analysis permitted in § 26.163(a)(2). For alcohol testing, a positive result means the result reported by a collection site when the BAC indicated by testing a specimen exceeds the cutoff concentrations established in this part.

Potentially disqualifying FFD information means information demonstrating that an individual has—

(1) Violated a licensee's or other entity's FFD policy;

(2) Had authorization denied or terminated unfavorably under §§ 26.35(c)(2), 26.53(i), 26.63(d), 26.65(g), 26.67(c), 26.69(f), or 26.75(b) through (e);

(3) Used, sold, or possessed illegal drugs;

(4) Abused legal drugs or alcohol;

(5) Subverted or attempted to subvert a drug or alcohol testing program;

(6) Refused to take a drug or alcohol test;

(7) Been subjected to a plan for substance abuse treatment (except for self-referral); or

(8) Had legal action or employment action, as defined in this section, taken for alcohol or drug use.

Protected area has the same meaning as in § 73.2(g) of this chapter: An area encompassed by physical barriers and to which access is controlled.

Quality control sample means a sample used to evaluate whether an analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative samples, and blind samples are collectively referred to as ''quality control samples'' and each is individually referred to as a ''sample.''

Questionable validity means the results of validity screening or initial validity tests at a licensee testing facility indicating that a urine specimen may be adulterated, substituted, dilute, or invalid.

Reviewing official means an employee of a licensee or other entity specified in § 26.3(a) through (c), who is designated by the licensee or other entity to be responsible for reviewing and evaluating any potentially disqualifying FFD information about an individual, including, but not limited to, the results of a determination of fitness, as defined in § 26.189, in order to determine whether the individual may be granted or maintain authorization.

Safety-related structures, systems, and components (SSCs) mean, for the purposes of this part, those structures, systems, and components that are relied on to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, or the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the guidelines in 10 CFR 50.34(a)(1).

Security-related SSCs mean, for the purposes of this part, those structures, systems, and components that the licensee will rely on to implement the licensee's physical security and safeguards contingency plans that either are required under Part 73 of this chapter if the licensee is a construction permit applicant or holder or an early site permit holder, as described in § 26.3(c)(3) through (c)(5), respectively, or are included in the licensee's application if the licensee is a combined license applicant or holder, as described in § 26.3(c)(1) and (c)(2), respectively.

Shift cycle means a series of consecutive work shifts and days off that is planned by the licensee or other entity to repeat regularly, thereby constituting a continuous shift schedule.

Standard means a reference material of known purity or a solution containing a reference material at a known concentration.

Strategic special nuclear material (SSNM) means uranium-235 (contained in uranium enriched to 20 percent or more in the uranium-235 isotope), uranium-233, or plutonium.

Substance abuse means the use, sale, or possession of illegal drugs, or the abuse of prescription and over-the-counter drugs, or the abuse of alcohol.

Substituted specimen means a specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology.

Subversion and subvert the testing process mean a willful act to avoid being tested or to bring about an inaccurate drug or alcohol test result for oneself or others at any stage of the testing process (including selection and notification of individuals for testing, specimen collection, specimen analysis, and test result reporting), and adulterating, substituting, or otherwise causing a specimen to provide an inaccurate test result.

Supervises or manages means the exercise of control over a work activity by an individual who is not directly involved in the execution of the work activity, but who either makes technical decisions for that activity without subsequent technical review, or is ultimately responsible for the correct performance of that work activity.

Ten (10)-hour shift schedule means a schedule that averages more than 9 hours, but not more than 11 hours, per workday over the entire shift cycle.

Transporter means a general licensee, under 10 CFR 70.20(a), who is authorized to possess formula quantities of SSNM, in the regular course of carriage for another or storage incident thereto, and includes the driver or operator of any conveyance, and the accompanying guards or escorts.

Twelve (12)-hour shift schedule means a schedule that averages more than 11 hours, but not more than 12 hours, per workday over the entire shift cycle.

Unit outage means, for the purposes of this part, that the reactor unit is disconnected from the electrical grid.

Validity screening test means a test to determine the need for initial validity testing of a urine specimen, using a non-instrumented test in which the endpoint result is obtained by visual evaluation (read by the human eye), or a test that is instrumented to the extent that results are machine-read.

Validity screening test lot means a group of validity screening tests that were made from the same starting material.

§ 26.7 Interpretations.

Except as specifically authorized by the Commission in writing, no interpretation of the meaning of the regulations in this part by any officer or employee of the Commission other than a written interpretation by the General Counsel will be recognized to be binding on the Commission.

§ 26.8 Information collection requirements: OMB approval.

(a) The NRC has submitted the information collection requirements contained in this part for approval by the Office of Management and Budget (OMB), as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC 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. OMB has approved the information collection requirements contained in this part under control number 3150–0146.

(b) The approved information collection requirements contained in this part appear in §§ 26.9, 26.27, 26.29, 26.31, 26.33, 26.35, 26.37, 26.39, 26.41, 26.53, 26.55, 26.57, 26.59, 26.61, 26.63, 26.65, 26.67, 26.69, 26.75, 26.77, 26.85, 26.87, 26.89, 26.91, 26.93, 26.95, 26.97, 26.99, 26.101, 26.103, 26.107, 26.109,

26.111, 26.113, 26.115, 26.117, 26.119, 26.125, 26.127, 26.129, 26.135, 26.137, 26.139, 26.153, 26.155, 26.157, 26.159, 26.163, 26.165, 26.167, 26.168, 26.169, 26.183, 26.185, 26.187, 26.189, 26.203, 26.205, 26.207, 26.211, 26.401, 26.403, 26.405, 26.406, 26.407, 26.411, 26.413, 26.415, 26.417, 26.711, 26.713, 26.715, 26.717, 26.719, and 26.821.

§ 26.9 Specific exemptions.

Upon application of any interested person or on its own initiative, the Commission may grant such exemptions from the requirements of the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

§ 26.11 Communications.

Except where otherwise specified in this part, all communications, applications, and reports concerning the regulations in this part must be sent either by mail addressed to ATTN: NRC Document Control Desk, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; by hand delivery to the NRC's offices at 11555 Rockville Pike, Rockville, Maryland, between the hours of 8:15 a.m. and 4 p.m. eastern time; or, where practicable, by electronic submission, for example, via Electronic Information Exchange, e-mail, or CD-ROM. Electronic submissions must be made in a manner that enables the NRC to receive, read, authenticate, distribute, and archive the submission, and process and retrieve it a single page at a time. Detailed guidance on making electronic submissions can be obtained by visiting the NRC's Web site at *http://www.nrc.gov/site-help/eie.html,* by calling (301) 415–6030, by e-mail to *EIE@nrc.gov,* or by writing to the Office of Information Services, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The guidance discusses, among other topics, the formats the NRC can accept, the use of electronic signatures, and the treatment of nonpublic information. Copies of all communications must be sent to the appropriate regional office and resident inspector (addresses for the NRC Regional Offices are listed in Appendix D to Part 20 of this chapter).

Subpart B—Program Elements

§ 26.21 Fitness-for-duty program.

The licensees and other entities specified in § 26.3(a) through (c) shall establish, implement, and maintain FFD programs that, at a minimum, comprise the program elements contained in this subpart. The individuals specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f), and, if necessary, § 26.4(j) shall be subject to these FFD programs. Licensees and other entities may rely on the FFD program or program elements of a C/V, as defined in § 26.5, if the C/V's FFD program or program elements meet the applicable requirements of this part.

§ 26.23 Performance objectives.

Fitness-for-duty programs must—

(a) Provide reasonable assurance that individuals are trustworthy and reliable as demonstrated by the avoidance of substance abuse;

(b) Provide reasonable assurance that individuals are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

(c) Provide reasonable measures for the early detection of individuals who are not fit to perform the duties that require them to be subject to the FFD program;

(d) Provide reasonable assurance that the workplaces subject to this part are free from the presence and effects of illegal drugs and alcohol; and

(e) Provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.

§ 26.25 [Reserved]

§ 26.27 Written policy and procedures.

(a) *General.* Each licensee and other entity shall establish, implement, and maintain written policies and procedures to meet the general performance objectives and applicable requirements of this part.

(b) *Policy.* The FFD policy statement must be clear, concise, and readily available, in its most current form, to all individuals who are subject to the policy. Methods of making the statement readily available include, but are not limited to, posting the policy in multiple work areas, providing individuals with brochures, or allowing individuals to print the policy from a computer. The policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy. At a minimum, the written policy statement must—

(1) Describe the consequences of the following actions:

(i) The use, sale, or possession of illegal drugs on or off site;

(ii) The abuse of legal drugs and alcohol; and

(iii) The misuse of prescription and over-the-counter drugs;

(2) Describe the requirement that individuals who are notified that they have been selected for random testing must report to the collection site within the time period specified by the licensee or other entity;

(3) Describe the actions that constitute a refusal to provide a specimen for testing, the consequences of a refusal to test, as well as the consequences of subverting or attempting to subvert the testing process;

(4) Prohibit the consumption of alcohol, at a minimum—

(i) Within an abstinence period of 5 hours preceding the individual's arrival at the licensee's or other entity's facility, except as permitted in § 26.27(c)(3); and

(ii) During the period of any tour of duty;

(5) Convey that abstinence from alcohol for the 5 hours preceding any scheduled tour of duty is considered to be a minimum that is necessary, but may not be sufficient, to ensure that the individual is fit for duty;

(6) Address other factors that could affect FFD, such as mental stress, fatigue, or illness, and the use of prescription and over-the-counter medications that could cause impairment;

(7) Provide a description of any program that is available to individuals who are seeking assistance in dealing with drug, alcohol, fatigue, or other problems that could adversely affect an individual's ability to safely and competently perform the duties that require an individual to be subject to this subpart;

(8) Describe the consequences of violating the policy;

(9) Describe the individual's responsibility to report legal actions, as defined in § 26.5;

(10) Describe the responsibilities of managers, supervisors, and escorts to report FFD concerns; and

(11) Describe the individual's responsibility to report FFD concerns.

(c) *Procedures.* Each licensee and other entity shall prepare, implement, and maintain written procedures that describe the methods to be used in implementing the FFD policy and the requirements of this part. The procedures must—

(1) Describe the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy and other rights (including due process) of an individual who provides a specimen, procedures for protecting the integrity of

the specimen, and procedures used to ensure that the test results are valid and attributable to the correct individual;

(2) Describe immediate and followup actions that will be taken, and the procedures to be used, in those cases in which individuals are determined to have—

(i) Been involved in the use, sale, or possession of illegal drugs;

(ii) Consumed alcohol to excess before the mandatory pre-work abstinence period, or consumed any alcohol during the mandatory pre-work abstinence period or while on duty, as determined by a test that measures BAC;

(iii) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means;

(iv) Refused to provide a specimen for analysis; or

(v) Had legal action taken relating to drug or alcohol use, as defined in § 26.5;

(3) Describe the process that the licensee or other entity will use to ensure that individuals who are called in to perform an unscheduled working tour are fit for duty. At a minimum—

(i) The procedure must require the individual who is called in to state whether the individual considers himself or herself fit for duty and whether he or she has consumed alcohol within the pre-duty abstinence period stated in the policy;

(ii) If the individual has consumed alcohol within this period and the individual is called in for an unscheduled working tour, including an unscheduled working tour to respond to an emergency, the procedure must—

(A) Require a determination of fitness by breath alcohol analysis or other means;

(B) Permit the licensee or other entity to assign the individual to duties that require him or her to be subject to this subpart, if the results of the determination of fitness indicate that the individual is fit to safely and competently perform his or her duties;

(C) Prohibit the licensee or other entity from assigning the individual to duties that require him or her to be subject to this subpart, if the individual is not required to respond to an emergency and the results of the determination of fitness indicate that the individual may be impaired;

(D) State that consumption of alcohol during the 5-hour abstinence period required in paragraph (b)(4)(i) of this section may not by itself preclude a licensee or other entity from using individuals who are needed to respond to an emergency. However, if the determination of fitness indicates that an individual who has been called in for an unscheduled working tour to respond to an emergency may be impaired, the procedure must require the establishment of controls and conditions under which the individual who has been called in can perform work, if necessary; and

(E) State that no sanctions may be imposed on an individual who is called in to perform any unscheduled working tour for having consumed alcohol within the pre-duty abstinence period stated in the policy.

(iii) If the individual reports that he or she considers himself or herself to be unfit for duty for other reasons, including illness, fatigue, or other potentially impairing conditions, and the individual is called in, the procedure must require the establishment of controls and conditions under which the individual can perform work, if necessary;

(4) Describe the process to be followed if an individual's behavior raises a concern regarding the possible use, sale, or possession of illegal drugs on or off site; the possible possession or consumption of alcohol on site; or impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her duties. The procedure must require that individuals who have an FFD concern about another individual's behavior shall contact the personnel designated in the procedures to report the concern.

(d) *Review.* The NRC may, at any time, review the written policy and procedures to assure that they meet the performance objectives and requirements of this part.

§ 26.29 Training.

(a) *Training content.* Licensees and other entities shall ensure that the individuals who are subject to this subpart have the following KAs:

(1) Knowledge of the policy and procedures that apply to the individual, the methods that will be used to implement them, and the consequences of violating the policy and procedures;

(2) Knowledge of the individual's role and responsibilities under the FFD program;

(3) Knowledge of the roles and responsibilities of others, such as the MRO and the human resources, FFD, and EAP staffs;

(4) Knowledge of the EAP services available to the individual;

(5) Knowledge of the personal and public health and safety hazards associated with abuse of illegal and legal drugs and alcohol;

(6) Knowledge of the potential adverse effects on job performance of prescription and over-the-counter drugs, alcohol, dietary factors, illness, mental stress, and fatigue;

(7) Knowledge of the prescription and over-the-counter drugs and dietary factors that have the potential to affect drug and alcohol test results;

(8) Ability to recognize illegal drugs and indications of the illegal use, sale, or possession of drugs;

(9) Ability to observe and detect performance degradation, indications of impairment, or behavioral changes; and

(10) Knowledge of the individual's responsibility to report an FFD concern and the ability to initiate appropriate actions, including referrals to the EAP and person(s) designated by the licensee or other entity to receive FFD concerns.

(b) *Comprehensive examination.* Individuals who are subject to this subpart shall demonstrate the successful completion of training by passing a comprehensive examination that addresses the KAs in paragraph (a) of this section. The examination must include a comprehensive random sampling of all KAs with questions that test each KA, including at least one question for each KA. The minimum passing score required must be 80 percent. Remedial training and testing are required for individuals who fail to answer correctly at least 80 percent of the test questions. The examination may be administered using a variety of media, including, but not limited to, hard-copy test booklets with separate answer sheets or computer-based questions.

(c) *Training administration.* Licensees and other entities shall ensure that individuals who are subject to this subpart are trained, as follows:

(1) Training must be completed before the licensee or other entity grants initial authorization, as defined in § 26.55, and must be current before the licensee or other entity grants an authorization update, as defined in § 26.57, or authorization reinstatement, as defined in § 26.59;

(2) Individuals shall complete refresher training on a nominal 12-month frequency, or more frequently where the need is indicated. Indications of the need for more frequent training include, but are not limited to, an individual's failure to properly implement FFD program procedures and the frequency, nature, or severity of problems discovered through audits or the administration of the program. Individuals who pass a comprehensive annual examination that meets the requirements in paragraph (b) of this

section may forgo the refresher training; and

(3) Initial and refresher training may be delivered using a variety of media (including, but not limited to, classroom lectures, required reading, video, or computer-based training systems). The licensee or other entity shall monitor the completion of training and provide a qualified instructor or designated subject matter expert to answer questions during the course of training.

(d) *Acceptance of training.* Licensees and other entities may accept training of individuals who have been subject to another training program that meets the requirements of this section and who have, within the past 12 months, either had initial or refresher training, or have successfully passed a comprehensive examination that meets the requirements in paragraph (b) of this section.

§ 26.31 Drug and alcohol testing.

(a) *General.* To provide a means to deter and detect substance abuse, licensees and other entities who are subject to this part shall implement drug and alcohol testing programs for individuals who are subject to this subpart.

(b) *Assuring the honesty and integrity of FFD program personnel.* (1) Licensees and other entities who are subject to this subpart shall carefully select and monitor FFD program personnel, as defined in § 26.4(g), based on the highest standards of honesty and integrity, and shall implement measures to ensure that these standards are maintained. The measures must ensure that the honesty and integrity of these individuals are not compromised and that FFD program personnel are not subject to influence attempts attributable to personal relationships with any individuals who are subject to testing, an undetected or untreated substance abuse problem, or other factors. At a minimum, these measures must include the following considerations:

(i) Licensees and other entities shall complete appropriate background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel before assignment to tasks directly associated with administration of the FFD program. The background investigations, credit and criminal history checks, and psychological assessments that are conducted to grant unescorted access authorization to individuals under a nuclear power plant licensee's access authorization program are acceptable to meet the requirements of this paragraph. The credit and criminal history checks and psychological assessments must be updated nominally every 5 years;

(ii) Individuals who have personal relationships with a donor may not perform any assessment or evaluation procedures, including, but not limited to, determinations of fitness. These personal relationships may include, but are not limited to, supervisors, coworkers within the same work group, and relatives of the donor;

(iii) Except if a directly observed collection is required, a collector who has a personal relationship with the donor may collect specimens from the donor only if the integrity of specimen collections in these instances is assured through the following means:

(A) The collection must be monitored by an individual who does not have a personal relationship with the donor and who is designated by the licensee or other entity for this purpose, including, but not limited to, security force or quality assurance personnel; and

(B) Individuals who are designated to monitor collections in these instances shall be trained to monitor specimen collections and the preparation of specimens for transfer or shipping under the requirements of this part;

(iv) If a specimen must be collected under direct observation, the collector or an individual who serves as the observer, as permitted under § 26.115(e), may not have a personal relationship with the donor; and

(v) FFD program personnel shall be subject to a behavioral observation program designed to assure that they continue to meet the highest standards of honesty and integrity. When an MRO and MRO staff are on site at a licensee's or other entity's facility, the MRO and MRO staff shall be subject to behavioral observation.

(2) Licensees and other entities may rely on a local hospital or other organization that meets the requirements of 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944; August 9, 2001) to collect specimens for drug and alcohol testing from the FFD program personnel listed in § 26.4(g).

(c) *Conditions for testing.* Licensees and other entities shall administer drug and alcohol tests to the individuals who are subject to this subpart under the following conditions:

(1) *Pre-access.* In order to grant initial, updated, or reinstated authorization to an individual, as specified in subpart C of this part;

(2) *For cause.* In response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse, as defined in § 26.5;

(3) *Post-event.* As soon as practical after an event involving a human error that was committed by an individual who is subject to this subpart, where the human error may have caused or contributed to the event. The licensee or other entity shall test the individual(s) who committed the error(s), and need not test individuals who were affected by the event whose actions likely did not cause or contribute to the event. The individual(s) who committed the human error(s) shall be tested if the event resulted in—

(i) A significant illness or personal injury to the individual to be tested or another individual, which within 4 hours after the event is recordable under the Department of Labor standards contained in 29 CFR 1904.7, ''General Recording Criteria,'' and subsequent amendments thereto, and results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury as diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness;

(ii) A radiation exposure or release of radioactivity in excess of regulatory limits; or

(iii) Actual or potential substantial degradations of the level of safety of the plant;

(4) Followup. As part of a followup plan to verify an individual's continued abstinence from substance abuse; and

(5) Random. On a statistically random and unannounced basis, so that all individuals in the population subject to testing have an equal probability of being selected and tested.

(d) *General requirements for drug and alcohol testing.* (1) Substances tested. At a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol.

(i) In addition, licensees and other entities may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other drugs with abuse potential are being used in the

geographical locale of the facility and by the local workforce that may not be detected in the panel of drugs and drug metabolites specified in paragraph (d)(1) of this section.

(A) When appropriate, the licensee or other entity may add other drugs identified under paragraph (d)(1)(i) of this section to the panel of substances for testing, but only if the additional drugs are listed in Schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. 812].

(B) The licensee or other entity shall establish appropriate cutoff limits for these substances.

(C) The licensee or other entity shall establish rigorous testing procedures for these substances that are consistent with the intent of this part, so that the MRO can evaluate the use of these substances.

(D) The licensee or other entity may not conduct an analysis for any drug or drug metabolites except those identified in paragraph (d)(1) of this section unless the assay and cutoff levels to be used are certified in writing as scientifically sound and legally defensible by an independent, qualified forensic toxicologist who has no relationships with manufacturers of the assays or instruments to be used or the HHS-certified laboratory that will conduct the testing for the licensee or other entity, which could be construed as a potential conflict of interest. The forensic toxicologist may not be an employee of the licensee or entity, and shall either be a Diplomate of the American Board of Forensic Toxicology or currently holds, has held, or is eligible to hold, the position of Responsible Person at an HHS-certified laboratory, as specified in § 26.155(a). All new assays and cutoff levels must be properly validated consistent with established forensic toxicological standards before implementation. Certification of the assay and cutoff levels is not required if the HHS Guidelines are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for the drug or drug metabolites, or if the licensee or other entity received written approval of the NRC to test for the additional drug or drug metabolites before April 30, 2008.

(ii) When conducting post-event, followup, and for-cause testing, as defined in § 26.31(c), licensees and other entities may test for any drugs listed on Schedules I through V of section 202 of the Controlled Substances Act [21 U.S.C. 812] that an individual is suspected of having abused, and may consider any drugs or metabolites so detected when determining appropriate action under subpart D of this part. If the drug or metabolites for which testing will be performed under this paragraph are not included in the FFD program's drug panel, the assay and cutoff levels to be used in testing for the additional drugs must be certified by a forensic toxicologist under paragraph (d)(1)(i)(D) of this section. Test results that fall below the established cutoff levels may not be considered when determining appropriate action under subpart D of this part, except if the specimen is dilute and the licensee or other entity has requested the HHS-certified laboratory to evaluate the specimen under §§ 26.163(a)(2) or 26.185(g)(3).

(iii) The licensee or other entity shall document the additional drug(s) for which testing will be performed in written policies and procedures in which the substances for which testing will be performed are described.

(2) *Random testing.* Random testing must—

(i) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected. At a minimum, the FFD program shall—

(A) Take reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period or create the appearance that specimens are being collected during a portion of each day on at least 4 days in each calendar week at each site. In the latter instance, the portions of each day and the days of the week must vary in a manner that cannot be predicted by donors; and

(B) Collect specimens on an unpredictable schedule, including weekends, backshifts, and holidays, and at various times during a shift;

(ii) At a minimum, be administered by the FFD program on a nominal weekly frequency;

(iii) Require individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program policy;

(iv) Ensure that all individuals in the population subject to testing have an equal probability of being selected and tested;

(v) Require that individuals who are off site when selected for testing, or who are on site and are not reasonably available for testing when selected, shall be tested at the earliest reasonable and practical opportunity when both the donor and collectors are available to collect specimens for testing and without prior notification to the individual that he or she has been selected for testing;

(vi) Provide that an individual completing a test is immediately eligible for another unannounced test; and

(vii) Ensure that the sampling process used to select individuals for random testing provides that the number of random tests performed annually is equal to at least 50 percent of the population that is subject to the FFD program.

(3) *Drug testing.* (i) Testing of urine specimens for drugs and validity, except validity screening and initial drug and validity tests performed by licensee testing facilities under paragraph (d)(3)(ii) of this section, must be performed in a laboratory that is certified by HHS for that purpose, consistent with its standards and procedures for certification. Specimens sent to HHS-certified laboratories must be subject to initial validity and initial drug testing by the laboratory. Specimens that yield positive initial drug test results or are determined by initial validity testing to be of questionable validity must be subject to confirmatory testing by the laboratory, except for invalid specimens that cannot be tested. Licensees and other entities shall ensure that laboratories report results for all specimens sent for testing, including blind performance test samples.

(ii) Licensees and other entities may conduct validity screening, initial validity, and initial drug tests of urine aliquots to determine which specimens are valid and negative and need no further testing, provided that the licensee's or other entity's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented.

(iii) At a minimum, licensees and other entities shall apply the cutoff levels specified in § 26.163(a)(1) for initial drug testing at either the licensee testing facility or HHS-certified laboratory, and in § 26.163(b)(1) for confirmatory drug testing at the HHS-certified laboratory. At their discretion, licensees and other entities may implement programs with lower cutoff levels in testing for drugs and drug metabolites.

(A) If a licensee or other entity implements lower cutoff levels, and the MRO determines that an individual has violated the FFD policy using the licensee's or other entity's more stringent cutoff levels, the individual shall be subject to all management actions and sanctions required by the licensee's or other entity's FFD policy

and this part, as if the individual had a confirmed positive drug test result using the cutoff levels specified in this subpart. The licensee or other entity shall document the more stringent cutoff levels in any written policies and procedures in which cutoff levels for drug testing are described.

(B) The licensee or other entity shall uniformly apply the cutoff levels listed in § 26.163(a)(1) for initial drug testing and in § 26.163(b)(1) for confirmatory drug testing, or any more stringent cutoff levels implemented by the FFD program, to all tests performed under this part and equally to all individuals who are tested under this part, except as permitted in §§ 26.31(d)(1)(ii), 26.163(a)(2), and 26.165(c)(2).

(C) In addition, the scientific and technical suitability of any more stringent cutoff levels must be evaluated and certified, in writing, by a forensic toxicologist who meets the requirements set forth in § 26.31(d)(1)(i)(D). Certification of the more stringent cutoff levels is not required if the HHS Guidelines are revised to lower the cutoff levels for the drug or drug metabolites in Federal workplace drug testing programs and the licensee or other entity implements the cutoff levels published in the HHS Guidelines, or if the licensee or other entity received written approval of the NRC to test for lower cutoff levels before April 30, 2008.

(4) *Alcohol testing.* Initial tests for alcohol must be administered by breath or oral fluids analysis using alcohol analysis devices that meet the requirements of § 26.91(a). If the initial test shows a BAC of 0.02 percent or greater, a confirmatory test for alcohol must be performed. The confirmatory test must be performed with an EBT that meets the requirements of § 26.91(b).

(5) *Medical conditions.* (i) If an individual has a medical condition that makes collection of breath, oral fluids, or urine specimens difficult or hazardous, the MRO may authorize an alternative evaluation process, tailored to the individual case, to meet the requirements of this part for drug and alcohol testing. The alternative process must include measures to prevent subversion and achieve results that are comparable to those produced by urinalysis for drugs and breath analysis for alcohol.

(ii) If an individual requires medical attention, including, but not limited to, an injured worker in an emergency medical facility who is required to have a post-event test, treatment may not be delayed to conduct drug and alcohol testing.

(6) *Limitations of testing.* Specimens collected under NRC regulations may only be designated or approved for testing as described in this part and may not be used to conduct any other analysis or test without the written permission of the donor. Analyses and tests that may not be conducted include, but are not limited to, DNA testing, serological typing, or any other medical or genetic test used for diagnostic or specimen identification purposes.

§ 26.33 Behavioral observation.

Licensees and other entities shall ensure that the individuals who are subject to this subpart are subject to behavioral observation. Behavioral observation must be performed by individuals who are trained under § 26.29 to detect behaviors that may indicate possible use, sale, or possession of illegal drugs; use or possession of alcohol on site or while on duty; or impairment from fatigue or any cause that, if left unattended, may constitute a risk to public health and safety or the common defense and security. Individuals who are subject to this subpart shall report any FFD concerns about other individuals to the personnel designated in the FFD policy.

§ 26.35 Employee assistance programs.

(a) Each licensee and other entity who is subject to this part shall maintain an EAP to strengthen the FFD program by offering confidential assessment, short-term counseling, referral services, and treatment monitoring to individuals who have problems that could adversely affect the individuals' abilities to safely and competently perform their duties. Employee assistance programs must be designed to achieve early intervention and provide for confidential assistance.

(b) Licensees and other entities need not provide EAP services to a C/V's employees, including those whose work location is a licensee's or other entity's facility, or to individuals who have applied for, but have not yet been granted, authorization under subpart C of this part.

(c) The EAP staff shall protect the identity and privacy of any individual (including those who have self-referred) seeking assistance from the EAP, except if the individual waives the right to privacy in writing or a determination is made that the individual's condition or actions pose or have posed an immediate hazard to himself or herself or others.

(1) Licensees and other entities may not require the EAP to routinely report the names of individuals who self-refer to the EAP or the nature of the assistance the individuals sought.

(2) If EAP personnel determine that an individual poses or has posed an immediate hazard to himself or herself or others, EAP personnel shall so inform FFD program management, and need not obtain a written waiver of the right to privacy from the individual. The individual conditions or actions that EAP personnel shall report to FFD program management include, but are not limited to, substantive reasons to believe that the individual—

(i) Is likely to commit self-harm or harm to others;

(ii) Has been impaired from using drugs or alcohol while in a work status and has a continuing substance abuse disorder that makes it likely he or she will be impaired while in a work status in the future; or

(iii) Has ever engaged in any acts that would be reportable under § 26.719(b)(1) through (b)(3).

(3) If a licensee or other entity receives a report from EAP personnel under paragraph (c)(2) of this section, the licensee or other entity shall ensure that the requirements of §§ 26.69(d) and 26.77(b) are implemented, as applicable.

§ 26.37 Protection of information.

(a) Each licensee or other entity who is subject to this subpart who collects personal information about an individual for the purpose of complying with this part, shall establish, use, and maintain a system of files and procedures that protects the individual's privacy.

(b) Licensees and other entities shall obtain a signed consent that authorizes the disclosure of the personal information collected and maintained under this part before disclosing the personal information, except for disclosures to the following individuals:

(1) The subject individual or his or her representative, when the individual has designated the representative in writing for specified FFD matters;

(2) Assigned MROs and MRO staff;

(3) NRC representatives;

(4) Appropriate law enforcement officials under court order;

(5) A licensee's or other entity's representatives who have a need to have access to the information to perform their assigned duties under the FFD program, including determinations of fitness, FFD program audits, or some human resources functions;

(6) The presiding officer in a judicial or administrative proceeding that is initiated by the subject individual;

(7) Persons deciding matters under review in § 26.39; and

(8) Other persons pursuant to court order.

(c) Personal information that is collected under this subpart must be

disclosed to other licensees and entities, including C/Vs, or their authorized representatives, who are legitimately seeking the information for authorization decisions as required by this part and who have obtained a signed release from the subject individual.

(d) Upon receipt of a written request by the subject individual or his or her designated representative, the FFD program, including but not limited to, the collection site, HHS-certified laboratory, substance abuse expert (SAE), or MRO, possessing such records shall promptly provide copies of all FFD records pertaining to the individual, including, but not limited to, records pertaining to a determination that the individual has violated the FFD policy, drug and alcohol test results, MRO reviews, determinations of fitness, and management actions pertaining to the subject individual. The licensee or other entity shall obtain records related to the results of any relevant laboratory certification, review, or revocation-of-certification proceedings from the HHS-certified laboratory and provide them to the subject individual on request.

(e) A licensee's or other entity's contracts with HHS-certified laboratories and C/Vs providing specimen collection services, and licensee testing facility procedures, must require test records to be maintained in confidence, except as provided in paragraphs (b), (c), and (d) of this section.

(f) This section does not authorize the licensee or other entity to withhold evidence of criminal conduct from law enforcement officials.

§ 26.39 Review process for fitness-for-duty policy violations.

(a) Each licensee and other entity who is subject to this subpart shall establish procedures for the review of a determination that an individual who they employ or who has applied for authorization has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy.

(b) The procedure must provide notice to the individual of the grounds for the determination that the individual has violated the FFD policy, and must provide an opportunity for the individual to respond and submit additional relevant information.

(c) The procedure must ensure that the individual who conducts the review is not associated with the administration of the FFD program [see the description of FFD program personnel in § 26.4(g)]. Individuals who conduct the review may be management personnel.

(d) If the review finds in favor of the individual, the licensee or other entity shall update the relevant records to reflect the outcome of the review and delete or correct all information the review found to be inaccurate.

(e) When a C/V is administering an FFD program on which licensees and other entities rely, and the C/V determines that its employee, subcontractor, or applicant has violated its FFD policy, the C/V shall ensure that the review procedure required in this section is provided to the individual. Licensees and other entities who rely on a C/V's FFD program need not provide the review procedure required in this section to a C/V's employee, subcontractor, or applicant when the C/V is administering its own FFD program and the FFD policy violation was determined under the C/V's program.

§ 26.41 Audits and corrective action.

(a) *General.* Each licensee and other entity who is subject to this subpart is responsible for the continuing effectiveness of the FFD program, including FFD program elements that are provided by C/Vs, the FFD programs of any C/Vs that are accepted by the licensee or other entity, any FFD program services that are provided to the C/V by a subcontractor, and the programs of the HHS-certified laboratories on whom the licensee or other entity and its C/Vs rely. Each licensee and other entity shall ensure that these programs are audited and that corrective actions are taken to resolve any problems identified.

(b) *FFD program.* Each licensee and other entity who is subject to this subpart shall ensure that the entire FFD program is audited as needed, but no less frequently than nominally every 24 months. Licensees and other entities are responsible for determining the appropriate frequency, scope, and depth of additional auditing activities within the nominal 24-month period based on the review of FFD program performance, including, but not limited to, the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, and previous audit findings.

(c) *C/Vs and HHS-certified laboratories.* (1) FFD services that are provided to a licensee or other entity by C/V personnel who are off site or are not under the direct daily supervision or observation of the licensee's or other entity's personnel and HHS-certified laboratories must be audited on a nominal 12-month frequency.

(2) Audits of HHS-certified laboratories that are conducted for licensees and other entities who are subject to this subpart need not duplicate areas inspected in the most recent HHS certification inspection. However, the licensee and other entity shall review the HHS certification inspection records and reports to identify any areas in which the licensee or other entity uses services that the HHS certification inspection did not address. The licensee or other entity shall ensure that any such areas are audited on a nominal 12-month frequency. Licensees and other entities need not audit organizations and professionals who may provide an FFD program service to the licensee or other entity, but who are not routinely involved in providing services to a licensee's or other entity's FFD program, as specified in § 26.4(i)(1).

(d) *Contracts.* (1) The contracts of licensees and other entities contracts with C/Vs and HHS-certified laboratories must reserve the right to audit the C/V, the C/V's subcontractors providing FFD program services, and the HHS-certified laboratories at any time, including at unannounced times, as well as to review all information and documentation that is reasonably relevant to the audits.

(2) Licensees' and other entities' contracts with C/Vs and HHS-certified laboratories must also permit the licensee or other entity to obtain copies of and take away any documents, including reviews and inspections pertaining to a laboratory's certification by HHS, and any other data that may be needed to assure that the C/V, its subcontractors, or the HHS-certified laboratory are performing their functions properly and that staff and procedures meet applicable requirements. In a contract with a licensee or other entity who is subject to this subpart, an HHS-certified laboratory may reasonably limit the use and dissemination of any documents copied or taken away by the licensee's or other entity's auditors in order to ensure the protection of proprietary information and donors' privacy.

(3) In addition, before awarding a contract, the licensee or other entity shall ensure completion of pre-award inspections and/or audits of the procedural aspects of the HHS-certified laboratory's drug-testing operations, except as provided in paragraph (g)(5) of this section.

(e) *Conduct of audits.* Audits must focus on the effectiveness of the FFD program or program element(s), as appropriate, and must be conducted by individuals who are qualified in the

subject(s) being audited. The individuals performing the audit of the FFD program or program element(s) shall be independent from both the subject FFD program's management and from personnel who are directly responsible for implementing the FFD program.

(f) *Audit results.* The result of the audits, along with any recommendations, must be documented and reported to senior corporate and site management. Each audit report must identify conditions that are adverse to the proper performance of the FFD program, the cause of the condition(s), and recommended corrective actions. The licensee or other entity shall review the audit findings and take corrective actions, including re-auditing of the deficient areas where indicated, to preclude, within reason, repetition of the condition. The resolution of the audit findings and corrective actions must be documented.

(g) *Sharing of audits.* Licensees and other entities may jointly conduct audits, or may accept audits of C/Vs and HHS-certified laboratories that were conducted by other licensees and entities who are subject to this subpart, if the audit addresses the services obtained from the C/V or HHS-certified laboratory by each of the sharing licensees and other entities.

(1) Licensees and other entities shall review audit records and reports to identify any areas that were not covered by the shared or accepted audit.

(2) Licensees and other entities shall ensure that FFD program elements and services on which the licensee or entity relies are audited, if the program elements and services were not addressed in the shared audit.

(3) Sharing licensees and other entities need not re-audit the same C/V or HHS-certified laboratory for the same period of time.

(4) Each sharing licensee and other entity shall maintain a copy of the shared audit and HHS certification inspection records and reports, including findings, recommendations, and corrective actions.

(5) If an HHS-certified laboratory loses its certification, in whole or in part, a licensee or other entity is permitted to immediately use another HHS-certified laboratory that has been audited within the previous 12 months by another NRC licensee or entity who is subject to this subpart. Within 3 months after the change, the licensee or other entity shall ensure that an audit is completed of any areas that have not been audited by another licensee or entity who is subject to this subpart within the past 12 months.

Subpart C—Granting and Maintaining Authorization

§ 26.51 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals in § 26.4(a) through (d), and, at the licensee's or other entity's discretion, in § 26.4(g) and, if necessary, § 26.4(j). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to meet the requirements of this subpart. Certain requirements in this subpart also apply to the individuals specified in § 26.4(h).

§ 26.53 General provisions.

(a) In order to grant authorization to an individual, a licensee or other entity shall ensure that the requirements in this subpart have been met for either initial authorization, authorization update, authorization reinstatement, or authorization with potentially disqualifying FFD information, as applicable.

(b) For individuals who have previously held authorization under this part but whose authorization has since been favorably terminated, the licensee or other entity shall implement the requirements for either initial authorization, authorization update, or authorization reinstatement, based on the total number of days that the individual's authorization is interrupted, to include the day after the individual's last period of authorization was terminated and the intervening days until the day on which the licensee or other entity grants authorization to the individual. If potentially disqualifying FFD information is disclosed or discovered about an individual, licensees and other entities shall implement the applicable requirements in § 26.69 in order to grant or maintain an individual's authorization.

(c) The licensee or other entity shall ensure that an individual has met the applicable FFD training requirements in §§ 26.29 and 26.203(c) before granting authorization to the individual.

(d) Licensees and other entities who are seeking to grant authorization to an individual who is maintaining authorization under another FFD program that is implemented by a licensee or entity who is subject to this subpart may rely on the transferring FFD program to satisfy the requirements of this subpart. The individual may maintain his or her authorization if he or she continues to be subject to either the receiving FFD program or the transferring FFD program, or a combination of elements from both programs that collectively satisfy the applicable requirements of this part. The receiving FFD program shall ensure that the program elements to which the individual is subject under the transferring FFD program remain current.

(e) Licensees and other entities in § 26.3(a) through (c) may also rely on a C/V's FFD program or program elements when granting or maintaining the authorization of an individual who is or has been subject to the C/V's FFD program, if the C/V's program or program elements meet the applicable requirements of this part.

(1) A C/V's FFD program may grant and maintain an individual's authorization, as defined in § 26.5, under the C/V's FFD program. However, only a licensee or other entity in § 26.3(a) through (c) may grant or maintain an individual's authorization to have the types of access or perform the duties specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f).

(2) If a C/V's FFD program denies or unfavorably terminates an individual's authorization, and the individual is performing any duties for a licensee or other entity that are specified in § 26.4(a) through (e) and (g), or, at the licensee's or other entity's discretion, § 26.4(f), then the C/V shall inform the affected licensee or other entity of the denial or unfavorable termination. The licensee or other entity shall deny or unfavorably terminate the individual's authorization to perform those duties on the day that the licensee or other entity receives the information from the C/V, or implement the applicable process in § 26.69 to maintain the individual's authorization.

(3) If an individual is maintaining authorization under a C/V's FFD program, a licensee or other entity in § 26.3(a) through (c) may grant authorization to the individual to have the types of access and perform the duties specified in § 26.4(a) through (e) and (g), and, at the licensee's or other entity's discretion, § 26.4(f), and maintain his or her authorization, if the individual continues to be subject to either the receiving FFD program or a combination of elements from the

receiving FFD program and the C/V's program that collectively satisfy the applicable requirements of this part. The receiving licensee's or other entity's FFD program shall ensure that the program elements to which the individual is subject under the C/V's FFD program remain current.

(f) Licensees and other entities who are seeking to grant authorization to an individual who has been subject to an FFD program under subpart K may not rely on that program or its program elements to meet the requirements of this subpart, except if the program or program element(s) of the FFD program for construction satisfy the applicable requirements of this part.

(g) The licensees and other entities specified in § 26.3(a) and, as applicable, (c) and (d), shall identify any violation of any requirement of this part to any licensee who has relied on or intends to rely on the FFD program element that is determined to be in violation of this part.

(h) The licensees and other entities specified in § 26.3(a) and, as applicable, (c) and (d), may not initiate any actions under this subpart without the knowledge and written consent of the subject individual. The individual may withdraw his or her consent at any time. If an individual withdraws his or her consent, the licensee or other entity may not initiate any elements of the authorization process specified in this subpart that were not in progress at the time the individual withdrew his or her consent, but shall complete and document any elements that are in progress at the time consent is withdrawn. The licensee or other entity shall record the individual's application for authorization; his or her withdrawal of consent; the reason given by the individual for the withdrawal, if any; and any pertinent information gathered from the elements that were completed (e.g., the results of pre-access drug tests, information obtained from the suitable inquiry). The licensee or other entity to whom the individual has applied for authorization shall inform the individual that—

(1) Withdrawal of his or her consent will withdraw the individual's current application for authorization under the licensee's or other entity's FFD program; and

(2) Other licensees and entities will have access to information documenting the withdrawal as a result of the information sharing that is required under this part.

(i) The licensees and other entities specified in § 26.3(a) and, as applicable, (c) and(d), shall inform, in writing, any individual who is applying for authorization that the following actions related to providing and sharing the personal information required under this subpart are sufficient cause for denial or unfavorable termination of authorization:

(1) Refusal to provide written consent for the suitable inquiry;

(2) Refusal to provide or the falsification of any personal information required under this part, including, but not limited to, the failure to report any previous denial or unfavorable termination of authorization;

(3) Refusal to provide written consent for the sharing of personal information with other licensees or other entities required under this part; and

(4) Failure to report any legal actions, as defined in § 26.5.

§ 26.55 Initial authorization.

(a) Before granting authorization to an individual who has never held authorization under this part or whose authorization has been interrupted for a period of 3 years or more and whose last period of authorization was terminated favorably, the licensee or other entity shall ensure that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under the applicable requirements of § 26.63;

(3) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual is subject to random drug and alcohol testing under the applicable requirements of § 26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee or other entity may not grant authorization to the individual, except under § 26.69.

§ 26.57 Authorization update.

(a) Before granting authorization to an individual whose authorization has been interrupted for more than 365 days but less than 3 years and whose last period of authorization was terminated favorably, the licensee or other entity shall ensure that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under the applicable requirements of § 26.63;

(3) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual is subject to random drug and alcohol testing under the applicable requirements of § 26.67.

(b) If potentially disqualifying FFD information is disclosed or discovered, the licensee or other entity may not grant authorization to the individual, except under § 26.69.

§ 26.59 Authorization reinstatement.

(a) In order to grant authorization to an individual whose authorization has been interrupted for a period of more than 30 days but no more than 365 days and whose last period of authorization was terminated favorably, the licensee or other entity shall ensure that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) A suitable inquiry has been completed under the requirements of § 26.63 within 5 business days of reinstating authorization. If the suitable inquiry is not completed within 5 business days due to circumstances that are outside of the licensee's or other entity's control and the licensee or other entity is not aware of any potentially disqualifying information regarding the individual within the past 5 years, the licensee or other entity may maintain the individual's authorization for an additional 5 business days. If the suitable inquiry is not completed within 10 business days of reinstating authorization, the licensee or other entity shall administratively withdraw the individual's authorization until the suitable inquiry is completed;

(3) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65; and

(4) The individual is subject to random drug and alcohol testing under the applicable requirements of § 26.67.

(b) If a licensee or other entity administratively withdraws an individual's authorization under paragraph (a)(2) of this section, and until the suitable inquiry is completed, the licensee or other entity may not record the administrative action to withdraw authorization as an unfavorable termination and may not disclose it in response to a suitable inquiry conducted under the provisions of § 26.63, a background investigation conducted under the provisions of this chapter, or any other inquiry or investigation. The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information, except if the individual's authorization was subsequently denied or terminated unfavorably by the licensee or other entity.

(c) Before granting authorization to an individual whose authorization has

been interrupted for a period of no more than 30 days and whose last period of authorization was terminated favorably, the licensee or other entity shall ensure that—

(1) A self-disclosure has been obtained and reviewed under the applicable requirements of § 26.61;

(2) The individual has been subject to pre-access drug and alcohol testing under the applicable requirements of § 26.65, if the individual's authorization was interrupted for more than 5 days; and

(3) The individual is subject to random drug and alcohol testing under the applicable requirements of § 26.67.

(d) If potentially disqualifying FFD information is disclosed or discovered, the licensee or other entity may not grant authorization to the individual, except under § 26.69.

§ 26.61 Self-disclosure and employment history.

(a) Before granting authorization, the licensee or other entity shall ensure that a written self-disclosure and employment history has been obtained from the individual who is applying for authorization, except as follows:

(1) If an individual previously held authorization under this part, and the licensee or other entity has verified that the individual's last period of authorization was terminated favorably, and the individual has been subject to a behavioral observation program that includes arrest reporting, which meets the requirements of this part, throughout the period since the individual's last authorization was terminated, the granting licensee or other entity need not obtain the self-disclosure or employment history in order to grant authorization; and

(2) If the individual's last period of authorization was terminated favorably within the past 30 days, the licensee or other entity need not obtain the employment history.

(b) The written self-disclosure must—

(1) State whether the individual has—

(i) Violated a licensee's or other entity's FFD policy;

(ii) Had authorization denied or terminated unfavorably under §§ 26.35(c)(2), 26.53(i), 26.63(d), 26.65(g), 26.67(c), 26.69(f), or 26.75(b) through (e);

(iii) Used, sold, or possessed illegal drugs;

(iv) Abused legal drugs or alcohol;

(v) Subverted or attempted to subvert a drug or alcohol testing program;

(vi) Refused to take a drug or alcohol test;

(vii) Been subject to a plan for substance abuse treatment (except for self-referral); or

(viii) Had legal action or employment action, as defined in § 26.5, taken for alcohol or drug use;

(2) Address the specific type, duration, and resolution of any matter disclosed, including, but not limited to, the reason(s) for any unfavorable termination or denial of authorization; and

(3) Address the shortest of the following periods:

(i) The past 5 years;

(ii) Since the individual's eighteenth birthday; or

(iii) Since the individual's last period of authorization was terminated, if authorization was terminated favorably within the past 3 years.

(c) The individual shall provide a list of all employers, including the employer by whom the individual claims to have been employed on the day before he or she completes the employment history, if any, with dates of employment, for the shortest of the following periods:

(1) The past 3 years;

(2) Since the individual's eighteenth birthday; or

(3) Since authorization was last terminated, if authorization was terminated favorably within the past 3 years.

§ 26.63 Suitable inquiry.

(a) In order to grant authorization, licensees and other entities shall ensure that a suitable inquiry has been conducted, on a best effort basis, to verify the individual's self-disclosed information and determine whether any potentially disqualifying FFD information is available, except if all of the following conditions are met:

(1) The individual previously held authorization under this part;

(2) The licensee or other entity has verified that the individual's last period of authorization was terminated favorably; and

(3) The individual has been subject to a behavioral observation program that includes arrest reporting, which meets the requirements of this part, throughout the period of interruption.

(b) To meet the suitable inquiry requirement, licensees and other entities may rely on the information that other licensees and entities who are subject to this subpart have gathered for previous periods of authorization. Licensees and other entities may also rely on those licensees' and entities' determinations of fitness that were conducted under § 26.189, as well as their reviews and resolutions of potentially disqualifying FFD information, for previous periods of authorization.

(c) The licensee or other entity shall ensure that the suitable inquiry has been conducted, on a best effort basis, by questioning former employers, and the employer by whom the individual claims to have been employed on the day before he or she completes the employment history, if an employment history is required under § 26.61.

(1) For the claimed employment period, the suitable inquiry must ascertain the reason for termination, eligibility for rehire, and other information that could reflect on the individual's fitness to be granted authorization.

(2) If the claimed employment was military service, the licensee or other entity who is conducting the suitable inquiry shall request a characterization of service, reason for separation, and any disciplinary actions related to potentially disqualifying FFD information. If the individual's last duty station cannot provide this information, the licensee or other entity may accept a hand-carried copy of the DD 214 presented by the individual which on face value appears to be legitimate. The licensee or other entity may also accept a copy of a DD 214 provided by the custodian of military records.

(3) If a company, previous employer, or educational institution to whom the licensee or other entity has directed a request for information refuses to provide information or indicates an inability or unwillingness to provide information within 3 business days of the request, the licensee or other entity shall document this refusal, inability, or unwillingness in the licensee's or other entity's record of the investigation, and obtain a confirmation of employment or educational enrollment and attendance from at least one alternate source, with suitable inquiry questions answered to the best of the alternate source's ability. This alternate source may not have been previously used by the licensee or other entity to obtain information about the individual's character. If the licensee or other entity uses an alternate source because employer information is not forthcoming within 3 business days of the request, the licensee or other entity need not delay granting authorization to wait for any employer response, but shall evaluate and document the response if it is received.

(d) When any licensee or other entity in § 26.3(a) through (d) is legitimately seeking the information required for an authorization decision under this subpart and has obtained a signed release from the subject individual authorizing the disclosure of information, any licensee or other entity who is subject to this part shall disclose whether the subject individual's authorization was denied or terminated

unfavorably as a result of a violation of an FFD policy and shall make available the information on which the denial or unfavorable termination of authorization was based, including, but not limited to, drug or alcohol test results, treatment and followup testing requirements or other results from a determination of fitness, and any other information that is relevant to an authorization decision.

(e) In conducting a suitable inquiry, a licensee or other entity may obtain information and documents by electronic means, including, but not limited to, telephone, facsimile, or e-mail. The licensee or other entity shall make a record of the contents of the telephone call and shall retain that record, and any documents or electronic files obtained electronically, under §§ 26.711 and 26.713(a), (b), and (c), as applicable.

(f) For individuals about whom no potentially disqualifying FFD information is known (or about whom potentially disqualifying FFD information is known, but it has been resolved by a licensee or other entity who is subject to this subpart) at the time at which the suitable inquiry is initiated, the licensee or other entity shall ensure that a suitable inquiry has been conducted as follows:

(1) Initial authorization. The period of the suitable inquiry must be the past 3 years or since the individual's eighteenth birthday, whichever is shorter. For the 1-year period immediately preceding the date on which the individual applies for authorization, the licensee or other entity shall ensure that the suitable inquiry has been conducted with every employer, regardless of the length of employment. For the remaining 2-year period, the licensee or other entity shall ensure that the suitable inquiry has been conducted with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(2) Authorization update. The period of the suitable inquiry must be the period since authorization was terminated. For the 1-year period immediately preceding the date on which the individual applies for authorization, the licensee or other entity shall ensure that the suitable inquiry has been conducted with every employer, regardless of the length of employment. For the remaining period since authorization was terminated, the licensee or other entity shall ensure that the suitable inquiry has been conducted with the employer by whom the individual claims to have been employed the longest within each calendar month, if the individual claims employment during the given calendar month.

(3) Authorization reinstatement after an interruption of more than 30 days. The period of the suitable inquiry must be the period since authorization was terminated. The licensee or other entity shall ensure that the suitable inquiry has been conducted with the employer by whom the individual claims to have been employed the longest within the calendar month, if the individual claims employment during the given calendar month.

§ 26.65 Pre-access drug and alcohol testing.

(a) *Purpose.* This section contains pre-access testing requirements for granting authorization to an individual who either has never held authorization or whose last period of authorization was terminated favorably and about whom no potentially disqualifying FFD information has been discovered or disclosed that was not previously reviewed and resolved by a licensee or other entity under the requirements of this subpart.

(b) *Accepting tests conducted within the past 30 days.* If an individual has negative results from drug and alcohol tests that were conducted under the requirements of this part before the individual applied for authorization from the licensee or other entity, and the specimens for such testing were collected within the 30-day period preceding the day on which the licensee or other entity grants authorization to the individual, the licensee or other entity may rely on the results of those drug and alcohol tests to meet the requirements for pre-access testing in this section.

(c) *Initial authorization and authorization update.* Before granting authorization to an individual who has never held authorization or whose authorization has been interrupted for a period of more than 365 days, the licensee or other entity shall verify that the results of pre-access drug and alcohol tests, which must be performed within the 30-day period preceding the day the licensee or other entity grants authorization to the individual, are negative. The licensee or other entity need not conduct pre-access testing if—

(1) The individual previously held authorization under this part and has been subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, from the date the individual's last authorization was terminated through the date the individual is granted authorization; or

(2) The licensee or other entity relies on negative results from drug and alcohol tests that were conducted under the requirements of this part at any time before the individual applied for authorization, and the individual has remained subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, beginning on the date the drug and alcohol testing was conducted through the date the individual is granted authorization and thereafter.

(d) *Authorization reinstatement after an interruption of more than 30 days.* (1) To reinstate authorization for an individual whose authorization has been interrupted for a period of more than 30 days but no more than 365 days, except as permitted in paragraph (d)(2) of this section, the licensee or other entity shall—

(i) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing within the 30-day period preceding the day the licensee reinstates the individual's authorization; and

(ii) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until the drug test results are received.

(2) The licensee or other entity need not conduct pre-access testing of these individuals if—

(i) The individual previously held authorization under this part and has been subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, beginning on the date the individual's last authorization was terminated through the date the individual is granted authorization; or

(ii) The licensee or other entity relies on negative results from drug and alcohol tests that were conducted under the requirements of this part at any time before the individual applied for authorization, and the individual remains subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, beginning on the date the drug and alcohol testing was conducted through the date the individual is granted authorization.

(e) *Authorization reinstatement after an interruption of 30 or fewer days.* (1) The licensee or other entity need not conduct pre-access testing before granting authorization to an individual whose authorization has been interrupted for 5 or fewer days. In addition, the licensee or other entity need not conduct pre-access testing if the individual has been subject to a drug and alcohol testing program that includes random testing and a behavioral observation program that includes arrest reporting, which both meet the requirements of this part, from the date the individual's last authorization was terminated through the date the individual is granted authorization.

(2) In order to reinstate authorization for an individual whose authorization has been interrupted for a period of more than 5 days but not more than 30 days, except as permitted in paragraph (e)(1) of this section, the licensee or other entity shall take the following actions:

(i) The licensee or other entity shall subject the individual to random selection for pre-access drug and alcohol testing at a one-time probability that is equal to or greater than the normal testing rate specified in § 26.31(d)(2)(vii) calculated for a 30-day period;

(ii) If the individual is not selected for pre-access testing under paragraph (e)(2)(i) of this section, the licensee or other entity need not perform pre-access drug and alcohol tests; or

(iii) If the individual is selected for pre-access testing under this paragraph, the licensee or other entity shall—

(A) Verify that the individual has negative results from alcohol testing and collect a specimen for drug testing before reinstating authorization; and

(B) Verify that the drug test results are negative within 5 business days of specimen collection or administratively withdraw authorization until negative drug test results are received.

(f) *Administrative withdrawal of authorization.* If a licensee or other entity administratively withdraws an individual's authorization under paragraphs (d)(1)(ii) or (e)(2)(iii)(B) of this section, and until the drug test results are known, the licensee or other entity may not record the administrative action to withdraw authorization as an unfavorable termination. The individual may not be required to disclose the administrative action in response to requests for self-disclosure of potentially disqualifying FFD information, except if the individual's authorization was subsequently denied or terminated unfavorably by a licensee or entity. Immediately on receipt of negative test results, the licensee or other entity shall ensure that any matter that could link the individual to the temporary administrative action is eliminated from the donor's personnel record and other records.

(g) *Sanctions.* If an individual has confirmed positive, adulterated, or substituted test results from any drug, validity, or alcohol tests that may be required in this section, the licensee or other entity shall, at a minimum and as appropriate—

(1) Deny authorization to the individual, as required by § 26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been reinstated, under § 26.75(e)(1) or (f); or

(3) Grant authorization to the individual under § 26.69.

§ 26.67 Random drug and alcohol testing of individuals who have applied for authorization.

(a) When the licensee or other entity collects specimens from an individual for any pre-access testing that may be required under §§ 26.65 or 26.69, and thereafter, the licensee or other entity shall subject the individual to random testing under § 26.31(d)(2), except if—

(1) The licensee or other entity does not grant authorization to the individual; or

(2) The licensee or other entity relies on drug and alcohol tests that were conducted before the individual applied for authorization to meet the applicable requirements for pre-access testing. If the licensee or other entity relies on drug and alcohol tests that were conducted before the individual applied for authorization, the licensee or other entity shall subject the individual to random testing when the individual arrives at a licensee's or other entity's facility for in-processing and thereafter.

(b) If an individual is selected for one or more random tests after any applicable requirement for pre-access testing in §§ 26.65 or 26.69 has been met, the licensee or other entity may grant authorization before random testing is completed, if the individual has met all other applicable requirements for authorization.

(c) If an individual has confirmed positive, adulterated, or substituted test results from any drug, validity, or alcohol test required in this section, the licensee or other entity shall, at a minimum and as appropriate—

(1) Deny authorization to the individual, as required by § 26.75(b), (d), (e)(2), or (g);

(2) Terminate the individual's authorization, if it has been granted, as required by § 26.75(e)(1) or (f); or

(3) Grant authorization to the individual under § 26.69.

§ 26.69 Authorization with potentially disqualifying fitness-for-duty information.

(a) *Purpose.* This section defines the management actions that licensees and other entities who are subject to this subpart shall take to grant or maintain, at the licensee's or other entity's discretion, the authorization of an individual who is in the following circumstances:

(1) Potentially disqualifying FFD information within the past 5 years has been disclosed or discovered about the individual by any means, including, but not limited to, the individual's self-disclosure, the suitable inquiry, drug and alcohol testing, the administration of any FFD program under this part, a self-report of a legal action, behavioral observation, or other sources of information, including, but not limited to, any background investigation or credit and criminal history check conducted under the requirements of this chapter; and

(2) The potentially disqualifying FFD information has not been reviewed and favorably resolved by a previous licensee or other entity under this section.

(b) *Authorization after a first confirmed positive drug or alcohol test result or a 5-year denial of authorization.* The requirements in this paragraph apply to individuals whose authorization was denied or terminated unfavorably for a first violation of an FFD policy involving a confirmed positive drug or alcohol test result and individuals whose authorization was denied for 5 years under § 26.75(c), (d), (e)(2), or (f). To grant, and subsequently maintain, the individual's authorization, the licensee or other entity shall—

(1) Obtain and review a self-disclosure and employment history from the individual that addresses the shorter period of either the past 5 years or since the individual's last period of authorization was terminated, and verify that the self-disclosure does not contain any previously undisclosed potentially disqualifying FFD information before granting authorization;

(2) Complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the employment history obtained under paragraph (b)(1) of this section, and obtain and review any records that other licensees or entities who are subject to this part may have developed related to the unfavorable termination or denial of authorization;

(3) If the individual was subject to a 5-year denial of authorization under this part, verify that he or she has abstained from substance abuse for at least the past 5 years;

(4) Ensure that an SAE has conducted a determination of fitness and concluded that the individual is fit to safely and competently perform his or her duties.

(i) If the individual's authorization was denied or terminated unfavorably for a first confirmed positive drug or alcohol test result, ensure that clinically appropriate treatment and followup testing plans have been developed by an SAE before granting authorization;

(ii) If the individual was subject to a 5-year denial of authorization, ensure that any recommendations for treatment and followup testing from an SAE's determination of fitness are initiated before granting authorization; and

(iii) Verify that the individual is in compliance with, and successfully completes, any followup testing and treatment plans.

(5) Within 10 business days before granting authorization, perform a pre-access alcohol test, collect a specimen for drug testing under direct observation, and ensure that the individual is subject to random testing thereafter. Verify that the pre-access drug and alcohol test results are negative before granting authorization.

(6) If the individual's authorization was denied or terminated unfavorably for a first confirmed positive drug or alcohol test result and a licensee or other entity grants authorization to the individual, ensure that the individual is subject to unannounced testing at least quarterly for 3 calendar years after the date the individual is granted authorization. Both random and followup tests, as defined in § 26.31(c), satisfy this requirement. Verify that the individual has negative test results from a minimum of 15 tests distributed over the 3-year period, except as follows:

(i) If the individual does not continuously hold authorization during the 3-year period, the licensee or other entity shall ensure that at least one unannounced test is conducted in any quarter during which the individual holds authorization;

(ii) If the 15 tests are not completed within the 3-year period specified in this paragraph due to periods during which the individual does not hold authorization, the followup testing program may be extended up to 5 calendar years to complete the 15 tests;

(iii) If the individual does not hold authorization during the 5-year period a sufficient number of times or for sufficient periods of time to complete the 15 tests required in this paragraph, the licensee or other entity shall ensure that an SAE conducts a determination of fitness to assess whether further followup testing is required and implement the SAE's recommendations; and

(7) Verify that any drug and alcohol tests required in this paragraph, and any other drug and alcohol tests that are conducted under this part since authorization was terminated or denied, yield results indicating no further drug abuse, as determined by the MRO after review, or alcohol abuse, as determined by the result of confirmatory alcohol testing.

(c) *Granting authorization with other potentially disqualifying FFD information.* The requirements in this paragraph apply to an individual who has applied for authorization, and about whom potentially disqualifying FFD information has been discovered or disclosed that is not a first confirmed positive drug or alcohol test result or a 5-year denial of authorization. If potentially disqualifying FFD information is obtained about an individual by any means, including, but not limited to, the individual's self-disclosure, the suitable inquiry, the administration of any FFD program under this part, a self-report of a legal action, behavioral observation, or other sources of information, including, but not limited to, any background investigation or credit and criminal history check conducted under the requirements of this chapter, before granting authorization to the individual, the licensee or other entity shall—

(1) Obtain and review a self-disclosure and employment history that addresses the shortest of the following periods:

(i) The past 5 years;

(ii) Since the individual's eighteenth birthday; or

(iii) Since the individual's last period of authorization was terminated;

(2) Complete a suitable inquiry with every employer by whom the individual claims to have been employed during the period addressed in the employment history required under paragraph (c)(1) of this section. If the individual held authorization within the past 5 years, obtain and review any records that other licensees or entities who are subject to this part may have developed with regard to potentially disqualifying FFD information about the individual from the past 5 years;

(3) If the designated reviewing official determines that a determination of fitness is required, verify that a professional with the appropriate qualifications, as specified in § 26.187(a), has indicated that the individual is fit to safely and competently perform his or her duties;

(4) Ensure that the individual is in compliance with, or has completed, any plans for treatment and drug and alcohol testing from the determination of fitness, which may include the collection of a urine specimen under direct observation; and

(5) Verify that the results of pre-access drug and alcohol tests are negative before granting authorization, and that the individual is subject to random testing after the specimens have been collected for pre-access testing and thereafter.

(d) *Maintaining authorization with other potentially disqualifying FFD information.* If an individual is authorized when other potentially disqualifying FFD information is disclosed or discovered, in order to maintain the individual's authorization, the licensee or other entity shall—

(1) Ensure that the licensee's or other entity's designated reviewing official completes a review of the circumstances associated with the information;

(2) If the designated reviewing official concludes that a determination of fitness is required, verify that a professional with the appropriate qualifications, as specified in § 26.187(a), has indicated that the individual is fit to safely and competently perform his or her duties; and

(3) If the reviewing official determines that maintaining the individual's authorization is warranted, implement any recommendations for treatment and followup drug and alcohol testing from the determination of fitness, which may include the collection of urine specimens under direct observation, and ensure that the individual complies with and successfully completes the treatment plans.

(e) *Accepting followup testing and treatment plans from another FFD program.* Licensees and other entities may rely on followup testing, treatment plans, and determinations of fitness that meet the requirements of § 26.189 and were conducted under the FFD program of another licensee or entity who is subject to this subpart.

(1) If an individual leaves the FFD program in which a treatment and/or followup testing plan was required under paragraphs (b), (c), or (d) of this section, the licensee or other entity who imposed the treatment and/or followup testing plan shall ensure that information documenting the treatment and/or followup testing plan is identified to any subsequent licensee or other entity who seeks to grant

authorization to the individual. If the individual is granted authorization by the same or another licensee or entity, the licensee or other entity who grants authorization to the individual shall ensure that any followup testing requirements are met and that the individual complies with any treatment plan, with accountability assumed by the granting licensee or other entity. If it is impractical for the individual to comply with a treatment plan that was developed under another FFD program because of circumstances that are outside of the individual's or licensee's or other entity's control (e.g., geographical distance, closure of a treatment facility), then the granting FFD program shall ensure that an SAE develops a comparable treatment plan, with accountability for monitoring the individual's compliance with the plan assumed by the granting licensee or other entity.

(2) If the previous licensee or other entity determined that the individual successfully completed any required treatment and followup testing, and the individual's last period of authorization was terminated favorably, the receiving licensee or entity may rely on the previous determination of fitness and no further review or followup is required.

(f) *Sanctions.* If an individual has confirmed positive, adulterated, or substituted test results from any drug, validity, or alcohol test required in this section, the licensee or other entity shall, at a minimum and as appropriate—

(1) Deny authorization to the individual, as required by § 26.75(b), (d), (e)(2), or (g); or

(2) Terminate the individual's authorization, if it has been granted, as required by § 26.75(e)(1) or (f).

§ 26.71 Maintaining authorization.

(a) Individuals may maintain authorization under the following conditions:

(1) The individual complies with the licensee's or other entity's FFD policies and procedures, as described in § 26.27, including the responsibility to report any legal actions, as defined in § 26.5;

(2) The individual remains subject to a drug and alcohol testing program that meets the requirements of § 26.31, including random testing;

(3) The individual remains subject to a behavioral observation program that meets the requirements of § 26.33; and

(4) The individual successfully completes required FFD training on the schedule specified in § 26.29(c).

(b) If an authorized individual is not subject to an FFD program that meets the requirements of this section for more than 30 continuous days, then the licensee or other entity shall terminate the individual's authorization and the individual shall meet the requirements in this subpart, as applicable, to regain authorization.

Subpart D—Management Actions and Sanctions To Be Imposed

§ 26.73 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), (b), and, as applicable, (c) for the categories of individuals specified in § 26.4(a) through (d) and (g). The requirements in this subpart also apply to the licensees and other entities specified in § 26.3(c), as applicable, for the categories of individuals in § 26.4(e). At the discretion of a licensee or other entity in § 26.3(c), the requirements of this subpart also may be applied to the categories of individuals identified in § 26.4(f). In addition, the requirements in this subpart apply to the entities in § 26.3(d) to the extent that a licensee or other entity relies on the C/V to meet the requirements of this subpart. The regulations in this subpart also apply to the individuals specified in § 26.4(h) and (j), as appropriate.

§ 26.75 Sanctions.

(a) This section defines the minimum sanctions that licensees and other entities shall impose when an individual has violated the drug and alcohol provisions of an FFD policy. A licensee or other entity may impose more stringent sanctions, except as specified in paragraph (h) of this section.

(b) Any act or attempted act to subvert the testing process, including, but not limited to, refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under § 26.31(c) must result in the immediate unfavorable termination of the individual's authorization and permanent denial of authorization thereafter.

(c) Any individual who is determined to have been involved in the sale, use, or possession of illegal drugs or the consumption of alcohol within a protected area of any nuclear power plant, within a facility that is licensed to possess or use formula quantities of SSNM, within a transporter's facility or vehicle, or while performing the duties that require the individual to be subject to this subpart shall immediately have his or her authorization unfavorably terminated and denied for a minimum of 5 years from the date of the unfavorable termination of authorization.

(d) Any individual who resigns or withdraws his or her application for authorization before authorization is terminated or denied for a first violation of the FFD policy involving a confirmed positive drug or alcohol test result shall immediately have his or her authorization denied for a minimum of 5 years from the date of termination or denial. If an individual resigns or withdraws his or her application for authorization before his or her authorization is terminated or denied for any violation of the FFD policy, the licensee or other entity shall record the resignation or withdrawal, the nature of the violation, and the minimum sanction that would have been required under this section had the individual not resigned or withdrawn his or her application for authorization.

(e) Lacking any other evidence to indicate the use, sale, or possession of illegal drugs or consumption of alcohol on site, a confirmed positive drug or alcohol test result must be presumed to be an indication of offsite drug or alcohol use in violation of the FFD policy.

(1) The first violation of the FFD policy involving a confirmed positive drug or alcohol test result must, at a minimum, result in the immediate unfavorable termination of the individual's authorization for at least 14 days from the date of the unfavorable termination.

(2) Any subsequent confirmed positive drug or alcohol test result, including during an assessment or treatment period, must result in the denial of authorization for a minimum of 5 years from the date of denial.

(f) Paragraph (e) of this section does not apply to the misuse of prescription and over-the-counter drugs, except if the MRO determines that misuse of the prescription or over-the-counter drug represents substance abuse. Sanctions for misuse of prescription and over-the-counter drugs must be sufficient to deter misuse of those substances.

(g) For individuals whose authorization was denied for 5 years under paragraphs (c), (d), (e)(2), or (f) of this section, any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization.

(h) A licensee or other entity may not terminate an individual's authorization and may not subject the individual to other administrative action based solely on a positive test result from any initial drug test, other than positive initial test results for marijuana or cocaine metabolites from a specimen that is

reported to be valid on the basis of either validity screening or initial validity testing performed at a licensee testing facility, unless other evidence, including information obtained under the process set forth in § 26.189, indicates that the individual is impaired or might otherwise pose a safety hazard. The licensee or other entity may not terminate an individual's authorization or subject an individual to any other administrative action under this section based on the results of validity screening or initial validity testing performed at a licensee testing facility indicating that a specimen is of questionable validity.

(i) With respect to positive initial drug test results from a licensee testing facility for marijuana and cocaine metabolites from a valid specimen, licensee testing facility personnel may inform licensee or other entity management of the positive initial drug test result and the specific drugs or metabolites identified, and licensees or other entities may administratively withdraw the donor's authorization or take lesser administrative actions against the donor, provided that the licensee or other entity complies with the following conditions:

(1) For the drug for which action will be taken, at least 85 percent of the specimens that were determined to be positive as a result of initial drug tests at the licensee testing facility during the past 12-month data reporting period submitted to the NRC under § 26.717 were subsequently reported as positive by the HHS-certified laboratory as the result of confirmatory testing;

(2) There is no loss of compensation or benefits to the donor during the period of temporary administrative action;

(3) Immediately on receipt of a negative report from the HHS-certified laboratory or MRO, any matter that could link the donor to the temporary administrative action is eliminated from the donor's personnel record and other records; and

(4) Licensees and other entities may not disclose the temporary administrative action against an individual whose initial drug test result is not subsequently confirmed by the MRO as a violation of the FFD policy in response to a suitable inquiry conducted under the provisions of § 26.63, a background investigation conducted under the provisions of this chapter, or to any other inquiry or investigation.

(i) To ensure that no records are retained, access to the system of files and records must be provided to personnel who are conducting reviews, inquiries into allegations, or audits under the provisions of § 26.41, and to NRC inspectors.

(ii) The licensee or other entity shall provide the donor with a written statement that the records specified in §§ 26.713 and 26.715 have not been retained with respect to the temporary administrative action and shall inform the donor in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information.

§ 26.77 Management actions regarding possible impairment.

(a) This section defines management actions that licensees and other entities who are subject to this subpart must take when an individual who is subject to this subpart shows indications that he or she may not be fit to safely and competently perform his or her duties.

(b) If an individual appears to be impaired or the individual's fitness is questionable, except as permitted under §§ 26.27(c)(3), 26.207, and 26.209, the licensee or other entity shall take immediate action to prevent the individual from performing the duties that require him or her to be subject to this subpart.

(1) If an observed behavior or physical condition creates a reasonable suspicion of possible substance abuse, the licensee or other entity shall perform drug and alcohol testing. The results must be negative before the individual returns to performing the duties that require the individual to be subject to this subpart. However, if the physical condition is the smell of alcohol with no other behavioral or physical indications of impairment, then only an alcohol test is required and the results must be negative before the individual returns to performing his or her duties.

(2) If a licensee or C/V who is subject to subpart I of this part is certain that the observed behavior or physical condition is the result solely of fatigue, the licensee or C/V shall ensure that a fatigue assessment is conducted under § 26.211. If the results of the fatigue assessment confirm that the observed behavior or physical condition is the result solely of fatigue, the licensee or C/V need not perform drug and alcohol tests or implement the determination of fitness process otherwise required by § 26.189.

(3) For other indications of possible impairment that do not create a reasonable suspicion of substance abuse (or fatigue, in the case of licensees and C/Vs who are subject to subpart I of this part), the licensee or other entity may permit the individual to return to performing his or her duties only after the impairing or questionable conditions are resolved and a determination of fitness indicates that the individual is fit to safely and competently perform his or her duties.

(c) If a licensee or other entity has a reasonable belief that an NRC employee or NRC contractor may be under the influence of any substance, or is otherwise unfit for duty, the licensee or other entity may not deny access but shall escort the individual. In any such instance, the licensee or other entity shall immediately notify the appropriate Regional Administrator by telephone, followed by written notification (e.g., e-mail or fax) to document the oral notification. If the Regional Administrator cannot be reached, the licensee or other entity shall notify the NRC Operations Center.

Subpart E—Collecting Specimens for Testing

§ 26.81 Purpose and applicability.

This subpart contains requirements for collecting specimens for drug testing and conducting alcohol tests by or on behalf of the licensees and other entities in § 26.3(a) through (d) for the categories of individuals specified in § 26.4(a) through (d) and (g). At the discretion of a licensee or other entity in § 26.3(c), specimen collections and alcohol tests must be conducted either under this subpart for the individuals specified in § 26.4(e) and (f) or the licensee or other entity may rely on specimen collections and alcohol tests conducted under the requirements of 49 CFR Part 40 for the individuals specified in § 26.4(e) and (f). The requirements of this subpart do not apply to specimen collections and alcohol tests that are conducted under the requirements of 49 CFR Part 40, as permitted in this paragraph and under §§ 26.4(j) and 26.31(b)(2) and Subpart K.

§ 26.83 Specimens to be collected.

Except as permitted under § 26.31(d)(5), licensees and other entities who are subject to this subpart shall—

(a) Collect either breath or oral fluids for initial tests for alcohol. Breath must be collected for confirmatory tests for alcohol; and

(b) Collect only urine specimens for both initial and confirmatory tests for drugs.

§ 26.85 Collector qualifications and responsibilities.

(a) *Urine collector qualifications.* Urine collectors shall be knowledgeable of the requirements of this part and the FFD policy and procedures of the

licensee or other entity for whom collections are performed, and shall keep current on any changes to urine collection procedures. Collectors shall receive qualification training that meets the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before serving as a collector. At a minimum, qualification training must provide instruction on the following subjects:

(1) All steps necessary to complete a collection correctly and the proper completion and transmission of the custody-and-control form;

(2) Methods to address ''problem'' collections, including, but not limited to, collections involving ''shy bladder'' and attempts to tamper with a specimen;

(3) How to correct problems in collections; and

(4) The collector's responsibility for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the donor, and avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(b) *Alcohol collector qualifications.* Alcohol collectors shall be knowledgeable of the requirements of this part and the FFD policy and procedures of the licensee or other entity for whom collections are performed, and shall keep current on any changes to alcohol collection procedures. Collectors shall receive qualification training meeting the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before serving as a collector. At a minimum, qualification training must provide instruction on the following subjects:

(1) The alcohol testing requirements of this part;

(2) Operation of the particular alcohol testing device(s) [i.e., the alcohol screening devices (ASDs) or EBTs] to be used, consistent with the most recent version of the manufacturers' instructions;

(3) Methods to address ''problem'' collections, including, but not limited to, collections involving ''shy lung'' and attempts to tamper with a specimen;

(4) How to correct problems in collections; and

(5) The collector's responsibility for maintaining the integrity of the specimen collection process, carefully ensuring the privacy of the donor, and avoiding any conduct or remarks that might be construed as accusatorial or otherwise offensive or inappropriate.

(c) *Alternative collectors.* A medical professional, technologist, or technician may serve as a collector without meeting the collector qualification requirements in paragraphs (a) or (b) of this section, as applicable, only if all of the following conditions are met:

(1) A collector who meets the requirements of paragraphs (a) or (b) of this section cannot reasonably be made available at the time the collection must occur;

(2) The individual is not employed by the licensee's or other entity's FFD program and his or her normal workplace is not at the licensee's or other entity's facility;

(3) The individual does not routinely provide FFD program services to the licensee or other entity;

(4) The individual is licensed or otherwise approved to practice in the jurisdiction in which the collection occurs; and

(5) The individual is provided with detailed, clearly-illustrated, written instructions for collecting specimens under this subpart and follows those instructions.

(d) *Personnel available to testify at proceedings.* The licensee or other entity shall ensure that qualified collection site personnel, when required, are available to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on positive drug or alcohol test results or adulterated or substituted test results from specimens collected by or under contract to the licensee or other entity.

(e) *Files.* Collection site personnel files must include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests to establish employee competency for the position he or she holds, including, but not limited to, certification that collectors are proficient in administering alcohol tests consistent with the most recent manufacturer's instructions for the instruments and devices used; and appropriate data to support determinations of honesty and integrity conducted under § 26.31(b).

§ 26.87 Collection sites.

(a) Each FFD program must have one or more designated collection sites that have all necessary personnel, materials, equipment, facilities, and supervision to collect specimens for drug testing and to perform alcohol testing. Each collection site must provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a drug testing laboratory; the collection of oral fluids or breath specimens; and the security of alcohol testing devices and test results. A properly equipped mobile facility that meets the requirements of this section is an acceptable collection site.

(b) The collection site must provide for the donor's visual privacy while the donor and collector are viewing the results of an alcohol test, and for individual privacy while the donor is submitting a urine specimen, except if a directly observed urine specimen collection is required. Unauthorized personnel may not be present for the specimen collection.

(c) Contracts for collection site services must permit representatives of the NRC, licensee, or other entity to conduct unannounced inspections and audits and to obtain all information and documentation that is reasonably relevant to the inspections and audits.

(d) Licensees and other entities shall take the following measures to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens.

(1) Unauthorized personnel may not be permitted in any part of the designated collection site where specimens are collected or stored;

(2) A designated collection site must be secure. If a collection site is dedicated solely to specimen collection, it must be secure at all times. Methods of assuring security may include, but are not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection site when it is not occupied; and

(3) If a collection site cannot be dedicated solely to collecting specimens, the portion of the facility that is used for specimen collection must be secured and, during the time period during which a specimen is being collected, a sign must be posted to indicate that access is permitted only for authorized personnel.

(e) The following steps must be taken to deter the dilution and adulteration of urine specimens at the collection site:

(1) Agents that color any source of standing water in the stall or room in which the donor will provide a specimen, including, but not limited to, the toilet bowl or tank, must be placed in the source of standing water, so that the reservoirs of water are neither yellow nor colorless;

(2) There must be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs, or the source of water must be rendered unusable; and

(3) Chemicals or products that could be used to contaminate or otherwise alter the specimen must be removed from the collection site or secured. The collector shall inspect the enclosure in which urination will occur before each collection to ensure that no materials are available that could be used to subvert the testing process.

(f) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement to collect a urine specimen, including, but not limited to, an event investigation, then the licensee or other entity may use a public rest room, onsite rest room, or hospital examining room according to the following procedures:

(1) The facility must be secured by visual inspection to ensure that no unauthorized persons are present, and that undetected access (e.g., through a rear door not in the view of the collector) is impossible. Security during the collection may be maintained by restricting access to collection materials and specimens. In the case of a public rest room, a sign must be posted or an individual assigned to ensure that no unauthorized personnel are present during the entire collection procedure to avoid embarrassment of the donor and distraction of the collector.

(2) If practical, a water coloring agent that meets the requirements of § 26.87(e)(1) must be placed in the toilet bowl to be used by the donor and in any other accessible source of standing water, including, but not limited to, the toilet tank. The collector shall instruct the donor not to flush the toilet.

(3) A collector of the same gender as the donor shall accompany the donor into the area that will be used for specimen collection, but remain outside of the stall, if it is a multi-stalled rest room, or outside of the door to the room, if it is a single rest room, in which the donor will provide the specimen. If a collector of the same gender is not available, the collector shall select a same-gender person to accompany the donor. This person shall be instructed on the collection procedures specified in this subpart and his or her identity must be documented on the custody-and-control form.

(4) After the collector has possession of the specimen, the collector shall inspect the toilet bowl and area to ensure that there is no evidence of a subversion attempt and shall then flush the toilet. The collector shall instruct the donor to participate with the collector in completing the chain-of-custody procedures.

(5) If it is impractical to maintain continuous physical security of a collection site from the time a urine specimen is presented until the sealed container is transferred for shipment, the specimen must remain under the direct control of an individual who is authorized by the licensee or other entity until the specimen is prepared for transfer, storage, or shipping, as required by § 26.117. The authorized individual shall be instructed on his or her responsibilities for maintaining custody and control of the specimen and his or her custody of the specimen must be documented on the custody-and-control form.

§ 26.89 Preparing to collect specimens for testing.

(a) When an individual has been notified of a requirement for testing and does not appear at the collection site within the time period specified by FFD program procedures, the collector shall inform FFD program management that the individual has not reported for testing. FFD program management shall ensure that the necessary steps are taken to determine whether the individual's undue tardiness or failure to appear for testing constitutes a violation of the licensee's or other entity's FFD policy. If FFD program management determines that the undue tardiness or failure to report for testing represents an attempt to subvert the testing process, the licensee or other entity shall impose on the individual the sanctions in § 26.75(b). If FFD program management determines that the undue tardiness or failure to report does not represent a subversion attempt, the licensee or other entity may not impose sanctions but shall ensure that the individual is tested at the earliest reasonable and practical opportunity after locating the individual.

(b) Donors shall provide acceptable identification before testing.

(1) Acceptable identification includes photo-identification issued by a licensee or other entity who is subject to this part, or by the Federal, State, or local government. Licensees and other entities may not accept faxes or photocopies of identification.

(2) If the donor cannot produce acceptable identification before any testing that is required under this part other than pre-access testing, the collector shall proceed with the test and immediately inform FFD program management that the donor did not present acceptable identification. When so informed, FFD program management shall contact the individual's supervisor to verify in-person the individual's identity, or, if the supervisor is not available, take other steps to establish the individual's identity and determine whether the lack of identification was an attempt to subvert the testing process. The donor may not leave the collection site except under supervision until his or her identity has been established.

(3) If the donor is scheduled for pre-access testing and cannot produce acceptable identification, the collector may not proceed with the collection, and shall inform FFD program management that the individual did not present acceptable identification. When so informed, FFD program management will take the necessary steps to determine whether the lack of identification was an attempt to subvert the testing process.

(4) The collector shall explain the testing procedure to the donor, show the donor the form(s) to be used, and ask the donor to sign a consent-to-testing form. The donor may not be required to list prescription medications or over-the-counter preparations that he or she has recently used.

(c) The collector shall inform the donor that, if the donor refuses to cooperate in the specimen collection process (including, but not limited to, behaving in a confrontational manner that disrupts the testing process; admitting to the collector that he or she adulterated, diluted, or adulterated the specimen; is found to have a device, such as a prosthetic appliance, the purpose of which is to interfere with providing an actual urine specimen; or leaving the collection site before all of the collection procedures are completed), it will be considered a refusal to test, and sanctions for subverting the testing process will be imposed under § 26.75(b). If the donor refuses to cooperate in the collection procedures, the collector shall inform FFD program management to obtain guidance on the actions to be taken.

(d) In order to promote the security of specimens, avoid distraction of the collector, and ensure against any confusion in the identification of specimens, a collector shall conduct only one collection procedure at any given time. For this purpose, a urine collection procedure is complete when the urine specimen container has been sealed and initialed, the chain-of-custody form has been executed, and the donor has departed the collection site.

§ 26.91 Acceptable devices for conducting initial and confirmatory tests for alcohol and methods of use.

(a) *Acceptable alcohol screening devices.* Alcohol screening devices (ASDs), including devices that test specimens of oral fluids or breath, must be approved by the National Highway

Traffic Safety Administration (NHTSA) and listed in the most current version of NHTSA's Conforming Products List (CPL) for such devices. An ASD that is listed in the NHTSA CPL may be used only for initial tests for alcohol, and may not be used for confirmatory tests.

(b) *Acceptable evidential breath testing devices.* Evidential breath testing devices listed in the NHTSA CPL for evidential devices that meet the requirements of paragraph (c) of this section must be used to conduct confirmatory alcohol tests, and may be used to conduct initial alcohol tests. Note that, among the devices listed in the CPL for EBTs, only those devices listed without an asterisk (*) may be used for confirmatory alcohol testing under this subpart.

(c) *EBT capabilities.* An EBT that is listed in the NHTSA CPL for evidential devices that has the following capabilities may be used for conducting initial alcohol tests and must be used for confirmatory alcohol tests under this subpart:

(1) Provides a printed result of each breath test;

(2) Assigns a unique number to each completed test, which the collector and donor can read before each test and which is printed on each copy of the test result;

(3) Prints, on each copy of the test result, the manufacturer's name for the device, its serial number, and the time of the test;

(4) Distinguishes alcohol from acetone at the 0.02 alcohol concentration level;

(5) Tests an air blank; and

(6) Permits performance of an external calibration check.

(d) *Quality assurance and quality control of ASDs.* (1) Licensees and other entities shall implement the most recent version of the quality assurance plan submitted to NHTSA for any ASD that is used for initial alcohol testing.

(2) Licensees and other entities may not use an ASD that fails the specified quality control checks or that has passed its expiration date.

(3) For ASDs that test breath specimens and meet EBT requirements for confirmatory testing, licensees and other entities shall also follow the device use and care requirements specified in paragraph (e) of this section.

(e) *Quality assurance and quality control of EBTs.* (1) Licensees and other entities shall implement the most recent version of the manufacturer's instructions for the use and care of the EBT consistently with the quality assurance plan submitted to NHTSA for the EBT, including performing external calibration checks no less frequently than at the intervals specified in the manufacturer's instructions.

(2) When conducting external calibration checks, licensees and other entities shall use only calibration devices appearing on NHTSA's CPL for ''Calibrating Units for Breath Alcohol Tests.''

(3) If an EBT fails an external check of calibration, the licensee or other entity shall take the EBT out of service. The EBT may not be used again for alcohol testing under this subpart until it is repaired and passes an external calibration check.

(4) In order to ensure that confirmed positive alcohol test results are derived from an EBT that is calibrated, the licensee or other entity shall implement one of the following procedures:

(i) If an EBT fails any external check of calibration, cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check; or

(ii) After every confirmed positive test result obtained from using an EBT, conduct an external check of calibration of the EBT in the presence of the donor. If the EBT fails the external calibration check, cancel the donor's test result and conduct another initial and confirmatory test on a different EBT as soon as practicable.

(5) Inspection, maintenance, and calibration of the EBT must be performed by its manufacturer or a maintenance representative or other individual who is certified either by the manufacturer or by a State health agency or other appropriate State agency.

§ 26.93 Preparing for alcohol testing.

(a) Immediately before collecting a specimen for alcohol testing, the collector shall—

(1) Ask the donor whether he or she, in the past 15 minutes, has had anything to eat or drink, belched, or put anything into his or her mouth (including, but not limited to, a cigarette, breath mint, or chewing gum), and instruct the donor that he or she should avoid these activities during the collection process;

(2) If the donor states that he or she has not engaged in the activities listed in paragraph (a)(1) of this section, alcohol testing may proceed;

(3) If the donor states that he or she has engaged in any of the activities listed in paragraph (a)(1) of this section, inform the donor that a 15-minute waiting period is necessary to prevent an accumulation of mouth alcohol from leading to an artificially high reading;

(4) Explain that it is to the donor's benefit to avoid the activities listed in paragraph (a)(1) of this section during the collection process;

(5) Explain that the initial and confirmatory tests, if a confirmatory test is necessary, will be conducted at the end of the waiting period, even if the donor has not followed the instructions; and

(6) Document that the instructions were communicated to the donor.

(b) With the exception of the 15-minute waiting period, if necessary, the collector shall begin for-cause alcohol and/or drug testing as soon as reasonably practical after the decision is made that for-cause testing is required. When for-cause alcohol testing is required, alcohol testing may not be delayed by collecting a specimen for drug testing.

§ 26.95 Conducting an initial test for alcohol using a breath specimen.

(a) The collector shall perform the initial breath test as soon as practical after the donor indicates that he or she has not engaged in the activities listed in § 26.93(a)(1) or after the 15-minute waiting period has elapsed, if required.

(b) To perform the initial test, the collector shall—

(1) Select, or allow the donor to select, an individually wrapped or sealed mouthpiece from the testing materials;

(2) Open the individually wrapped or sealed mouthpiece in view of the donor and insert it into the device as required by the manufacturer's instructions;

(3) Instruct the donor to blow steadily and forcefully into the mouthpiece for at least 6 seconds or until the device indicates that an adequate amount of breath has been obtained;

(4) Show the donor the displayed or printed test result; and

(5) Ensure that the test result record can be associated with the donor and is maintained secure.

(c) Unless problems in administering the breath test require an additional collection, only one breath specimen may be collected for the initial test. If an additional collection(s) is required, the collector shall rely on the test result from the first successful collection to determine the need for confirmatory testing.

§ 26.97 Conducting an initial test for alcohol using a specimen of oral fluids.

(a) To perform the initial test, the collector shall—

(1) Check the expiration date on the device and show it to the donor (the device may not be used after its expiration date);

(2) Open an individually wrapped or sealed package containing the device in the presence of the donor;

(3) Offer the donor the choice of using the device or having the collector use it. If the donor chooses to use it, instruct the donor to insert the device into his or her mouth and use it in the manner described by the device's manufacturer;

(4) If the donor chooses not to use the device, or in all cases when a new test is necessary because the device failed to activate, insert the device into the donor's mouth, and gather oral fluids in the manner described by the device's manufacturer (wear single-use examination or similar gloves while doing so and change them following each test); and

(5) When the device is removed from the donor's mouth, follow the manufacturer's instructions regarding necessary next steps to ensure that the device has activated.

(b) If the steps in paragraph (a) of this section could not be completed successfully (e.g., the device breaks, the device is dropped on the floor, the device fails to activate), the collector shall—

(1) Discard the device and conduct a new test using a new device. The new device must be one that has been under the collector's control before the test;

(2) Record the reason for the new test;

(3) Offer the donor the choice of using the device or having the collector use it unless the donor, in the opinion of the collector, was responsible for the new test needing to be conducted. If the collector concludes that the donor was responsible, then the collector shall use the device to conduct the test; and

(4) Repeat the procedures in paragraph (a) of this section.

(c) If the second collection attempt in paragraph (b) of this section could not be completed, the collector shall—

(1) End the collection of oral fluids and document the reason(s) that the collection could not be completed; and

(2) Immediately conduct another initial test using an EBT.

(d) The collector shall read the result displayed on the device no sooner than the device's manufacturer instructs. In all cases, the collector shall read the result within 15 minutes of the test. The collector shall then show the device and its reading to the donor, record the result, and record that an ASD was used.

(e) Devices, swabs, gloves, and other materials used in collecting oral fluids may not be re-used.

§ 26.99 Determining the need for a confirmatory test for alcohol.

(a) If the initial test result is less than 0.02 percent BAC, the collector shall declare the test result as negative.

(b) If the initial test result is 0.02 percent BAC or higher, the collector shall ensure that the time at which the test was concluded (i.e., the time at which the test result was known) is recorded and inform the donor that a confirmatory test for alcohol is required.

§ 26.101 Conducting a confirmatory test for alcohol.

(a) The confirmatory test must begin as soon as possible, but no more than 30 minutes after the conclusion of the initial test.

(b) To complete the confirmatory test, the collector shall—

(1) In the presence of the donor, conduct an air blank on the EBT before beginning the confirmatory test and show the result to the donor;

(2) Verify that the reading is 0.00. If the reading is 0.00, the test may proceed. If not, then conduct another air blank;

(3) If the reading on the second air blank is 0.00, the test may proceed. If the reading is greater than 0.00, take the EBT out of service and proceed with the test using another EBT. If an EBT is taken out of service for this reason, the EBT may not be used for further testing until it is found to be within tolerance limits on an external check of calibration;

(4) Open an individually wrapped or sealed mouthpiece in view of the donor and insert it into the device as required by the manufacturer's instructions;

(5) Read the unique test number displayed on the EBT, and ensure that the donor reads the same number;

(6) Instruct the donor to blow steadily and forcefully into the mouthpiece for at least 6 seconds or until the device indicates that an adequate amount of breath has been obtained; and

(7) Show the donor the result displayed on or printed by the EBT, record the result, and document the time at which the confirmatory test result was known.

(c) Unless there are problems in administering the breath test that require an additional collection, the collector shall collect only one breath specimen for the confirmatory test. If an additional collection(s) is required because of problems in administering the breath test, the collector shall rely on the breath specimen from the first successful collection to determine the confirmatory test result. Collection procedures may not require collectors to calculate an average or otherwise combine results from two or more breath specimens to determine the confirmatory test result.

(d) If an EBT that meets the requirements of § 26.91(b) and (c) was used for the initial alcohol test, the same EBT may be used for confirmatory testing.

§ 26.103 Determining a confirmed positive test result for alcohol.

(a) A confirmed positive test result for alcohol must be declared under any of the following conditions:

(1) When the result of the confirmatory test for alcohol is 0.04 percent BAC or higher;

(2) When the result of the confirmatory test for alcohol is 0.03 percent BAC or higher and the donor had been in a work status for at least 1 hour at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.); or

(3) When the result of the confirmatory test for alcohol is 0.02 percent BAC or higher and the donor had been in a work status for at least 2 hours at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.).

(b) When the result of the confirmatory test for alcohol is equal to or greater than 0.01 percent BAC but less than 0.02 percent BAC and the donor has been in a work status for 3 hours or more at the time the initial test was concluded (including any breaks for rest, lunch, dental/doctor appointments, etc.), the collector shall declare the test result as negative and inform FFD program management. The licensee or other entity shall prohibit the donor from performing any duties that require the individual to be subject to this subpart and may not return the individual to performing such duties until a determination of fitness indicates that the donor is fit to safely and competently perform his or her duties.

§ 26.105 Preparing for urine collection.

(a) The collector shall ask the donor to remove any unnecessary outer garments, such as a coat or jacket, which might conceal items or substances that the donor could use to tamper with or adulterate his or her urine specimen. The collector shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments outside of the room or stall in which the urine specimen is collected. The donor may retain his or her wallet.

(b) The collector shall also ask the donor to empty his or her pockets and display the items in them to enable the collector to identify items that the donor could use to adulterate or substitute his or her urine specimen. The donor shall permit the collector to make this observation. If the donor refuses to show the collector the items in his or her

pockets, this is considered a refusal to test. If an item is found that appears to have been brought to the collection site with the intent to adulterate or substitute the specimen, the collector shall contact the MRO or FFD program manager to determine whether a directly observed collection is required. If the item appears to have been inadvertently brought to the collection site, the collector shall secure the item and continue with the normal collection procedure. If the collector identifies nothing that the donor could use to adulterate or substitute the specimen, the donor may place the items back into his or her pockets.

(c) The collector shall instruct the donor to wash and dry his or her hands before urinating.

(d) After washing his or her hands, the donor shall remain in the presence of the collector and may not have access to any water fountain, faucet, soap dispenser, cleaning agent, or other materials that he or she could use to adulterate the urine specimen.

(e) The collector may select, or allow the donor to select, an individually wrapped or sealed collection container from the collection kit materials. Either the collector or the donor, with both present, shall unwrap or break the seal of the collection container. With the exception of the collection container, the donor may not take anything from the collection kit into the room or stall used for urination.

§ 26.107 Collecting a urine specimen.

(a) The collector shall direct the donor to go into the room or stall used for urination, provide a specimen of the quantity that has been predetermined by the licensee or other entity, as defined in § 26.109(a), not flush the toilet, and return with the specimen as soon as the donor has completed the void.

(1) The donor shall provide his or her urine specimen in the privacy of a room, stall, or otherwise partitioned area (private area) that allows for individual privacy, except if a directly observed collection is required, as described in § 26.115;

(2) Except in the case of a directly observed collection, no one may go with the donor into the room or stall in which the donor will provide his or her specimen; and

(3) The collector may set a reasonable time limit for voiding.

(b) The collector shall pay careful attention to the donor during the entire collection process to note any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine is in plain view or an attempt to bring an adulterant or urine substitute into the private area used for urination). If any such conduct is detected, the collector shall document the conduct on the custody-and-control form and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115.

(c) After the donor has provided the urine specimen and submitted it to the collector, the donor shall be permitted to wash his or her hands. The collector shall inspect the toilet bowl and room or stall in which the donor voided to identify any evidence of a subversion attempt, and then flush the toilet.

§ 26.109 Urine specimen quantity.

(a) Licensees and other entities who are subject to this subpart shall establish a predetermined quantity of urine that donors are requested to provide when submitting a specimen. At a minimum, the predetermined quantity must include 30 milliliters (mL) to ensure that a sufficient quantity of urine is available for initial and confirmatory validity and drug tests at an HHS-certified laboratory, and for retesting of an aliquot of the specimen if requested by the donor under § 26.165(b). The licensee's or other entity's predetermined quantity may include more than 30 mL, if the testing program follows split specimen procedures, tests for additional drugs, or performs initial testing at a licensee testing facility. Where collected specimens are to be split under the provisions of this subpart, the predetermined quantity must include an additional 15 mL.

(b) If the quantity of urine in the first specimen provided by the donor is less than 30 mL, the collector shall take the following steps:

(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen containing at least 30 mL. The collector shall provide the donor with a separate collection container for each successive specimen;

(2) Once the donor provides a specimen of at least 30 mL, the collection must end. If the specimen quantity is at least 30 mL but is less than the licensee's or other entity's predetermined quantity, the licensee or other entity may not require the donor to provide additional specimens and may not impose any sanctions on the donor. If the donor provides a specimen of 30 mL or more, but the specimen quantity is less than the predetermined quantity, the collector shall forward the specimen to the HHS-certified laboratory for testing. If the donor provides a specimen of at least the predetermined quantity, the specimen may be processed under the FFD program's usual testing procedures;

(3) If the donor has not provided a specimen of at least 30 mL within 3 hours of the first unsuccessful attempt to provide a specimen of the predetermined quantity, the collector shall discontinue the collection and notify the FFD program manager or MRO to initiate the ''shy bladder'' procedures in § 26.119; and

(4) Neither the donor nor the collector may combine specimens. The collector shall discard specimens of less than 30 mL, except if there is reason to believe that the donor has diluted, adulterated, substituted, or otherwise tampered with the specimen, based on the collector's observations of the donor's behavior during the collection process or the specimen's characteristics, as specified in § 26.111. If the collector has a reason to believe that a specimen that is 15 mL or more, but less than 30 mL, has been diluted, adulterated, substituted, or altered, the collector shall prepare the suspect specimen for shipping to the HHS-certified laboratory and contact FFD program management to determine whether a directly observed collection is required, as described in § 26.115.

§ 26.111 Checking the acceptability of the urine specimen.

(a) Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature-measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 °F to 100 °F (32 °C to 38 °C), that is a reason to believe the donor may have altered or substituted the specimen.

(b) Immediately after the donor provides a urine specimen, including specimens of less than 30 mL but equal to or greater than 15 mL, the collector shall also inspect the specimen to determine its color and clarity and look for any signs of contaminants or adulteration. The collector shall note any unusual findings on the custody-and-control form.

(c) If there is reason to believe that the donor may have attempted to dilute, substitute, or adulterate the specimen based on specimen temperature or other observations made during the collection, the collector shall contact the

designated FFD program manager, who may consult with the MRO, to determine whether the donor has attempted to subvert the testing process or whether other circumstances may explain the observations. The FFD program manager or MRO may require the donor to provide a second specimen as soon as possible under direct observation. In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered or substituted the specimen.

(d) Any specimen of 15 mL or more that the collector suspects has been diluted, substituted, or adulterated, and any specimen of 15 mL or more that has been collected under direct observation under paragraph (c) of this section, must be sent directly to the HHS-certified laboratory for initial and, if required, confirmatory testing, and may not be subject to initial testing at a licensee testing facility.

(e) As much of the suspect specimen as possible must be preserved.

(f) An acceptable specimen is free of any apparent contaminants, meets the required basic quantity of at least 30 mL, and is within the acceptable temperature range.

§ 26.113 Splitting the urine specimen.

(a) Licensees and other entities may, but are not required to, use split-specimen methods of collection.

(b) If the urine specimen is to be split into two specimen bottles, hereinafter referred to as Bottle A and Bottle B, the collector shall take the following steps:

(1) The collector shall instruct the donor to urinate into a specimen container;

(2) The collector, in the presence of the donor and after determining specimen temperature as described in § 26.111(a), shall split the urine specimen. The collector shall pour 30 mL of urine into Bottle A and a minimum of 15 mL of urine into Bottle B. If the quantity of urine available for Bottle B is less than 15 mL, the collector shall pour the remaining urine into Bottle B and forward the specimens in Bottles A and B to the HHS-certified laboratory for drug and validity testing; and

(3) The collector shall ask the donor to observe the splitting of the urine specimen and to maintain visual contact with both specimen bottles until the custody-and-control form(s) for both specimens are completed, the specimens are sealed, and the specimens and form(s) are prepared for secure storage or shipping.

(c) Licensees and other entities may use aliquots of the specimen collected for validity screening and initial validity and drug testing at the licensee testing facility, as permitted under § 26.31(d)(3)(ii), or to test for additional drugs, as permitted under § 26.31(d)(1)(i)(A), but only if sufficient urine is available for this testing after the specimen has been split into Bottle A and Bottle B.

§ 26.115 Collecting a urine specimen under direct observation.

(a) Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this subpart or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

(1) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO reported to the licensee or other entity that there is no adequate medical explanation for the result;

(2) The donor has presented, at this collection, a urine specimen that falls outside the required temperature range;

(3) The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen; and

(4) A directly observed collection is required under § 26.69.

(b) Before collecting a urine specimen under direct observation, the collector shall obtain the agreement of the FFD program manager or MRO to obtain a urine specimen under direct observation. After obtaining agreement, the collector shall ensure that a specimen is collected under direct observation as soon as reasonably practicable.

(c) The collector shall explain to the donor the reason for direct observation of the collection under paragraph (a) of this section.

(d) The collector shall complete a new custody-and-control form for the specimen that is obtained from the directly observed collection. The collector shall record that the collection was observed and the reason(s) for the directly observed collection on the form.

(e) The collector shall ensure that the observer is the same gender as the individual. A person of the opposite gender may not act as the observer under any conditions. The observer may be a different person from the collector and need not be a qualified collector.

(f) If someone other than the collector is to observe the collection, the collector shall instruct the observer to follow the procedures in this paragraph. The individual who observes the collection shall follow these procedures:

(1) The observer shall instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed;

(2) The observer shall watch the donor urinate into the collection container. Specifically, the observer shall watch the urine go from the donor's body into the collection container;

(3) If the observer is not the collector, the observer may not take the collection container from the donor, but shall observe the specimen as the donor takes it to the collector; and

(4) If the observer is not the collector, the collector shall record the observer's name on the custody-and-control form.

(g) If a donor declines to allow a directly observed collection that is required or permitted under this section, the donor's refusal constitutes an act to subvert the testing process.

(h) If a collector learns that a directly observed collection should have been performed but was not, the collector shall inform the FFD program manager, or his or her designee. The FFD program manager or designee shall ensure that a directly observed collection is immediately performed.

§ 26.117 Preparing urine specimens for storage and shipping.

(a) Both the donor and the collector shall keep the donor's urine specimen(s) in view at all times before the specimen(s) are sealed and labeled. If any specimen or aliquot is transferred to another container, the collector shall ask the donor to observe the transfer and sealing of the container with a tamper-evident seal.

(b) Both the collector and the donor shall be present (at the same time) during the procedures outlined in this section.

(c) The collector shall place an identification label securely on each container. The label must contain the date, the donor's specimen number, and any other identifying information provided or required by the FFD program. The collector shall also apply a tamper-evident seal on each container if it is separate from the label. The specimen bottle must be securely sealed to prevent undetected tampering.

(d) The donor shall initial the identification label(s) on the specimen bottle(s) for the purpose of certifying that the specimen was collected from him or her. The collector shall also ask

the donor to read and sign a statement on the custody-and-control form certifying that the specimen(s) identified as having been collected from the donor is, in fact, the specimen(s) that he or she provided.

(e) The collector shall complete the custody-and-control form(s) and shall certify proper completion of the collection.

(f) The specimens and chain-of-custody forms must be packaged for transfer to the HHS-certified laboratory or the licensee's testing facility. If the specimens are not immediately prepared for transfer, they must be appropriately safeguarded during temporary storage.

(g) While any part of the chain-of-custody procedures is being performed, the specimens and custody documents must be under the control of the involved collector. The collector may not leave the collection site during the interval between presentation of the specimen by the donor and securing of the specimens with identifying labels bearing the donor's specimen identification numbers and seals initialed by the donor. If the involved collector momentarily leaves his or her workstation, the sealed specimens and custody-and-control forms must be secured or taken with him or her. If the collector is leaving for an extended period of time, the specimens must be packaged for transfer to the HHS-certified laboratory or the licensee testing facility and secured before the collector leaves the collection site.

(h) The specimen(s) sealed in a shipping container must be immediately transferred, appropriately safeguarded during temporary storage, or kept under the personal control of an authorized individual until transferred. These minimum procedures apply to the transfer of specimens to licensee testing facilities from collection sites (except where co-located) as well as to the shipping of specimens to HHS-certified laboratories. As an option, licensees and other entities may ship several specimens via courier in a locked or sealed shipping container.

(i) Collection site personnel shall ensure that a custody-and-control form is packaged with its associated urine specimen bottle. Unless a collection site and a licensee testing facility are co-located, the sealed and labeled specimen bottles, with their associated custody-and-control forms that are being transferred from the collection site to the drug testing laboratory must be placed in a second, tamper-evident shipping container. The second container must be designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, shipping bags, padded mailers, or bulk insulated shipping containers with that capability), so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.

(j) Collection site personnel shall arrange to transfer the collected specimens to the HHS-certified laboratory or the licensee testing facility. Licensees and other entities shall take appropriate and prudent actions to minimize false negative results from specimen degradation. Specimens that have not been shipped to the HHS-certified laboratory or the licensee testing facility within 24 hours of collection and any specimen that is suspected of having been substituted, adulterated, or tampered with in any way must be maintained cooled to not more than 6°C (42.8 °F) until they are shipped to the HHS-certified laboratory. Specimens must be shipped from the collection site to the HHS-certified laboratory or the licensee testing facility as soon as reasonably practical but, except under unusual circumstances, the time between specimen shipment and receipt of the specimen at the licensee testing facility or HHS-certified laboratory should not exceed 2 business days.

(k) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, there is no requirement that such personnel document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

§ 26.119 Determining ''shy'' bladder.

(a) When a donor has not provided a specimen of at least 30 mL within the 3 hours permitted for urine collection, FFD program personnel shall direct the donor to obtain, within 5 business days, an evaluation from a licensed physician who is acceptable to the MRO and has expertise in the medical issues raised by the donor's failure to provide a sufficient specimen. The MRO may perform this evaluation if the MRO has the appropriate expertise.

(b) If another physician will perform the evaluation, the MRO shall provide the other physician with the following information and instructions:

(1) The donor was required to take a drug test, but was unable to provide a sufficient quantity of urine to complete the test;

(2) The potential consequences of refusing to take the required drug test; and

(3) The physician must agree to follow the requirements of paragraphs (c) through (f) of this section.

(c) The physician who conducts this evaluation shall make one of the following determinations:

(1) A medical condition has, or with a high degree of probability could have, precluded the donor from providing a sufficient amount of urine; or

(2) There is an inadequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the donor from providing a sufficient quantity of urine.

(d) For purposes of this section, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration.

(e) The physician who conducts this evaluation shall provide a written statement of his or her determination and the basis for it to the MRO. This statement may not include detailed information on the donor's medical condition beyond what is necessary to explain the determination.

(f) If the physician who conducts this evaluation determines that the donor's medical condition is a serious and permanent or long-term disability that is highly likely to prevent the donor from providing a sufficient amount of urine for a very long or indefinite period of time, the physician shall set forth this determination and the reasons for it in the written statement to the MRO.

(g) The MRO shall seriously consider and assess the information provided by the physician in deciding whether the donor has a medical condition that has, or with a high degree of probability could have, precluded the donor from providing a sufficient amount of urine, as follows:

(1) If the MRO concurs with the physician's determination, then the MRO shall declare that the donor has not violated the FFD policy and the licensee or other entity shall take no further action with respect to the donor;

(2) If the MRO determines that the medical condition has not, or with a high degree of probability could not have, precluded the donor from providing a sufficient amount of urine, then the MRO shall declare that there has been a refusal to test; or

(3) If the MRO determines that the medical condition is highly likely to prevent the donor from providing a sufficient amount of urine for a very

long or indefinite period of time, then the MRO shall authorize an alternative evaluation process, tailored to the individual case, for drug testing.

Subpart F—Licensee Testing Facilities

§ 26.121 Purpose.

This subpart contains requirements for facilities that are operated by licensees and other entities who are subject to this part to perform initial tests of urine specimens for validity, drugs, and drug metabolites.

§ 26.123 Testing facility capabilities.

Each licensee testing facility shall have the capability, at the same premises, to perform either validity screening tests or initial validity tests or both, and initial drug tests for each drug and drug metabolite for which testing is conducted.

§ 26.125 Licensee testing facility personnel.

(a) Each licensee testing facility shall have one or more individuals who are responsible for day-to-day operations and supervision of the testing technicians. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or equivalent. He or she shall also have training and experience in the theory and practice of the procedures used in the licensee testing facility, and a thorough understanding of quality control practices and procedures, the review, interpretation, and reporting of test results, and proper remedial actions to be taken in response to detection of abnormal test or quality control results.

(b) Other technicians or non-technical staff shall have the necessary training and skills for their assigned tasks. Technicians who perform urine specimen testing shall have documented proficiency in operating the testing instruments and devices used at the licensee testing facility.

(c) Licensee testing facility personnel files must include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish employee competency for the position he or she holds, including, but not limited to, certification that personnel are proficient in conducting testing in accordance with manufacturer's most recent instructions for the instruments and devices used and tests for color blindness; and appropriate data to support determinations of honesty and integrity required by this part.

§ 26.127 Procedures.

(a) Licensee testing facilities shall develop, implement, and maintain clear and well-documented procedures for accession, shipment, and testing of urine specimens.

(b) Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS-certified laboratory, and continuing until final disposition of the specimens.

(c) Licensee testing facilities shall develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. If a licensee testing facility performs validity screening tests, the licensee testing facility shall develop, implement, and maintain written standard operating procedures for each test. The procedures must include, but are not limited to, detailed descriptions of—

(1) The principles of each test;

(2) Preparation of reagents, standards, and controls;

(3) Calibration procedures;

(4) Derivation of results;

(5) Linearity of the methods;

(6) Sensitivity of the methods;

(7) Cutoff values;

(8) Mechanisms for reporting results;

(9) Controls;

(10) Criteria for unacceptable specimens and results;

(11) Reagents and expiration dates; and

(12) References.

(d) Licensee testing facilities shall develop, implement, and maintain written procedures for instrument and test setup and normal operation, including the following:

(1) A schedule for checking critical operating characteristics for all instruments and validity screening tests;

(2) Tolerance limits for acceptable function checks; and

(3) Instructions for major troubleshooting and repair.

(e) Licensee testing facilities shall develop, implement, and maintain written procedures for remedial actions to be taken when systems, and instrumented and non-instrumented tests are out of acceptable limits or errors are detected. Each facility shall maintain documentation that these procedures are followed and that all necessary corrective actions are taken. In addition, each facility shall have systems in place to verify all stages of testing and reporting and to document the verification.

§ 26.129 Assuring specimen security, chain of custody, and preservation.

(a) Each licensee testing facility must be secure at all times. Each licensee or other entity shall have sufficient security measures in place to control access to the licensee testing facility and to ensure that no unauthorized personnel handle specimens or gain access to the licensee testing facility's processes or areas where records are stored. Access to these secured areas must be limited to specifically authorized individuals whose authorization is documented. All authorized visitors and maintenance and service personnel shall be escorted at all times while in the licensee testing facility.

(b) When specimens are received, licensee testing facility personnel shall inspect each package for evidence of possible tampering and shall compare information on the specimen containers within each package to the information on the accompanying custody-and-control forms. Licensee testing facility personnel shall attempt to resolve any discrepancies identified in the information on specimen bottles or on the accompanying custody-and-control forms. When resolving any discrepancies, licensee testing facility personnel shall obtain a memorandum for the record from the specimen collector involved in the discrepancy to document correction of the discrepancy. This memorandum must accompany the specimen(s) and custody-and-control forms to the HHS-certified laboratory if the specimen(s) must be transferred.

(1) Indications of tampering with specimens in transit from the collection site, or at a licensee testing facility, must be reported to senior licensee or other entity management as soon as practical and no later than 8 hours after the indications are identified. In response to a report, licensee or other entity management personnel shall initiate an investigation to determine whether tampering has occurred.

(i) If the investigation determines that tampering has occurred, licensee or other entity management shall ensure that corrective actions are taken.

(ii) If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on the specimen bottle and on the accompanying custody-and-control forms that cannot be resolved), the specimen may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal

remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen:

(i) The custody-and-control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity;

(ii) The identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form;

(iii) A specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist;

(iv) The specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist; or

(v) As required under § 26.165(f)(2).

(c) The licensee testing facility shall retain specimen containers within the testing facility's accession area until all analyses have been completed. Testing facility personnel shall use aliquots of the specimen and licensee testing facility chain-of-custody forms, or other appropriate methods of tracking aliquot custody and control, when conducting validity screening and initial validity and drug tests. The original specimen bottles and the original custody-and-control forms must remain in secure storage. Licensee testing facility personnel may discard specimens and aliquots as soon as practical after validity screening or initial validity tests have demonstrated that the specimen appears valid and initial test results for drugs and drug metabolites are negative.

(d) The licensee testing facility's procedure for tracking custody and control of specimens and aliquots must protect the identity of the donor, and provide documentation of the testing process and transfers of custody of the specimen and aliquots. Each time a specimen or aliquot is handled or transferred within the licensee testing facility, testing facility personnel shall document the date and purpose and every individual in the chain of custody must be identified.

(e) Urine specimens identified as positive or of questionable validity at a licensee testing facility must be shipped to an HHS-certified laboratory for testing as soon as reasonably practical.

(f) Licensee testing facility personnel shall take appropriate and prudent actions to minimize false negative results from specimen degradation. If validity screening or initial validity testing indicate that the specimen is of questionable validity, or initial drug test results are positive, or if a specimen has not been tested within 24 hours of receipt at the licensee testing facility, then the facility shall maintain the specimen cooled to not more than 6 °C (42.8 °F) until it is forwarded to the HHS-certified laboratory for further testing, if required. Split specimens in Bottle B that are associated with positive specimens or specimens of questionable validity in Bottle A must also be maintained cooled (as previously specified) until test results from the HHS-certified laboratory are known to be negative for Bottle A; until the MRO informs the licensee testing facility that Bottle B must be forwarded to an HHS-certified laboratory for testing; or until the specimen is moved to long-term, frozen storage, under § 26.135(c).

(g) Licensee testing facility personnel shall ensure that the original custody-and-control form is packaged with its associated urine specimen bottle. Sealed and labeled specimen bottles, with their associated custody-and-control forms, being transferred from the licensee testing facility to the HHS-certified laboratory must be placed in a second, tamper-evident shipping container designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are no longer accessible without breaking a tamper-evident seal.

(h) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, such personnel are not required to document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

§ 26.131 Cutoff levels for validity screening and initial validity tests.

(a) Each validity test result from the licensee testing facility must be based on performing either a validity screening test or an initial validity test, or both, on one or more aliquots of a urine specimen. The licensee testing facility shall forward any specimen that yields a questionable validity screening or initial validity test result to the HHS-certified laboratory for further testing. Licensee testing facilities need not perform validity screening tests before conducting initial validity tests of a specimen.

(b) At a minimum, the licensee testing facility shall test each urine specimen for creatinine, pH, and one or more oxidizing adulterants. Licensees and other entities may not specify more stringent cutoff levels for validity screening and initial validity tests than those specified in this section. If tests or observations indicate one or more of the following from either a validity screening test or an initial validity test, the licensee testing facility shall forward the specimen to the HHS-certified laboratory for additional testing:

(1) Creatinine is less than 20 milligrams (mg) per deciliter (dL);

(2) The pH of the specimen is either less than 4.5 or equal to or greater than 9, using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter that is capable of measuring pH to one decimal place (for initial validity tests), or colorimetric pH tests, dipsticks, and pH paper (for pH validity screening tests) that have a narrow dynamic range;

(3) Nitrite or other oxidant concentration is equal to or greater than 200 micrograms (mcg) per mL or equal to or greater than 200 mcg/mL nitrite-equivalents using either a nitrite colorimetric test or a general oxidant colorimetric test;

(4) The possible presence of an oxidizing adulterant (e.g., chromium (VI), pyridine (pyridinium chlorochromate)) is determined using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL);

(5) The possible presence of halogen (e.g., bleach, iodine, fluoride) is determined using a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or equal to or greater than 50 mcg/mL chromium (VI)-equivalents), a halogen colorimetric test (halogen concentration equal to or greater than the limit of detection (LOD)), or the odor of the specimen;

(6) The possible presence of glutaraldehyde is determined using either an aldehyde test (aldehyde present) or the characteristic immunoassay response is observed on one or more drug immunoassay tests;

(7) The possible presence of a surfactant is determined by using a surfactant colorimetric test with a cutoff

equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent or a foam/shake test; or

(8) The specimen shows evidence of adulterants, including, but not limited to, the following:

(i) Abnormal physical characteristics;

(ii) Reactions or responses characteristic of an adulterant obtained during the validity screening or initial test; or

(iii) A possible unidentified interfering substance or adulterant, demonstrated by interference occurring on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained).

§ 26.133 Cutoff levels for drugs and drug metabolites.

Subject to the provisions of § 26.31(d)(3)(iii), licensees and other entities may specify more stringent cutoff levels for drugs and drug metabolites than those in the table below and, in such cases, may report initial test results for only the more stringent cutoff levels. Otherwise, the following cutoff levels must be used for initial testing of urine specimens to determine whether they are negative for the indicated drugs and drug metabolites:

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2000
Phencyclidine (PCP)	25
Amphetamines	1000

§ 26.135 Split specimens.

(a) If the FFD program follows split-specimen procedures, as described in § 26.113, the licensee testing facility shall analyze aliquots of the specimen for the licensee's or other entity's purposes as described in this part. Except as provided in paragraph (b) in this section, the licensee testing facility shall store Bottles A and B of the specimen in a secure manner until the facility has finished testing. If the initial validity and drug test results are negative and the specimen in Bottle A will not be forwarded to the HHS-certified laboratory, the licensee testing facility may discard both Bottle A and Bottle B. If any test results are positive or indicate that the specimen is of questionable validity, the licensee testing facility shall forward Bottle A to the HHS-certified laboratory for testing and shall retain Bottle B in secure storage, under the requirements of § 26.159(i), or may forward it to the HHS-certified laboratory for storage.

(b) If the MRO confirms any positive, adulterated, or substituted result for a specimen in Bottle A, based on the results of confirmatory testing at an HHS-certified laboratory, and the licensee testing facility has elected to retain Bottle B of the specimen, and the donor requests testing of the specimen in Bottle B, as permitted under § 26.165(b), the MRO shall ensure that Bottle B is forwarded to an HHS-certified laboratory other than the laboratory that tested the specimen in Bottle A, under the procedures specified in § 26.165(b).

(c) If the MRO confirms that the specimen in Bottle A is positive, adulterated, substituted, or invalid and the donor does not request that Bottle B be tested, the licensee or other entity shall ensure that Bottle B is maintained in long-term, frozen storage (− 20 °C/ − 68 °F or less) for a minimum of 1 year. If a licensee testing facility elects to retain the specimen in Bottle B, rather than forwarding it to the HHS-certified laboratory with Bottle A, the licensee testing facility shall ensure proper storage conditions in the event of a prolonged power failure. After the end of 1 year, the licensee or other entity may discard Bottle B, with the exception that the licensee testing facility shall retain any specimens under legal challenge, or as requested by the NRC, until the specimen is no longer needed.

§ 26.137 Quality assurance and quality control.

(a) *Quality assurance program.* Each licensee testing facility shall have a quality assurance program that encompasses all aspects of the testing process including, but not limited to, specimen acquisition, chain of custody, security and reporting of results, validity screening (if validity screening tests are performed), initial validity and drug testing, and validation of analytical procedures. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the process of validity testing and testing for drugs and drug metabolites.

(b) *Performance testing and quality control requirements for validity screening tests.* (1) Licensee testing facilities may rely on validity screening tests to determine the need for initial tests of specimen validity either at the licensee testing facility or HHS-certified laboratory. Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting confirmatory testing for any adulterant for which the licensee testing facility conducts validity screening tests. Licensee testing facilities shall use only validity screening tests that meet the following criteria:

(i) Either the test, by lot number, has been placed on the Substance Abuse and Mental Health Services Administration (SAMHSA) list of point-of-collection tests that are approved for use in the Federal Workplace Drug Testing Program; or

(ii) Before using the test, the licensee or other entity has ensured that the validity screening test, by lot number, effectively identifies specimens of questionable validity by meeting the following performance testing and quality control requirements:

(A) The creatinine validity screening test must use a 20 mg/dL cutoff concentration;

(B) A pH specimen validity screening test must be able to determine if pH is less than 4.5 and if pH is equal to or greater than 9; and

(C) An oxidant validity screening test must be able to determine if an oxidant concentration is equal to or greater than a 200 mcg/mL nitrite-equivalent cutoff, and/or a chromium screening test must be able to determine concentrations equal to or greater than a 50 mcg/mL chromium(VI)-equivalent cutoff, and/or a halogen screening test must be able to determine the halogen concentration is equal to or greater than the LOD. Licensees and other entities who use validity screening tests for additional adulterants shall establish performance testing requirements to challenge the licensee testing facility and the HHS-certified laboratory for the additional validity screening test(s);

(D) The manufacturer has conducted validation studies to document the validity screening test's performance characteristics around each applicable cutoff specified in this section, using performance testing samples that have been formulated to challenge the validity screening test around the applicable cutoffs. These validation studies must demonstrate the validity screening test's ability to differentiate valid samples from those of questionable validity and the performance of the validity screening test(s) around the applicable cutoffs specified in this section; and

(E) The licensee testing facility shall submit three consecutive sets of performance testing samples to the manufacturer, using performance testing samples that have been formulated to challenge the validity screening test around the applicable cutoffs specified

in this paragraph and whose formulation levels have been confirmed by an HHS-certified laboratory. For example, one set of performance testing samples used to challenge a creatinine validity screening test must include at least six samples formulated at different concentrations ranging from 0 to 20 mg/dL. A set of performance testing samples used to challenge a pH validity screening test must include at least six samples formulated with different pH levels that are equal to or less than 4.5, and six samples formulated with different pH levels that are equal to or greater than 9. And, a set of performance testing samples used to challenge an oxidizing adulterant validity screening test must include at least six samples to challenge each validity screening test used. The performance testing samples for oxidizing adulterants must contain nitrite and other oxidizing adulterant concentrations in a range of less than or equal to a 200 mcg/mL nitrite-equivalent cutoff to a 500 mcg/mL nitrite-equivalent cutoff; chromium samples formulated in a range less than or equal to a 50 mcg/mL chromium(VI)-equivalent cutoff to 100 mcg/mL chromium(VI)-equivalent cutoff; or halogen samples formulated in a concentration at or near the LOD and 25 percent above the LOD. The results of analyzing the three consecutive sets of performance test samples for each validity screening test (i.e., creatinine, pH, nitrite and general oxidants, chromium, or halogen) must demonstrate that the validity screening test, by lot number, correctly identified at least 90 percent of the total validity performance test challenges on each of three sets of performance testing samples, and, for each individual specimen validity screening test, the test, by lot number, correctly identified at least 90 percent of the validity performance test challenges on each of three sets of performance testing samples; and

(iii) After the licensee testing facility has placed a validity screening test in service, the licensee or other entity shall verify that the test, by lot number, remains on the SAMHSA-approved list. Or, if the SAMHSA-approved list is unavailable, the licensee or other entity shall ensure that the test continues to identify specimens of questionable validity, as demonstrated by documentation from the manufacturer that a set of validity screening tests from each lot in use by the licensee testing facility correctly identified at least 90 percent of the total validity test challenges on a set of performance testing samples, and, for each individual specimen validity screening test, that the test, by lot number, correctly identified at least 90 percent of the validity test challenges. This performance testing must be performed at a nominal annual frequency after the date on which the manufacturer completed the initial validation studies required under paragraph (b)(1)(ii)(D) of this section. The performance testing samples used must be formulated to challenge the validity screening test around the applicable cutoffs of this subpart.

(2) In addition, licensee testing facility personnel who perform the validity screening tests shall conduct quality control testing of validity screening tests as follows:

(i) At the beginning of any 8-hour period during which the licensee testing facility will perform validity screening tests, licensee testing facility personnel shall test a minimum of one quality control sample that is negative for each specific validity test to be performed (e.g., creatinine, pH, nitrites, chromium) during the 8-hour period, and one quality control sample that is formulated to challenge the validity screening test(s) around the cutoffs specified in this subpart for each specific validity test to be performed during the 8-hour period. The results of these quality control tests must be correct before any donor specimens may be tested.

(ii) After screening every ten donor specimens during the 8-hour period, licensee testing facility personnel shall also challenge each validity screening test with at least one quality control sample that is formulated to challenge the validity screening test(s) around the cutoffs specified in this subpart. If fewer than ten donor specimens were screened during the 8-hour period or the number of donor specimens tested exceeds a multiple of ten but is less than the next multiple of ten (e.g., 24 donor specimens, 48 donor specimens), licensee testing facility personnel shall challenge each validity screening test at the end of the 8-hour period during which the validity screening tests were performed.

(3) The licensee testing facility shall also submit at least one specimen out of every ten donor specimens that test negative using each validity screening test that the licensee testing facility uses to an HHS-certified laboratory as part of the licensee testing facility's quality assurance program.

(4) Licensee testing facilities shall store specimen validity tests as specified by the manufacturer's instructions and may not use such tests after the manufacturer's expiration date.

(c) *Validity screening test results.* If the results of a validity screening test indicate that the specimen is of questionable validity, the licensee testing facility may either perform initial validity testing or shall forward the specimen to the HHS-certified laboratory for further testing.

(d) *Quality control requirements for performing initial validity tests.* Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting confirmatory testing for any adulterant for which the licensee testing facility conducts initial validity tests.

(1) Creatinine. Creatinine concentration must be measured to 1 decimal place. The initial creatinine test must have a control in the range of 3 to 20 mg/dL and a control in the range of 21 to 25 mg/dL.

(2) Requirements for performing initial pH tests are as follows:

(i) Colorimetric pH tests that have a dynamic range of 2 to 12 and pH meters and must be capable of measuring pH to one decimal place.

(ii) An initial colorimetric pH test must have the following calibrators and controls:

(A) One calibrator at 3;

(B) One calibrator at 11;

(C) One control in the range of 2 to 2.8;

(D) One control in the range of 3.2 to 4;

(E) One control in the range of 4.5 to 9;

(F) One control in the range of 10 to 10.8; and

(G) One control in the range of 11.2 to 12.

(iii) If a pH screening test is not used, an initial pH meter test must have the following calibrators and controls:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One calibrator at 10;

(D) One control in the range of 2 to 2.8;

(E) One control in the range of 3.2 to 4;

(F) One control in the range of 10 to 10.8; and

(G) One control in the range of 11.2 to 12.

(iv) If a pH screening test is used, an initial pH meter test must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One control in the range of 2 to 2.8; and

(D) One control in the range of 3.2 to 4.

(v) If a pH screening test is used, an initial pH meter test must have the following calibrators and controls when the screening test result indicates that the pH is above the upper decision point in use:

(A) One calibrator at 7;

(B) One calibrator at 10;

(C) One control in the range of 10 to 10.8; and

(D) One control in the range of 11.2 to 12.

(3) Oxidizing adulterants. Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration for the compound of interest, a control without the compound of interest (i.e., a certified negative control), and a control with at least one of the compounds of interest at a measurable concentration. For nitrite, the licensee testing facility shall have one control in the range of 200 to 400 mcg/mL, one control in the range of 500 to 625 mcg/mL, and a control without nitrite (i.e., a certified negative control).

(4) Other adulterants. Initial tests for other adulterants must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(5) Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a donor specimen to the laboratory analysts.

(6) The licensee testing facility shall also submit at least one specimen out of every 10 donor specimens that test negative on the initial validity tests performed by the licensee testing facility to an HHS-certified laboratory as part of the licensee testing facility's quality assurance program.

(e) *Quality control requirements for initial drug tests.* (1) Any initial drug test performed by a licensee testing facility must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Licensee testing facilities may not use non-instrumented immunoassay testing devices that are pending HHS/SAMHSA review and approval for initial drug testing under this part. In addition, licensees and other entities may not take management actions on the basis of any drug test results obtained from non-instrumented devices that may be used for validity screening tests.

(2) Licensee testing facilities shall discard negative specimens or may pool them for use in the licensee testing facility's internal quality control program after certification by an HHS-certified laboratory that the specimens are negative and valid. Licensee testing facilities may not retain any information linking donors to specimens that are pooled for use in the internal quality control program.

(3) Licensee testing facilities may perform multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements of this part. For example, a licensee testing facility may use immunoassay technique ''A'' for all drugs using the licensee's or other entity's cutoff levels, but specimens testing positive for amphetamines may also be tested using immunoassay technique ''B'' to eliminate any possible positives due to structural analogues; or, a valid analytical result cannot be obtained using immunoassay technique ''A'' and immunoassay technique ''B'' is used in an attempt to obtain a valid analytical result.

(4) Licensee testing facilities need not assess their false positive testing rates for drugs, because all specimens that test as positive on the initial tests for drugs and drug metabolites must be forwarded to an HHS-certified laboratory for initial and confirmatory testing.

(5) To ensure that the rate of false negative drug tests is kept to the minimum that the immunoassay technology supports, licensee testing facilities shall submit to the HHS-certified laboratory a minimum of 5 percent (or at least one) of the donor specimens screened as negative from every analytical run.

(6) A minimum of 10 percent of all specimens in each analytical run of specimens to be initially tested for drugs by the licensee testing facility must be quality control samples, which the licensee testing facility shall use for internal quality control purposes. (These samples are not forwarded to the HHS-certified laboratory for further testing, other than for performance testing of the samples.) Licensee testing facilities shall ensure that quality control samples that are positive for each drug and metabolite for which the FFD program conducts testing are included in at least one analytical run each calendar quarter. The quality control samples for each analytical run must include—

(i) Sample(s) certified by an HHS-certified laboratory to contain no drugs or drug metabolites (i.e., negative urine samples);

(ii) At least one positive control with drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff;

(iii) At least one positive control with drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff;

(iv) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff (after acceptable values are obtained for the known calibrators, those values will be used to calculate sample data); and

(v) At least one positive control, certified to be positive by an HHS-certified laboratory, that appears to be a donor specimen to the laboratory analysts.

(7) Licensee testing facilities shall document the implementation of procedures to ensure that carryover does not contaminate the testing of a donor's specimen.

(f) *Errors in testing.* Each licensee testing facility shall investigate any testing errors or unsatisfactory performance discovered in the testing of quality control samples, in the testing of actual specimens, or through the processing of management reviews and/or MRO reviews, as well as any other errors or matters that could adversely reflect on the licensee testing facility's testing process.

(1) Whenever possible, the investigation must determine relevant facts and identify the root cause(s) of the testing or process error.

(2) The licensee testing facility shall take action to correct the cause(s) of any errors or unsatisfactory performance that are within the licensee testing facility's control.

(3) If false negative results are obtained in any analytical run from testing the quality control samples specified in paragraphs (b), (d), and (e) of this section at the licensee testing facility, the licensee testing facility shall forward all donor specimens from that analytical run to the HHS-certified laboratory for additional testing and implement corrective actions before resuming testing of donor specimens for the drug(s), drug metabolite(s), adulterant(s), or other specimen characteristics (i.e., creatinine, pH) associated with the quality control sample that yielded the false negative result(s).

(4) If a donor specimen that yielded negative validity or drug test results at the licensee testing facility yields positive, substituted, adulterated, or invalid results after confirmatory testing by the HHS-certified laboratory under paragraphs (b)(3), (d)(6), or (e)(5) of this section, the licensee or other entity shall implement corrective actions before resuming testing of donor specimens for the drug(s), drug metabolite(s), adulterant(s), or other specimen

characteristics (i.e., creatinine, pH) associated with the donor specimen that yielded the false negative result(s). In addition to resolving any technical, methodological, or administrative errors in the licensee testing facility's testing process, the licensee or other entity may re-collect and test specimens from any donor whose test results from the licensee testing facility may have been inaccurate.

(5) A record of the investigative findings and the corrective actions taken, where applicable, must be dated and signed by the individuals who are responsible for the day-to-day management of the licensee testing facility and reported to appropriate levels of management.

(g) *Accuracy.* Volumetric pipettes and measuring devices must be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors must be checked for accuracy and reproducibility before being placed in service, and periodically thereafter.

(h) *Calibrators and controls.* Calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

§ 26.139 Reporting initial validity and drug test results.

(a) The licensee testing facility shall report as negative all specimens that are valid on the basis of validity screening or initial validity tests, or both, and are negative on the initial tests for drugs and drug metabolites. Except as permitted under § 26.75(h), positive test results from initial drug tests at the licensee testing facility may not be reported to licensee or other entity management. In addition, the licensee testing facility may not report results from validity screening or initial validity testing indicating that a specimen is of questionable validity or positive initial drug test results from specimens that are of questionable validity.

(b) Except as provided in §§ 26.37 and 26.75(h), access to the results of initial tests must be limited to the licensee testing facility's staff, the MRO and MRO staff, the FFD program manager, and, when appropriate, EAP staff and the SAE.

(c) The licensee testing facility shall provide qualified personnel, when required, to testify in an administrative or disciplinary proceeding against an individual when that proceeding is based on urinalysis results reported by the licensee testing facility.

(d) The licensee testing facility shall prepare the information required for the annual report to the NRC, as required in § 26.717.

(e) The data in the annual report to the NRC must be presented for either the cutoff levels specified in this part, or for more stringent cutoff levels, if the FFD program uses more stringent cutoff levels for drugs and drug metabolites. If the FFD program tests for drugs and drug metabolites that are not specified in § 26.31(d)(1), the summary must also include the number of positive test results and the cutoff levels used for those drugs and drug metabolites.

(f) The designated FFD program official shall use the available information from the licensee testing facility's validity and drug test results, the results of quality control testing performed at the licensee testing facility, and the results from testing the quality control samples that the licensee testing facility submits to the HHS-certified laboratory to evaluate continued testing program effectiveness and detect any local trends in drugs of abuse that may require management action or FFD program adjustments. FFD program adjustments may include, but are not limited to, training enhancements, procedure changes, the expansion of the FFD program's drug panel to include additional drugs to be tested, or changes in the types of assays, validity screening tests, or instruments used.

Subpart G—Laboratories Certified by the Department of Health and Human Services

§ 26.151 Purpose.

This subpart contains requirements for the HHS-certified laboratories that licensees and other entities who are subject to this part use for testing urine specimens for validity and the presence of drugs and drug metabolites.

§ 26.153 Using certified laboratories for testing urine specimens.

(a) Licensees and other entities who are subject to this part shall use only laboratories certified under the Department of Health and Human Services (HHS) Mandatory Guidelines for Federal Workplace Drug Testing Programs [published in the **Federal Register** on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13,1998 (63 FR 63483), and April 13, 2004 (69 FR 19643)] for specimen validity and drug testing, except as permitted under § 26.31(d)(3)(ii). Information concerning the current certification status of laboratories is available from the Division of Workplace Programs, Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration, Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857.

(b) HHS-certified laboratories shall have the capability, at the same premises, to perform both initial and confirmatory tests for specimen validity and for each drug and drug metabolite for which the HHS-certified laboratory provides services to the licensee or other entity.

(c) An HHS-certified laboratory may not subcontract and shall perform all work with its own personnel and equipment unless otherwise authorized by the licensee or other entity.

(d) Licensees and other entities shall use only HHS-certified laboratories that agree to follow the same rigorous specimen testing, quality control, and chain-of-custody procedures when testing for more stringent cutoff levels as may be specified by licensees and other entities for the classes of drugs identified in this part, and for any other substances included in the licensees' or other entities' panels.

(e) Before awarding a contract to an HHS-certified laboratory, the licensee or other entity shall ensure that qualified personnel conduct a pre-award inspection and evaluation of the procedural aspects of the laboratory's drug testing operations. However, if an HHS-certified laboratory loses its certification, in whole or in part, a licensee or other entity may immediately begin using another HHS-certified laboratory that is being used by another licensee or entity who is subject to this part, as permitted by § 26.41(g)(5).

(f) All contracts between licensees or other entities who are subject to this part and HHS-certified laboratories must require the laboratory to implement all applicable requirements of this part. At a minimum, licensees' and other entities' contracts with HHS-certified laboratories must include the following requirements:

(1) Laboratory facilities shall comply with the applicable provisions of any State licensor requirements;

(2) The laboratory shall make available qualified personnel to testify in an administrative or disciplinary

proceeding against an individual when that proceeding is based on urinalysis results reported by the HHS-certified laboratory;

(3) The laboratory shall maintain test records in confidence, consistent with the requirements of § 26.39, and use them with the highest regard for individual privacy;

(4) Consistent with the principles established in section 503 of Public Law 100–71, any employee of a licensee or other entity who is the subject of a drug test (or his or her representative designated under § 26.37(d)) shall, on written request, have access to the laboratory's records related to his or her validity and drug test and any records related to the results of any relevant certification, review, or revocation-of-certification proceedings;

(5) The laboratory may not enter into any relationship with the licensee's or other entity's MRO(s) that may be construed as a potential conflict of interest, including, but not limited to, the relationships described in § 26.183(b), and may not derive any financial benefit by having a licensee or other entity use a specific MRO; and

(6) The laboratory shall permit representatives of the NRC and any licensee or other entity using the laboratory's services to inspect the laboratory at any time, including unannounced inspections.

(g) If licensees or other entities use a form other than the current Federal custody-and-control form, licensees and other entities shall provide a memorandum to the laboratory explaining why a non-Federal form was used, but must ensure, at a minimum, that the form used contains all the required information on the Federal custody-and-control form.

§ 26.155 Laboratory personnel.

(a) *Day-to-day management of the HHS-certified laboratory.* HHS-certified laboratories shall have a responsible person to assume professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facilities.

(1) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are as follows:

(i) Certification by the appropriate State as a laboratory director in forensic or clinical laboratory toxicology; or

(ii) A PhD in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the responsible person shall also have the following minimum qualifications:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology (e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors that qualify the individual as an expert witness in forensic toxicology).

(2) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory, even if another individual has overall responsibility for an entire multi-specialty laboratory.

(3) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(4) This individual shall be responsible for ensuring that the laboratory has a manual of standard operating procedures that are complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedures must be reviewed, signed, and dated by this responsible person whenever the procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. This individual shall ensure that copies of all procedures and records of the dates on which they are in effect are maintained. (Specific contents of the procedures are described in § 26.157.)

(5) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; maintaining acceptable analytical performance for all controls and standards; maintaining quality control testing; and assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(6) This individual shall be responsible for taking all remedial actions that may be necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, including errors in result reporting or in the analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.

(b) *Certifying scientist.* (1) HHS-certified laboratories shall have one or more certifying scientists who review all pertinent data and quality control results to certify the laboratory's test results.

(2) A certifying scientist shall be an individual with at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain-of-custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience must also include the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to aberrant test or quality control results, or a determination that test systems are out of control limits.

(3) A laboratory may designate certifying scientists who only certify results that are reported negative and certifying scientists who certify results that are reported both negative and adulterated, substituted, dilute, or invalid.

(c) *Day-to-day operations and supervision of analysts.* HHS-certified laboratories shall assign one or more individuals who are responsible for day-to-day operations and supervision of the technical analysts. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field. The individual(s) shall also have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; review, interpretation, and reporting of test results; maintenance of the chain of

custody; and proper remedial actions to be taken in response to aberrant test or quality control results, or the finding that test systems are out of control limits.

(d) *Other personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for their assigned tasks.

(e) *Training.* HHS-certified laboratories shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* At a minimum, each laboratory personnel file must include a résumé, any professional certification(s) or license(s), a job description, and documentation to show that the individual has been properly trained to perform his or her job.

§ 26.157 Procedures.

(a) HHS-certified laboratories shall develop, implement, and maintain clear and well-documented procedures for accession, receipt, shipment, and testing of urine specimens.

(b) Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to another HHS-certified laboratory, if required, and continuing until final disposition of specimens.

(c) HHS-certified laboratories shall develop, implement, and maintain a written manual of standard operating procedures for each assay performed for licensees and other entities for drug and specimen validity testing. The procedures must include, but are not limited to, detailed descriptions of—

(1) The principles of each test;

(2) Preparation of reagents, standards, and controls;

(3) Calibration procedures;

(4) Derivation of results;

(5) Linearity of methods;

(6) Sensitivity of the methods;

(7) Cutoff values;

(8) Mechanisms for reporting results;

(9) Controls;

(10) Criteria for unacceptable specimens and results;

(11) Reagents and expiration dates; and

(12) References.

(d) HHS-certified laboratories shall develop, implement, and maintain written procedures for instrument setup and normal operation, including the following:

(1) A schedule for checking critical operating characteristics for all instruments;

(2) Tolerance limits for acceptable function checks; and

(3) Instructions for major troubleshooting and repair.

(e) HHS-certified laboratories shall develop, implement, and maintain written procedures for remedial actions to be taken when errors are detected or systems are out of acceptable limits. The laboratory shall maintain documentation that its personnel follow these procedures and take all necessary corrective actions. In addition, the laboratory shall have systems in place to verify all stages of testing and reporting and to document the verification.

§ 26.159 Assuring specimen security, chain of custody, and preservation.

(a) The HHS-certified laboratories performing services for licensees and other entities under this part shall be secure at all times. Each laboratory shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or areas where records are stored. Access to these secured areas must be limited to specially authorized individuals whose authorization is documented. All authorized visitors, and maintenance and service personnel, shall be escorted at all times in the laboratory, except personnel who are authorized to conduct inspections and audits on behalf of licensees, other entities, the NRC, or the HHS Secretary, and emergency personnel (including but not limited to firefighters and medical rescue teams).

(b) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and shall compare information on specimen bottles within each package to the information on the accompanying custody-and-control forms.

(1) Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the custody-and-control forms attached to the shipment must be reported to the licensee or other entity within 24 hours of the discovery and must be noted on the custody-and-control forms for each specimen contained in the package. When notified, the licensee or other entity shall ensure that an investigation is initiated to determine whether tampering has occurred.

(i) If the investigation determines that tampering has occurred, the licensee or other entity shall ensure that corrective actions are taken.

(ii) If the licensee or other entity has reason to question the integrity and identity of the specimens, the specimens may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen:

(i) The custody-and-control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity;

(ii) The identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form;

(iii) A specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist;

(iv) The specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist; or

(v) As required under § 26.165(f)(2).

(c) The HHS-certified laboratory shall retain specimen bottles within the laboratory's accession area until all analyses have been completed. Laboratory personnel shall use aliquots and laboratory internal custody-and-control forms when conducting initial and confirmatory tests. The original specimen and the original custody-and-control form must remain in secure storage.

(d) The laboratory's internal custody-and-control form must allow for identification of the donor, and documentation of the testing process and transfers of custody of the specimen.

(e) Each time a specimen is handled or transferred within the laboratory, laboratory personnel shall document the date and purpose on the custody-and-control form and every individual in the chain shall be identified. Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(f) If a specimen is to be transferred to a second HHS-certified laboratory, laboratory personnel shall ensure that a copy of the custody-and-control form is packaged with the aliquot of a single specimen or Bottle B of a split specimen, as appropriate. Sealed and labeled specimen bottles and aliquots, with their associated custody-and-control forms, being transferred from one laboratory to another must be placed in a second, tamper-evident shipping container designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are inaccessible without breaking a tamper-evident seal.

(g) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, such personnel are not required to document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

(h) Specimens that do not receive an initial test within 7 days of arrival at the laboratory must be placed in secure refrigeration units for short-term storage. Temperatures may not exceed 6 °C (42.8 °F). The laboratory shall ensure proper storage conditions in the event of a prolonged power failure.

(i) Long-term frozen storage at a temperature of −20 °C (−68 °F) or less ensures that positive, adulterated, substituted, and invalid urine specimens and Bottle B of a split specimen will be available for any necessary retests. Unless otherwise authorized in writing by the licensee or other entity, laboratories shall retain and place in properly secured long-term frozen storage all specimens reported as positive, adulterated, substituted, or invalid. At a minimum, such specimens must be stored for 1 year. Within this 1-year period, a licensee, other entity, or the NRC may ask the laboratory to retain the specimen for an additional period of time. If no retention request is received, the laboratory may discard the specimen after the end of 1 year. However, the laboratory shall retain any specimens under review or legal challenge until they are no longer needed.

(j) The laboratory shall discard a valid specimen that tests negative on initial or confirmatory drug tests or may pool such specimens for use in the laboratory's internal quality control program after certifying that the specimens are negative and valid. The laboratory may not retain any information linking donors to specimens that are pooled for use in the internal quality control program.

§ 26.161 Cutoff levels for validity testing.

(a) *Validity test results.* Each validity test result for a specimen that the HHS-certified laboratory reports to the MRO as adulterated, substituted, dilute, or invalid must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot. Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting, and conducts, confirmatory testing for at least one oxidizing adulterant and any other adulterants specified by the licensee's or other entity's testing program. If initial validity test results indicate that the specimen is valid under the criteria in paragraphs (c) through (f) of this section, the HHS-certified laboratory need not perform confirmatory validity testing of the specimen.

(b) *Initial validity testing.* The HHS-certified laboratory shall perform initial validity testing of each specimen as follows:

(1) Determine the creatinine concentration;

(2) Determine the specific gravity of every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH;

(4) Perform one or more initial validity tests for oxidizing adulterants; and

(5) Perform additional validity tests, the choice of which depends on the observed indicators or characteristics below, when the following conditions are observed:

(i) Abnormal physical characteristics;

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

(c) *Results indicating an adulterated specimen.* The laboratory shall report a specimen as adulterated when the specimen yields any one or more of the following validity testing results:

(1) The pH is less than 3, or equal to or greater than 11, using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;

(4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a halogen colorimetric test (halogen concentration equal to or greater than the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the specimen yields the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and gas chromatography/mass spectrometry (GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOD of the analysis on the second aliquot;

(6) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and GC/MS for the confirmatory test with the pyridine concentration equal to or greater than the LOD of the analysis on the second aliquot;

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate equivalent on the second aliquot; or

(8) The presence of any other adulterant not specified in paragraphs (c)(3) through (c)(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(d) *Results indicating a substituted specimen.* The laboratory shall report a specimen as substituted when the specimen's creatinine concentration is less than 2 mg/dL and its specific gravity is less than or equal to 1.0010, or equal to or greater than 1.0200, on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

(e) *Results indicating a dilute specimen.* The laboratory shall report a specimen as dilute when the specimen's creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and its specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(f) *Results indicating an invalid specimen.* The laboratory shall report a specimen as invalid when the laboratory obtains any one or more of the following validity testing results:

(1) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 3 and less than 4.5, or equal to or greater than 9 and less than 11, using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test, or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial test and the confirmatory test, or, using either initial test, the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL using a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial test and the confirmatory test on two separate aliquots;

(5) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOD for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined using the same aldehyde test (aldehyde present) or the characteristic immunoassay response is observed on one or more drug immunoassay tests for both the initial test and the confirmatory test on two separate aliquots;

(7) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with cutoffs equal to or greater than 200 mcg/mL nitrite-equivalents, equal to or greater than 50 mcg/mL chromium (VI)-equivalents, or a halogen concentration equal to or greater than the LOD) for both the initial test and the confirmatory test on two separate aliquots;

(8) The possible presence of a surfactant is determined using the same surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent for both the initial test and the confirmatory test on two separate aliquots or a foam/shake test for the initial test;

(9) Interference occurs on the immunoassay drug tests on two separate aliquots (i.e., valid immunoassay drug test results cannot be obtained);

(10) Interference with the drug confirmation assay occurs on at least two separate aliquots of the specimen, and the laboratory is unable to identify the interfering substance;

(11) The physical appearance of the specimen indicates that testing may damage the laboratory's equipment; or

(12) The physical appearances of Bottles A and B (when a split specimen collection is used) are clearly different, and either the test result for Bottle A indicated it is an invalid specimen or the specimen in Bottle A was screened negative for drugs, or both.

(g) *Additional testing by a second laboratory.* If the presence of an interfering substance/adulterant is suspected that could make a test result invalid, but it cannot be identified (e.g., a new adulterant), laboratory personnel shall consult with the licensee's or other entity's MRO and, with the MRO's agreement, shall send the specimen to another HHS-certified laboratory that has the capability to identify the suspected substance.

(h) *More stringent validity test cutoff levels are prohibited.* Licensees and other entities may not specify more stringent cutoff levels for validity tests than those specified in this section.

§ 26.163 Cutoff levels for drugs and drug metabolites.

(a) *Initial drug testing.* (1) HHS-certified laboratories shall apply the following cutoff levels for initial testing of specimens to determine whether they are negative for the indicated drugs and drug metabolites, except if validity testing indicates that the specimen is dilute or the licensee or other entity has established more stringent cutoff levels:

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2000
Phencyclidine (PCP)	25
Amphetamines	1000

(2) At the licensee's or other entity's discretion, as documented in the FFD program policies and procedures, the licensee or other entity may require the HHS-certified laboratory to conduct special analyses of dilute specimens as follows:

(i) If initial validity testing indicates that a specimen is dilute, the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes;

(ii) If any response is equal to or greater than 50 percent of the cutoff, the HHS-certified laboratory shall conduct confirmatory testing of the specimen down to the LOD for those drugs and/or drug metabolites; and

(iii) The laboratory shall report the numerical values obtained from this special analysis to the MRO.

(b) *Confirmatory drug testing.* (1) A specimen that is identified as positive on an initial drug test must be subject to confirmatory testing for the class(es) of drugs for which the specimen initially tested positive. The HHS-certified laboratory shall apply the confirmatory cutoff levels specified in this paragraph, except if the licensee or other entity requires the special analysis of dilute specimens permitted in paragraph (a)(2) of this section or the licensee or other entity has established more stringent cutoff levels.

CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level (ng/mL)
Marijuana metabolite[1]	15
Cocaine metabolite[2]	150
Opiates:	
Morphine	2000
Codeine	2000
6-acetylmorphine[3]	10
Phencyclidine (PCP)	25
Amphetamines:	
Amphetamine	500
Methamphetamine[4]	500

[1] As delta-9-tetrahydrocannabinol-9-carboxylic acid.

[2] As benzoylecgonine.

[3] Test for 6–AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/mL.

[4] Specimen must also contain amphetamine at a concentration equal to or greater than 200 ng/mL.

(2) Each confirmatory drug test must provide a quantitative result. When the concentration of a drug or metabolite exceeds the linear range of the standard curve, the laboratory may record the result as ''exceeds the linear range of the test'' or as ''equal to or greater than <insert the value for the upper limit of the linear range>,'' or may dilute an aliquot of the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range.

§ 26.165 Testing split specimens and retesting single specimens.

(a) *Testing split specimens.* (1) If a specimen has been split into Bottle A and Bottle B at the collection site, and the specimen was not initially tested at a licensee testing facility, then the HHS-certified laboratory shall perform initial and confirmatory validity and drug testing, if required, of the specimen in Bottle A.

(2) If a specimen was initially tested at a licensee testing facility and positive or questionable validity test results were obtained, then the HHS-certified laboratory shall perform initial and confirmatory testing, if required, of the specimen in Bottle A.

(3) At the licensee's or other entity's discretion, Bottle B must either be forwarded to the HHS-certified laboratory or maintained in secure storage at the licensee testing facility, as required by § 26.135(a) and (c), as applicable. If the specimen in Bottle A is free of any evidence of drugs or drug metabolites, and is a valid specimen, then the licensee testing facility or HHS-certified laboratory may discard the specimens in Bottles A and B.

(b) *Donor request to MRO for a retest of a single specimen or testing Bottle B of a split specimen.* (1) For a confirmed positive, adulterated, or substituted result reported on a single specimen of 30 mL or more, or a specimen in Bottle A of a split specimen which the donor submitted to the licensee or other entity, a donor may request (through the MRO) that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. For an invalid test result, a donor may not request that an aliquot from the single specimen or the split specimen in Bottle B be tested by a second HHS-certified laboratory.

(2) The MRO shall inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen. The MRO shall provide the donor with specific instructions for making this request (i.e., providing telephone numbers or other contact information). The MRO shall have the ability to receive the donor's calls at all times during the 3-day period (e.g., by use of an answering machine with a ''time stamp'' feature when there is no one in the MRO's office to answer the phone). The donor's request may be oral or in writing.

(3) The donor shall provide his or her permission for retesting an aliquot of the single specimen or the testing of Bottle B. Neither the licensee, MRO, NRC, nor any other entity may order retesting of the single specimen or testing of the specimen in Bottle B without the donor's written permission, except as permitted in § 26.185(l).

(4) If the donor has not requested a retest of an aliquot of a single specimen or a test of the split specimen (Bottle B) within 3 business days, the donor may present to the MRO information documenting that serious injury, illness, lack of actual notice of the confirmed test result, inability to contact the MRO (e.g., there was no one in the MRO's office and the answering machine was not working), or other circumstances unavoidably prevented the donor from making a timely request. If the MRO concludes from the donor's information that there was a legitimate reason for the donor's failure to contact the MRO within the 3 business days permitted, the MRO shall direct the retesting of an aliquot of the single specimen or the test of the split specimen (Bottle B) take place, as if the donor had made a timely request.

(5) As soon as reasonably practical and not more than 1 business day following the day of the donor's request, as permitted in paragraph (b)(3) or (b)(4) of this section, the MRO shall ensure that the HHS-certified laboratory forwards an aliquot of a single specimen, or that the HHS-certified laboratory (or licensee testing facility, as appropriate) forwards Bottle B of a split specimen, to a second HHS-certified laboratory that did not test the specimen in Bottle A.

(6) The HHS-certified laboratory that retests an aliquot of a single specimen or tests the specimen in Bottle B shall provide quantitative test results to the MRO and the MRO shall provide them to the donor.

(c) *Retesting a specimen for drugs.* (1) The second laboratory shall use its confirmatory drug test when retesting an aliquot of a single specimen or testing Bottle B of a split specimen for the drug(s) or drug metabolite(s) for which the first laboratory reported a positive result(s), including retesting specimens that have been subject to the special analysis permitted in § 26.163(a)(2).

(2) Because some drugs or drug metabolites may deteriorate during storage, the retest by the second laboratory is not subject to a specific drug cutoff level, but must provide data sufficient to reconfirm the presence of the drug(s) or drug metabolite(s) down to the assay's LOD.

(3) If the second laboratory fails to reconfirm the presence of the drug(s) or drug metabolite(s) for which the first laboratory reported a positive result(s), the second laboratory shall attempt to determine the reason for not reconfirming the first laboratory's findings by conducting specimen validity tests. The second laboratory shall conduct the same specimen validity tests it would conduct on a single specimen or the specimen in Bottle A of a split specimen.

(4) The second laboratory shall report all results to the licensee's or other entity's MRO.

(d) *Retesting a specimen for adulterants.* A second laboratory shall use the required confirmatory validity

test and criteria in § 26.161(c) to reconfirm an adulterant result when retesting an aliquot from a single specimen or when testing Bottle B of a split specimen. The second laboratory may only conduct the confirmatory validity test needed to reconfirm the adulterant result reported by the first laboratory.

(e) *Retesting a specimen for substitution.* A second laboratory shall use its confirmatory creatinine and confirmatory specific gravity tests, when retesting an aliquot of a single specimen or testing Bottle B of a split specimen, to reconfirm that the creatinine concentration was less than 2 mg/dL and the specific gravity was less than or equal to 1.0010 or equal to or greater than 1.0200. The second laboratory may only conduct the confirmatory creatinine and specific gravity tests to reconfirm the substitution result reported by the first laboratory.

(f) *Management actions and sanctions.* (1) If the MRO confirms a positive, adulterated, or substituted test result(s) from the first HHS-certified laboratory and the donor requests testing of Bottle B of a split specimen or retesting of an aliquot from a single specimen, the licensee or other entity shall administratively withdraw the individual's authorization on the basis of the first confirmed positive, adulterated, or substituted test result until the results of testing Bottle B or retesting an aliquot of the single specimen are available and have been reviewed by the MRO. If the MRO reports that the results of testing Bottle B or retesting the aliquot of a single specimen reconfirm any of the original positive, adulterated, or substituted test result(s), the licensee or other entity shall impose the appropriate sanctions specified in subpart D. If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the licensee or other entity—

(i) May not impose any sanctions on the individual;

(ii) Shall eliminate from the donor's personnel file and other records any matter that could link the individual to the temporary administrative action;

(iii) May not disclose the temporary administrative action in response to a suitable inquiry conducted under the provisions of § 26.63 or to any other inquiry or investigation required in this chapter. To ensure that no records have been retained, access to the system of files and records must be provided to personnel conducting reviews, inquiries into allegations, or audits under the provisions of § 26.41, or to NRC inspectors; and

(iv) Shall provide the tested individual with a written statement that the records specified in §§ 26.713 and 26.715 have not been retained and shall inform the individual in writing that the temporary administrative action that was taken will not be disclosed and need not be disclosed by the individual in response to requests for self-disclosure of potentially disqualifying FFD information.

(2) If a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen or the specimen in Bottle B to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the original positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in subpart D of this part, but may not consider the original confirmed positive, adulterated, or substituted test result in determining the appropriate sanctions.

§ 26.167 Quality assurance and quality control.

(a) *Quality assurance program.* Each HHS-certified laboratory shall have a quality assurance program that encompasses all aspects of the testing process, including, but not limited to, specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. The performance characteristics (e.g., accuracy, precision, LOD, limit of quantitation (LOQ), specificity) of each test must be validated and documented for each test. Validation of procedures must document that carryover does not affect the donor's specimen results. Periodic re-verification of analytical procedures is required. Quality assurance procedures must be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) *Calibrators and controls required.* Each analytical run of specimens for which an initial or confirmatory validity test, or an initial or confirmatory drug test, is being performed must include the appropriate calibrators and controls.

(c) *Quality control requirements for performing initial and confirmatory validity tests.* (1) Requirements for performing creatinine tests:

(i) The creatinine concentration must be measured to one decimal place on both the initial and the confirmatory creatinine tests;

(ii) The initial creatinine test must have a calibrator at 2 mg/dL;

(iii) The initial creatinine test must have a control in the range of 1 to 1.5 mg/dL, a control in the range of 3 to 20 mg/dL, and a control in the range of 21 to 25 mg/dL; and

(iv) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have a calibrator at 2 mg/dL, a control in the range of 1.0 to 1.5 mg/dL, and a control in the range of 3 to 4 mg/dL.

(2) Requirements for performing specific gravity tests:

(i) The refractometer must report and display the specific gravity to four decimal places, and must be interfaced with a laboratory information management system, or computer, and/or generate a hard copy or digital electronic display to document the numerical result;

(ii) The initial and confirmatory specific gravity tests must have a calibrator or control at 1.0000; and

(iii) The initial and confirmatory specific gravity tests must have the following controls:

(A) One control targeted at 1.0020;

(B) One control in the range of 1.0040 to 1.0180; and

(C) One control equal to or greater than 1.0200 but not greater than 1.0250.

(3) Requirements for performing pH tests:

(i) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Dipsticks, colorimetric pH tests, and pH paper that have a narrow dynamic range and do not support the 2 to 12 pH cutoffs may be used only to determine whether initial validity tests must be performed;

(ii) At a minimum, pH screening tests must have the following controls:

(A) One control below the lower decision point in use;

(B) One control between the decision points in use; and

(C) One control above the upper decision point in use;

(iii) If a pH screening test is not used, an initial pH meter test must have the following calibrators and controls:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One calibrator at 10;

(D) One control in the range of 2 to 2.8;

(E) One control in the range of 3.2 to 4;

(F) One control in the range of 10 to 10.8; and

(G) One control in the range of 11.2 to 12;

(iv) If a pH screening test is used, an initial or confirmatory pH meter test must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(A) One calibrator at 4;

(B) One calibrator at 7;

(C) One control in the range of 2 to 2.8; and

(D) One control in the range of 3.2 to 4;

(v) If a pH screening test is used, an initial or confirmatory pH meter test must have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:

(A) One calibrator at 7;

(B) One calibrator at 10;

(C) One control in the range of 10 to 10.8; and

(D) One control in the range of 11.2 to 12; and

(vi) An initial colorimetric pH test must have the following calibrators and controls:

(A) One calibrator at 3;

(B) One calibrator at 11;

(C) One control in the range of 2 to 2.8;

(D) One control in the range of 3.2 to 4;

(E) One control in the range of 4.5 to 9;

(F) One control in the range of 10 to 10.8;

(G) One control in the range of 11.2 to 12.

(4) Requirements for performing oxidizing adulterant tests:

(i) Initial tests for oxidizing adulterants must include a calibrator at the appropriate cutoff concentration for the compound of interest as specified in § 26.161(c) and (f), a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and

(ii) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory analytical run must include a calibrator at the appropriate cutoff concentration for the compound of interest as specified in § 26.161(c) and (f), a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(5) Requirements for performing nitrite tests: The initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (i.e., certified negative urine specimen), one control in the range of 200 to 400 mcg/mL, and one control in the range of 500 to 625 mcg/mL.

(6) Requirements for performing ''other'' adulterant tests:

(i) The initial and confirmatory tests for any ''other'' adulterant that may be identified in the future must satisfy the requirements in § 26.161(a);

(ii) The confirmatory test for ''other'' adulterants must use a different analytical principle or chemical reaction than that used for the initial test; and

(iii) The initial and confirmatory tests for ''other'' adulterants must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.

(d) *Quality control requirements for performing initial drug tests.* (1) Any initial drug test performed by an HHS-certified laboratory must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Non-instrumented immunoassay testing devices that are pending HHS/SAMHSA review and approval may not be used for initial drug testing under this part.

(2) HHS-certified laboratories may perform multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements of this part. For example, an HHS-certified laboratory may use immunoassay technique ''A'' for all drugs using the licensee's or other entity's cutoff levels, but specimens testing positive for amphetamines may also be tested using immunoassay technique ''B'' to eliminate any possible positives due to structural analogues; or, a valid analytical result cannot be obtained using immunoassay technique ''A'' and immunoassay technique ''B'' is used in an attempt to obtain a valid analytical result.

(3) Quality control samples for each analytical run of specimens for initial testing must include—

(i) Sample(s) certified to contain no drugs or drug metabolites (i.e., negative urine samples);

(ii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff;

(iii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent below the cutoff;

(iv) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff (after acceptable values are obtained for the known calibrators, those values will be used to calculate sample data); and

(v) At least one control that appears to be a donor specimen to the laboratory analysts.

(4) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples, as defined by paragraphs (d)(3)(i) through (iv) of this section.

(e) *Quality control requirements for performing confirmatory drug tests.* (1) Confirmatory tests for drugs and drug metabolites must be performed using gas chromatography/mass spectrometry (GC/MS) or other confirmatory test methodologies that HHS-certified laboratories are permitted to use in Federal workplace drug testing programs for this purpose.

(2) At least 10 percent of the samples in each analytical run of specimens must be calibrators and controls.

(3) Each analytical run of specimens that are subjected to confirmatory testing must include—

(i) Sample(s) certified to contain no drug (i.e., negative urine samples);

(ii) Positive calibrator(s) and control(s) with a drug(s) or drug metabolite(s);

(iii) At least one positive control with a drug(s) or drug metabolite(s) targeted at 25 percent above the cutoff; and

(iv) At least one calibrator or control that is targeted at or below 40 percent of the cutoff.

(f) *Errors in testing.* The licensee or other entity shall ensure that the HHS-certified laboratory investigates any testing errors or unsatisfactory performance discovered in blind performance testing, as required under § 26.168, in the testing of actual specimens, or through the processing of reviews, as well as any other errors or matters that could adversely reflect on the testing process.

(1) Whenever possible, the investigation must determine relevant

facts and identify the root cause(s) of the testing or process error. The licensee or other entity, and the HHS-certified laboratory, shall take action to correct the causes of any errors or unsatisfactory performance that are within each entity's control. Sufficient records shall be maintained to furnish evidence of activities affecting quality. The licensee or other entity shall assure that the cause of the condition is determined and that corrective action is taken to preclude repetition. The identification of the significant condition, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

(2) If a false positive error occurs on a blind performance test sample or on a regular specimen, the licensee or other entity shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future. If there is reason to believe that the error could have been systematic, the licensee or other entity may also require review and re-analysis of previously run specimens.

(3) If a false positive error occurs on a blind performance test sample and the error is determined to be technical or methodological, the licensee or other entity shall instruct the laboratory to provide all quality control data from the batch or analytical run of specimens that included a false positive sample. In addition, the licensee or other entity shall require the laboratory to retest all specimens that analyzed as positive for that drug or metabolite, or as adulterated, substituted, dilute, or invalid in validity testing, from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting must be documented by a statement signed by the laboratory's responsible person. The licensee or other entity and the NRC also may require an onsite review of the laboratory, which may be conducted unannounced during any hours of operation of the laboratory.

(g) *Accuracy.* Volumetric pipettes and measuring devices must be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedures. Automatic pipetttes and dilutors must be checked for accuracy and reproducibility both before being placed in service and periodically thereafter.

(h) *Calibrators and controls.* Laboratory calibrators and controls must be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions that are obtained from commercial manufacturers and are properly labeled as to content and concentration. Calibrators and controls may not be prepared from the same stock solution. The standards and controls must be labeled with the following dates: when received; when prepared or opened; when placed in service; and when scheduled for expiration.

§ 26.168 Blind performance testing.

(a) Each licensee and other entity shall submit blind performance test samples to the HHS-certified laboratory.

(1) During the initial 90-day period of any contract with an HHS-certified laboratory (not including rewritten or renewed contracts), each licensee or other entity shall submit blind performance test samples to each HHS-certified laboratory with whom it contracts in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 100 blind performance specimens) or 30 blind performance test samples, whichever is greater.

(2) Following the initial 90-day period, the number of blind performance test samples submitted per quarter must be a minimum of one percent of all specimens (up to a maximum of 100) or ten blind performance test samples, whichever is greater.

(3) Both during the initial 90-day period and quarterly thereafter, licensees and other entities should attempt to submit blind performance test samples at a frequency that corresponds to the submission frequency for other specimens.

(b) Approximately 60 percent of the blind performance test samples submitted to the laboratory must be positive for one or more drugs or drug metabolites per sample and submitted so that all of the drugs for which the FFD program is testing are included at least once each calendar quarter, except as follows:

(1) Licensees and other entities shall submit blind performance test samples that are positive for marijuana metabolite at least two times each quarter; and

(2) In at least two quarters each year, licensees and other entities shall submit an additional blind performance test sample that is positive for cocaine instead of the required sample that is positive for PCP.

(c) The positive blind performance test samples must be positive for only those drugs for which the FFD program is testing and formulated at concentrations established in paragraph (g)(2) of this section.

(d) To challenge the HHS-certified laboratory's ability to limit false negatives, approximately 10 percent of the blind performance test samples submitted to the laboratory each quarter must be formulated at the concentrations established in paragraph (g)(3) of this section.

(e) To challenge the HHS-certified laboratory's ability to determine specimen validity, the licensee or other entity shall submit blind samples each quarter that are appropriately adulterated, diluted, or substituted, in the amount of 20 percent of the specimens submitted that quarter or at least three samples per quarter (one each that is adulterated, diluted, or substituted), whichever is greater. These samples must be formulated at the concentrations established in paragraphs (g)(4) through (g)(6) of this section.

(f) Approximately 10 percent of the blind performance test samples submitted to the laboratory each quarter must be negative, as specified in paragraph (g)(1) of this section.

(g) Licensees and other entities shall use only blind performance test samples that have been certified by the supplier to be—

(1) Negative. A negative blind performance test sample may not contain a measurable amount of a target drug analyte and must be certified by immunoassay and confirmatory testing;

(2) Drug positive. These samples must contain a measurable amount of the target drug or analyte in concentrations ranging between 150 and 200 percent of the initial cutoff values and be certified by immunoassay and confirmatory testing to contain one or more drug(s) or drug metabolite(s);

(3) A false negative challenge. This blind performance test sample must contain a measurable amount of the target drug or analyte in concentrations ranging between 130 and 155 percent of the initial cutoff values;

(4) Adulterated. The adulterated blind performance test sample must have a pH of less than or equal to 2, or greater than or equal to 12, or a nitrite or other oxidant concentration equal to or greater than 500 mcg/mL, equal to or greater than 50 mcg/mL chromium (VI)-equivalents, or a halogen concentration equal to or greater than the LOD. Blind performance test samples for other adulterants must have adulterant concentrations equal to or greater than (or equal to or less than, as appropriate) the initial cutoff levels used by the licensee's or other entity's HHS-certified laboratory;

(5) Dilute. The dilute blind performance test sample must contain a

creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030; or

(6) Substituted. The substituted blind performance test sample must contain less than 2 mg/dL of creatinine, and the specific gravity must be less than or equal to 1.0010, or equal to or greater than 1.0200.

(h) In order to ensure that blind performance test samples continue to meet the criteria set forth in paragraph (g) of this section, licensees and other entities shall—

(1) Ensure that all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory, and for no more than 6 months;

(2) Ensure that the supplier provides the expiration date for each blind performance test sample to ensure that each sample will have the expected value when it is submitted to and tested by a laboratory; and

(3) At a minimum, require the supplier to check each open lot bi-monthly (i.e., every two months) to ensure that samples remaining in the lot do not fall below 130 percent of the initial cutoff test concentration established by the assay manufacturer. Thus, for example, a lot that was certified by an HHS-certified laboratory at 155 percent of the manufacturer's assay cutoff level, and was reported by the licensee's or other entity's HHS-certified laboratory to be at or above 130 percent of that standard is acceptable. A test that indicated a result below 130 percent of that standard would be unacceptable. Licensees and other entities shall discard blind performance test samples from any lot that is outside of these parameters and may not use any further samples from that lot.

(i) Licensees and other entities shall ensure that each blind performance test sample is indistinguishable to laboratory personnel from a donor's specimen, as follows:

(1) The licensee or other entity shall submit blind performance test samples to the laboratory using the same channels (i.e., from the licensee's or other entity's collection site or licensee testing facility, as appropriate) through which donors' specimens are sent to the laboratory;

(2) The collector and licensee testing facility personnel, as appropriate, shall use a custody-and-control form, place fictional initials on the specimen bottles' labels/seals, and indicate for the MRO on the MRO's copy that the specimen is a blind performance test sample; and

(3) The licensee or other entity shall ensure that all blind performance test samples include split samples, when the FFD program includes split specimen procedures.

§ 26.169 Reporting Results.

(a) The HHS-certified laboratory shall report test results to the licensee's or other entity's MRO within 5 business days after receiving the specimen from the licensee or other entity. Before reporting any test result to the MRO, the laboratory's certifying scientist shall certify the result as correct. The report must identify the substances for which testing was performed; the results of the validity and drug tests; the cutoff levels for each; any indications of tampering, adulteration, or substitution that may be present; the specimen identification number assigned by the licensee or other entity; and the specimen identification number assigned by the laboratory.

(b) If licensees or other entities specify cutoff levels for drugs or drug metabolites that are more stringent than those specified in this part, the laboratory need only conduct the more stringent tests and shall report the results of the initial and confirmatory tests only for the more stringent cutoff levels.

(c) The HHS-certified laboratory shall report as negative all specimens that are negative on the initial or confirmatory drug and validity tests. Specimens that test as positive, adulterated, substituted, dilute, or invalid on the confirmatory analysis must be reported to the MRO as positive for a specific drug(s) or drug metabolite(s), or as meeting the criteria for an adulterated, substituted, dilute, or invalid specimen.

(1) The laboratory shall report all positive, adulterated, substituted, dilute, and invalid test results for each specimen to the MRO. For example, a specimen may be both adulterated and positive for one or more specific drugs.

(2) For a specimen that has a positive test result, the laboratory shall provide numerical values if the MRO requests such information. The MRO's request for positive confirmatory test results may be either a general request covering all such results or a specific case-by-case request. The laboratory shall routinely provide quantitative values for confirmatory opiate test results for morphine or codeine that are greater than or equal to 15,000 ng/mL, even if the MRO has not requested quantitative values for the test result.

(3) For a specimen that has an adulterated or substituted test result, the laboratory shall provide the MRO with the numerical values that support the reported result. The MRO may not disclose the numerical values to the licensee or other entity, except as permitted in § 26.37(b). If the numerical values for creatinine are below the LOD, the laboratory shall report to the MRO ''creatinine: none detected'' (i.e., substituted) along with the numerical values of the specific gravity test.

(4) For a specimen that has an invalid result, the laboratory shall contact the MRO and both will decide whether testing by another certified laboratory would be useful in being able to report a positive or adulterated result. This contact may occur through any secure electronic means (e.g., telephone, fax, e-mail). If no further testing is necessary, the laboratory shall report the invalid result to the MRO.

(5) When the concentration of a drug, metabolite, or adulterant exceeds the linear range of the standard curve, the laboratory may report to the MRO that the quantitative value ''exceeds the linear range of the test,'' that the quantitative value is ''equal to or greater than <insert the value for the upper limit of the linear range>,'' or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen.

(d) The MRO and MRO staff may not disclose quantitative test results to a licensee or other entity, but shall report only whether the specimen was positive (and for which analyte), adulterated, substituted, dilute, invalid, or negative, except as permitted under § 26.37(b). This paragraph does not preclude either the HHS-certified laboratory or the MRO from providing program performance data, as required under § 26.717.

(e) The laboratory may transmit results to the MRO by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner designed to ensure the confidentiality of the information. The laboratory may not provide results orally by telephone. The licensee or other entity, directly or through the HHS-certified laboratory, shall ensure the security of the data transmission and ensure only authorized access to any data transmission, storage, and retrieval system.

(f) For negative test results, the HHS-certified laboratory may fax, courier, mail, or electronically transmit a computer-generated electronic report and/or a legible image or copy of the completed custody-and-control form to the MRO. However, for positive, adulterated, substituted, dilute, and invalid results, the laboratory shall fax, courier, mail, or electronically transmit

a legible image or copy of the completed custody-and-control form to the MRO.

(g) For a specimen that has a positive, adulterated, substituted, dilute, or invalid result, the laboratory shall retain the original custody-and-control form and transmit to the MRO a copy of the original custody-and-control form signed by a certifying scientist.

(h) The HHS-certified laboratory shall provide to the licensee's or other entity's official responsible for coordination of the FFD program an annual statistical summary of urinalysis testing, which may not include any personal identifying information. To avoid sending data from which it is likely that information about a donor's test result can be readily inferred, the laboratory may not send a summary report if the licensee or other entity has fewer than 10 specimen test results in a 1-year period. The summary report must include test results that were reported within the year period. The laboratory shall send the summary report to the licensee or other entity within 14 calendar days after the end of the 1-year period covered by the report. The statistics must be presented either for the cutoff levels specified in this part or for any more stringent cutoff levels that the licensee or other entity may specify. The HHS-certified laboratory shall make available quantitative results for all specimens tested when requested by the NRC, licensee, or other entity for whom the laboratory is performing drug-testing services. If the FFD program tests for additional drugs beyond those listed in § 26.31(d), the summary must include drug test results for the additional drugs. The summary report must contain the following information:

(1) Total number of specimens received;

(2) Number of specimens reported as—

(i) Negative, and

(ii) Negative and dilute;

(3) Number of specimens reported as positive on confirmatory tests by drug or drug metabolite for which testing is conducted, including, but not limited to—

(i) Marijuana metabolite;

(ii) Cocaine metabolite;

(iii) Opiates (total);

(A) Codeine;

(B) Morphine; and

(C) 6-AM;

(iv) Phencyclidine;

(v) Amphetamines (total);

(A) Amphetamine; and

(B) Methamphetamine;

(4) Total number of specimens reported as adulterated;

(5) Total number of specimens reported as substituted;

(6) Total number of specimens reported as positive and dilute [including an indication as to whether the specimen was subject to the special analysis permitted in § 26.163(a)(2)];

(7) Total number of specimens reported as invalid; and

(8) Number of specimens reported as rejected for testing and the reason for the rejection.

Subpart H—Determining Fitness-for-Duty Policy Violations and Determining Fitness

§ 26.181 Purpose.

This subpart contains requirements for determining whether a donor has violated the FFD policy and for making a determination of fitness.

§ 26.183 Medical review officer.

(a) *Qualifications.* The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services. The MRO shall be a physician holding either a Doctor of Medicine or Doctor of Osteopathy degree who is licensed to practice medicine by any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. By March 31, 2010, the MRO shall have passed an examination administered by a nationally-recognized MRO certification board or subspecialty board for medical practitioners in the field of medical review of Federally mandated drug tests.

(b) *Relationships.* The MRO may be an employee of the licensee or other entity or a contractor. However, the MRO may not be an employee or agent of, or have any financial interest in, an HHS-certified laboratory or a contracted operator of a licensee testing facility for whom the MRO reviews drug test results. Additionally, the MRO may not derive any financial benefit by having the licensee or other entity use a specific drug testing laboratory or licensee testing facility operating contractor and may not have any agreement with such parties that may be construed as a potential conflict of interest. Examples of relationships between laboratories and MROs that create conflicts of interest, or the appearance of such conflicts, include, but are not limited to—

(1) The laboratory employs an MRO who reviews test results produced by the laboratory;

(2) The laboratory has a contract or retainer with the MRO for the review of test results produced by the laboratory;

(3) The laboratory designates which MRO the licensee or other entity is to use, gives the licensee or other entity a slate of MROs from which to choose, or recommends certain MROs;

(4) The laboratory gives the licensee or other entity a discount or other incentive to use a particular MRO;

(5) The laboratory has its place of business co-located with that of an MRO or MRO staff who review test results produced by the laboratory; or

(6) The laboratory permits an MRO, or an MRO's organization, to have a financial interest in the laboratory.

(c) *Responsibilities.* The primary role of the MRO is to review and interpret positive, adulterated, substituted, invalid, and at the licensee's or other entity's discretion, dilute test results obtained through the licensee's or other entity's testing program and to identify any evidence of subversion of the testing process. The MRO is also responsible for identifying any issues associated with collecting and testing specimens, and for advising and assisting FFD program management in planning and overseeing the overall FFD program.

(1) In carrying out these responsibilities, the MRO shall examine alternate medical explanations for any positive, adulterated, substituted, invalid, or, at the licensee's or other entity's discretion, dilute test result. This action may include, but is not limited to, conducting a medical interview with the donor, reviewing the donor's medical history, or reviewing any other relevant biomedical factors. The MRO shall review all medical records that the donor may make available when a positive, adulterated, substituted, invalid, or dilute test result could have resulted from responsible use of legally prescribed medication, a documented condition or disease state, or the demonstrated physiology of the donor.

(2) The MRO may only consider the results of tests of specimens that are collected and processed under this part, including the results of testing split specimens, in making his or her determination, as long as those split specimens have been stored and tested under the procedures described in this part.

(d) *MRO staff.* Individuals who provide administrative support to the MRO may be employees of a licensee or other entity, employees of the MRO, or employees of an organization with whom a licensee or other entity contracts for MRO services. Employees of a licensee or other entity who serve MRO staff functions may also perform other duties for the licensee or other entity and need not be under the

direction of the MRO while performing those other duties.

(1) Direction of MRO staff activities. MROs shall be directly responsible for all administrative, technical, and professional activities of individuals who are serving MRO staff functions while they are performing those functions, and those functions must be under the MRO's direction.

(i) The duties of MRO staff must be maintained independent from any other activity or interest of a licensee or other entity, in order to protect the integrity of the MRO function and donors' privacy.

(ii) An MRO's responsibilities for directing MRO staff must include, but are not limited to, ensuring that—

(A) The procedures being performed by MRO staff meet NRC regulations and HHS' and professional standards of practice;

(B) Records and other donor personal information are maintained confidential by MRO staff and are not released to other individuals or entities, except as permitted under this part;

(C) Data transmission is secure; and

(D) Drug test results are reported to the licensee's or other entity's designated reviewing official only as required by this part.

(iii) The MRO may not delegate any of his or her responsibilities for directing MRO staff to any other individual or entity, except another MRO.

(2) MRO staff responsibilities. MRO staff may perform routine administrative support functions, including receiving test results, reviewing negative test results, and scheduling interviews for the MRO.

(i) The staff under the direction of the MRO may receive, review, and report negative test results to the licensee's or other entity's designated representative.

(ii) The staff reviews of positive, adulterated, substituted, invalid, and, at the licensee's or other entity's discretion, dilute test results must be limited to reviewing the custody-and-control form to determine whether it contains any errors that may require corrective action and to ensure that it is consistent with the information on the MRO's copy. The staff may resolve errors in custody-and-control forms that require corrective action(s), but shall forward the custody-and-control forms to the MRO for review and approval of the resolution.

(iii) The staff may not conduct interviews with donors to discuss positive, adulterated, substituted, invalid, or dilute test results nor request medical information from a donor. Only the MRO may request and review medical information related to a positive, adulterated, substituted, or invalid test result or other matter from a donor.

(iv) Staff may not report nor discuss with any individuals other than the MRO and other MRO staff any positive, adulterated, substituted, invalid, or dilute test results received from the HHS-certified laboratory before those results have been reviewed and confirmed by the MRO. Any MRO staff discussions of confirmed positive, adulterated, substituted, invalid, or dilute test results must be limited to discussions only with the licensee's or other entity's FFD program personnel and may not reveal quantitative test results or any personal medical information about the donor that the MRO may have obtained in the course of reviewing confirmatory test results from the HHS-certified laboratory.

§ 26.185 Determining a fitness-for-duty policy violation.

(a) *MRO review required.* A positive, adulterated, substituted, dilute, or invalid drug test result does not automatically identify an individual as having used drugs in violation of the NRC's regulations, or the licensee's or other entity's FFD policy, or as having attempted to subvert the testing process. An individual who has a detailed knowledge of possible alternate medical explanations is essential to the review of the results. The MRO shall review all positive, adulterated, substituted, and invalid test results from the HHS-certified laboratory to determine whether the donor has violated the FFD policy before reporting the results to the licensee's or other entity's designated representative.

(b) *Reporting of initial test results prohibited.* Neither the MRO nor MRO staff may report positive, adulterated, substituted, dilute, or invalid initial test results that are received from the HHS-certified laboratory to the licensee or other entity.

(c) *Discussion with the donor.* Before determining that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation and reporting it to the licensee or other entity, the MRO shall give the donor an opportunity to discuss the test result or other occurrence with the MRO, except as described in paragraph (d) of this section. After this discussion, if the MRO determines that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation, the MRO shall immediately notify the licensee's or other entity's designated representative.

(d) *Donor unavailability.* The MRO may determine that a positive, adulterated, substituted, dilute, or invalid test result or other occurrence is an FFD policy violation without having discussed the test result or other occurrence directly with the donor in the following three circumstances:

(1) The MRO has made and documented contact with the donor and the donor expressly declined the opportunity to discuss the test result or other occurrence that may constitute an FFD policy violation;

(2) A representative of the licensee or other entity, or an MRO staff member, has successfully made and documented contact with the donor and has instructed him or her to contact the MRO, and more than 1 business day has elapsed since the date on which the licensee's representative or MRO's staff member successfully contacted the donor; or

(3) The MRO, after making all reasonable efforts and documenting the dates and time of those efforts, has been unable to contact the donor. Reasonable efforts include, at a minimum, three attempts, spaced reasonably over a 24-hour period, to reach the donor at the day and evening telephone numbers listed on the custody-and-control form.

(e) *Additional opportunity for discussion.* If the MRO determines that the donor has violated the FFD policy without having discussed the positive, adulterated, substituted, dilute, or invalid test result or other occurrence directly with the donor, the donor may, on subsequent notification of the MRO determination and within 30 days of that notification, present to the MRO information documenting the circumstances, including, but not limited to, serious illness or injury, which unavoidably prevented the donor from being contacted by the MRO or a representative of the licensee or other entity, or from contacting the MRO in a timely manner. On the basis of this information, the MRO may reopen the procedure for determining whether the donor's test result or other occurrence is an FFD policy violation and permit the individual to present information related to the issue. The MRO may modify the initial determination based on an evaluation of the information provided.

(f) *Review of invalid specimens.* (1) If the HHS-certified laboratory reports an invalid result, the MRO shall consult with the laboratory to determine whether additional testing by another HHS-certified laboratory may be useful in determining and reporting a positive or adulterated test result. If the MRO and the laboratory agree that further

testing would be useful, the HHS-certified laboratory shall forward the specimen to a second laboratory for additional testing.

(2) If the MRO and the laboratory agree that further testing would not be useful and there is no technical explanation for the result, the MRO shall contact the donor and determine whether there is an acceptable medical explanation for the invalid result. If there is an acceptable medical explanation, the MRO shall report to the licensee or other entity that the test result is not an FFD policy violation, but that a negative test result was not obtained. If the medical reason for the invalid result is, in the opinion of the MRO, a temporary condition, the licensee or other entity shall collect a second urine specimen from the donor as soon as reasonably practical and rely on the MRO's review of the test results from the second collection. The second specimen collected for the purposes of this paragraph may not be collected under direct observation. If the medical reason for the invalid result would similarly affect the testing of another urine specimen, the MRO may authorize an alternative method for drug testing. Licensees and other entities may not impose sanctions for an invalid test result due to a medical condition.

(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for the invalid test result, the MRO shall require that a second collection take place as soon as practical under direct observation. The licensee or other entity shall rely on the MRO's review of the test results from the directly observed collection.

(g) *Review of dilute specimens.* (1) If the HHS-certified laboratory reports that a specimen is dilute and that drugs or drug metabolites were detected in the specimen at or above the cutoff levels specified in this part or the licensee's or other entity's more stringent cutoff levels, and the MRO determines that there is no legitimate medical explanation for the presence of the drugs or drug metabolites in the specimen, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted, the MRO shall determine that the drug test results are positive and that the donor has violated the FFD policy.

(2) If the licensee or other entity requires the HHS-certified laboratory to conduct the special analysis of dilute specimens permitted in § 26.163(a)(2), the results of the special analysis are positive, the MRO determines that there is no legitimate medical explanation for the presence of the drug(s) or drug metabolite(s) in the specimen, and a clinical examination, if required under paragraph (g)(4) of this section, has been conducted under paragraph (j) of this section, the MRO shall determine whether the positive and dilute specimen is a refusal to test. If the MRO does not have sufficient reason to believe that the positive and dilute specimen is a subversion attempt, he or she shall determine that the drug test results are positive and that the donor has violated the FFD policy. When determining whether the donor has diluted the specimen in a subversion attempt, the MRO shall also consider the following circumstances, if applicable:

(i) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO determined that there is no adequate technical or medical explanation for the result;

(ii) The donor has presented a urine specimen of 30 mL or more that falls outside the required temperature range, even if a subsequent directly observed collection was performed; or

(iii) The collector observed conduct clearly and unequivocally indicating an attempt to dilute the specimen.

(3) If a dilute specimen was collected under direct observation, the MRO may require the laboratory to conduct confirmatory testing at the LOD for any drugs or drug metabolites, as long as each drug class is evaluated as required by § 26.31(d)(1)(ii).

(4) If the drugs detected in a dilute specimen are any opium, opiate, or opium derivative (e.g., morphine/codeine), or if the drugs or metabolites detected indicate the use of prescription or over-the-counter medications, before determining that the donor has violated the FFD policy under paragraph (a) of this section, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall conduct the clinical examination for abuse of these substances that is required in paragraph (j) of this section. An evaluation for clinical evidence of abuse is not required if the laboratory confirms the presence of 6–AM (i.e., the presence of this metabolite is proof of heroin use) in the dilute specimen.

(5) An MRO review is not required for specimens that the HHS-certified laboratory reports as negative and dilute. The licensee or other entity may not take any administrative actions or impose any sanctions on a donor who submits a negative and dilute specimen.

(h) *Review of substituted specimens.* (1) If the HHS-certified laboratory reports a specimen as substituted (i.e., the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200), the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the substituted result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the specimen for which the HHS-certified laboratory reported a substituted result. Any medical evidence must be submitted through a physician who is experienced and qualified in the medical issues involved, as verified by the MRO. Claims of excessive hydration, or claims based on unsubstantiated personal characteristics, including, but not limited to, race, gender, diet, and body weight, are not acceptable evidence without medical studies which demonstrate that the donor did produce the laboratory result.

(2) If the MRO determines that there is no legitimate medical explanation for the substituted test result, the MRO shall report to the licensee or other entity that the specimen was substituted.

(3) If the MRO determines that there is a legitimate medical explanation for the substituted test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the licensee or other entity that no FFD policy violation has occurred.

(i) *Review of adulterated specimens.* (1) If the HHS-certified laboratory reports a specimen as adulterated with a specific substance, the MRO shall contact the donor and offer the donor an opportunity to provide a legitimate medical explanation for the adulterated result. The burden of proof resides solely with the donor, who must provide legitimate medical evidence within 5 business days that he or she produced the adulterated result. Any medical evidence must be submitted through a physician experienced and qualified in the medical issues involved, as verified by the MRO.

(2) If the MRO determines there is no legitimate medical explanation for the adulterated test result, the MRO shall report to the licensee or other entity that the specimen is adulterated.

(3) If the MRO determines that there is a legitimate medical explanation for the adulterated test result and no drugs or drug metabolites were detected in the specimen, the MRO shall report to the

licensee or other entity that no FFD policy violation has occurred.

(j) *Review for opiates, prescription and over-the-counter medications.* (1) If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for opiates and before the MRO determines that the test result is a violation of the FFD policy, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall determine that there is clinical evidence, in addition to the positive confirmatory test result, that the donor has illegally used opium, an opiate, or an opium derivative (e.g., morphine/codeine). This requirement does not apply if the laboratory confirms the presence of 6-AM (i.e., the presence of this metabolite is proof of heroin use), or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. The MRO may not determine that the consumption of food products is a legitimate medical explanation for the presence of morphine or codeine at or above this concentration.

(2) If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for drugs other than opiates that are commonly prescribed or included in over-the-counter preparations (e.g., benzodiazepines in the first case, barbiturates in the second) and are listed in the licensee's or other entity's panel of substances to be tested, the MRO shall determine whether there is clinical evidence, in addition to the positive confirmatory test result, of abuse of any of these substances or their derivatives.

(3) If the MRO determines that the donor has used another individual's prescription medication, including a medication containing opiates, and no clinical evidence of drug abuse is found, the MRO shall report to the licensee or other entity that the donor has misused a prescription medication. If the MRO determines that the donor has used another individual's prescription medication and clinical evidence of drug abuse is found, the MRO shall report to the licensee that the donor has violated the FFD policy.

(4) In determining whether a legitimate medical explanation exists for a positive confirmatory test result for opiates or prescription or over-the-counter medications, the MRO may consider the use of a medication from a foreign country. The MRO shall exercise professional judgment consistently with the following principles:

(i) There can be a legitimate medical explanation only with respect to a drug that is obtained legally in a foreign country;

(ii) There can be a legitimate medical explanation only with respect to a drug that has a legitimate medical use. Use of a drug of abuse (e.g., heroin, PCP) or any other substance that cannot be viewed as having a legitimate medical use can never be the basis for a legitimate medical explanation, even if the drug is obtained legally in a foreign country; and

(iii) Use of the drug can form the basis of a legitimate medical explanation only if it is used consistently with its proper and intended medical purpose.

(5) The MRO may not consider consumption of food products, supplements, or other preparations containing substances that may result in a positive confirmatory drug test result, including, but not limited to supplements containing hemp products or coca leaf tea, as a legitimate medical explanation for the presence of drugs or drug metabolites in the urine specimen above the cutoff levels specified in § 26.163 or a licensee's or other entity's more stringent cutoff levels.

(6) The MRO may not consider the use of any drug contained in Schedule I of section 202 of the Controlled Substances Act [21 U.S.C. 812] as a legitimate medical explanation for a positive confirmatory drug test result, even if the drug may be legally prescribed and used under State law.

(k) *Results consistent with legitimate drug use.* If the MRO determines that there is a legitimate medical explanation for a positive confirmatory drug test result, and that the use of a drug identified through testing was in the manner and at the dosage prescribed, and the results do not reflect a lack of reliability or trustworthiness, then the donor has not violated the licensee's or other entity's FFD policy. The MRO shall report to the licensee or other entity that no FFD policy violation has occurred. The MRO shall further evaluate the positive confirmatory test result and medical explanation to determine whether use of the drug and/or the medical condition poses a potential risk to public health and safety as a result of the individual being impaired while on duty. If the MRO determines that such a risk exists, he or she shall ensure that a determination of fitness is performed.

(l) *Retesting authorized.* Should the MRO question the accuracy or scientific validity of a positive, adulterated, substituted, or invalid test result, only the MRO is authorized to order retesting of an aliquot of the original specimen or the analysis of any split specimen (Bottle B) in order to determine whether the FFD policy has been violated. Retesting must be performed by a second HHS-certified laboratory. The MRO is also the only individual who may authorize a reanalysis of an aliquot of the original specimen or an analysis of any split specimen (Bottle B) in response to a request from the donor tested.

(m) *Result scientifically insufficient.* Based on the review of inspection and audit reports, quality control data, multiple specimens, and other pertinent results, the MRO may determine that a positive, adulterated, substituted or invalid test result is scientifically insufficient for further action and may declare that a drug or validity test result is not an FFD policy violation, but that a negative test result was not obtained. In this situation, the MRO may request retesting of the original specimen before making this decision. The MRO is neither expected nor required to request such retesting, unless in the sole opinion of the MRO, such retesting is warranted. The MRO may request that the reanalysis be performed by the same laboratory, or that an aliquot of the original specimen be sent for reanalysis to another HHS-certified laboratory. The licensee testing facility and the HHS-certified laboratory shall assist in this review process, as requested by the MRO, by making available the individual(s) responsible for day-to-day management of the licensee testing facility or the HHS-certified laboratory, or other individuals who are forensic toxicologists or who have equivalent forensic experience in urine drug testing, to provide specific consultation as required by the MRO.

(n) *Evaluating results from a second laboratory.* After a second laboratory tests an aliquot of a single specimen or the split (Bottle B) specimen, the MRO shall take the following actions if the second laboratory reports the following results:

(1) If the second laboratory reconfirms any positive test results, the MRO may report an FFD policy violation to the licensee or other entity;

(2) If the second laboratory reconfirms any adulterated, substituted, or invalid validity test results, the MRO may report an FFD policy violation to the licensee or other entity;

(3) If the second laboratory does not reconfirm the positive test results, the MRO shall report that no FFD policy violation has occurred; or

(4) If the second laboratory does not reconfirm the adulterated, substituted,

or invalid validity test results, the MRO shall report that no FFD policy violation has occurred.

(o) *Re-authorization after a first violation for a positive test result.* The MRO is responsible for reviewing drug test results from an individual whose authorization was terminated or denied for a first violation of the FFD policy involving a confirmed positive drug test result and who is being considered for re-authorization. In order to determine whether subsequent positive confirmatory drug test results represent new drug use or remaining metabolites from the drug use that initially resulted in the FFD policy violation, the MRO shall request from the HHS-certified laboratory, and the laboratory shall provide, quantitation of the test results and other information necessary to make the determination. If the drug for which the individual first tested positive was marijuana and the confirmatory assay for delta-9-tetrahydrocannabinol-9-carboxylic acid yields a positive result, the MRO shall determine whether the confirmatory test result indicates further marijuana use since the first positive test result, or whether the test result is consistent with the level of delta-9-tetrahydrocannabinol-9-carboxylic acid that would be expected if no further marijuana use had occurred. If the test result indicates that no further marijuana use has occurred since the first positive test result, then the MRO shall declare the drug test result as negative.

(p) *Time to complete MRO review.* The MRO shall complete his or her review of positive, adulterated, substituted, and invalid test results and, in instances when the MRO determines that there is no legitimate medical explanation for the test result(s), notify the licensee's or other entity's designated representative within 10 business days of an initial positive, adulterated, substituted, or invalid test result. The MRO shall notify the licensee or other entity of the results of his or her review in writing and in a manner designed to ensure the confidentiality of the information.

§ 26.187 Substance abuse expert.

(a) *Implementation.* By March 31, 2010, any SAEs on whom licensees and other entities rely to make determinations of fitness under this part shall meet the requirements of this section. An MRO who meets the requirements of this section may serve as both an MRO and as an SAE.

(b) *Credentials.* An SAE shall have at least one of the following credentials:

(1) A licensed physician;

(2) A licensed or certified social worker;

(3) A licensed or certified psychologist;

(4) A licensed or certified employee assistance professional; or

(5) An alcohol and drug abuse counselor certified by the National Association of Alcoholism and Drug Abuse Counselors Certification Commission or by the International Certification Reciprocity Consortium/Alcohol and Other Drug Abuse.

(c) *Basic knowledge.* An SAE shall be knowledgeable in the following areas:

(1) Demonstrated knowledge of and clinical experience in the diagnosis and treatment of alcohol and controlled-substance abuse disorders;

(2) Knowledge of the SAE function as it relates to the public's interests in the duties performed by the individuals who are subject to this subpart; and

(3) Knowledge of this part and any changes thereto.

(d) *Qualification training.* SAEs shall receive qualification training on the following subjects:

(1) Background, rationale, and scope of this part;

(2) Key drug testing requirements of this part, including specimen collection, laboratory testing, MRO review, and problems in drug testing;

(3) Key alcohol testing requirements of this part, including specimen collection, the testing process, and problems in alcohol tests;

(4) SAE qualifications and prohibitions;

(5) The role of the SAE in making determinations of fitness and the return-to-duty process, including the initial evaluation, referrals for education and/or treatment, the followup evaluation, continuing treatment recommendations, and the followup testing plan;

(6) Procedures for SAE consultation and communication with licensees or other entities, MROs, and treatment providers;

(7) Reporting and recordkeeping requirements of this part; and

(8) Issues that SAEs confront in carrying out their duties under this part.

(e) *Continuing education.* During each 3-year period following completion of initial qualification training, the SAE shall complete continuing education consisting of at least 12 continuing professional education hours relevant to performing SAE functions.

(1) This continuing education must include material concerning new technologies, interpretations, recent guidance, rule changes, and other information about developments in SAE practice pertaining to this part, since the time the SAE met the qualification training requirements of this section.

(2) Continuing education activities must include documented assessment tools to assist in determining that the SAE has learned the material.

(f) *Documentation.* The SAE shall maintain documentation showing that he or she currently meets all requirements of this section. The SAE shall provide this documentation on request to NRC representatives, licensees, or other entities who are relying on or contemplating relying on the SAE's services, and to other individuals and entities, as required by § 26.37.

(g) *Responsibilities and prohibitions.* The SAE shall evaluate individuals who have violated the substance abuse provisions of an FFD policy and make recommendations concerning education, treatment, return to duty, followup drug and alcohol testing, and aftercare. The SAE is not an advocate for the licensee or other entity, or the individual. The SAE's function is to protect public health and safety and the common defense and security by professionally evaluating the individual and recommending appropriate education/treatment, follow-up tests, and aftercare.

(1) The SAE is authorized to make determinations of fitness in at least the following three circumstances:

(i) When potentially disqualifying FFD information has been identified regarding an individual who has applied for authorization under this part;

(ii) When an individual has violated the substance abuse provisions of a licensee's or other entity's FFD policy; and

(iii) When an individual may be impaired by alcohol, prescription or over-the-counter medications, or illegal drugs.

(2) After determining the best recommendation for assisting the individual, the SAE shall serve as a referral source to assist the individual's entry into an education and/or treatment program.

(i) To prevent the appearance of a conflict of interest, the SAE may not refer an individual requiring assistance to his or her private practice or to a person or organization from whom the SAE receives payment or in which the SAE has a financial interest. The SAE is precluded from making referrals to entities with whom the SAE is financially associated.

(ii) There are four exceptions to the prohibitions contained in the preceding paragraph. The SAE may refer an individual to any of the following providers of assistance, regardless of his or her relationship with them:

(A) A public agency (e.g., treatment facility) operated by a state, county, or municipality;

(B) A person or organization under contract to the licensee or other entity to provide alcohol or drug treatment and/or education services (e.g., the licensee's or other entity's contracted treatment provider);

(C) The sole source of therapeutically appropriate treatment under the individual's health insurance program (e.g., the single substance abuse in-patient treatment program made available by the individual's insurance coverage plan); or

(D) The sole source of therapeutically appropriate treatment reasonably available to the individual (e.g., the only treatment facility or education program reasonably located within the general commuting area).

§ 26.189 Determination of fitness.

(a) A determination of fitness is the process entered when there are indications that an individual specified in § 26.4(a) through (e), and at the licensee's or other entity's discretion as specified in § 26.4(f) and (g), may be in violation of the licensee's or other entity's FFD policy or is otherwise unable to safely and competently perform his or her duties. A determination of fitness must be made by a licensed or certified professional who is appropriately qualified and has the necessary clinical expertise, as verified by the licensee or other entity, to evaluate the specific fitness issues presented by the individual. A professional called on by the licensee or other entity may not perform a determination of fitness regarding fitness issues that are outside of his or her specific areas of expertise. The types of professionals and the fitness issues for which they are qualified to make determinations of fitness include, but are not limited to, the following:

(1) An SAE who meets the requirements of § 26.187 may determine the fitness of an individual who may have engaged in substance abuse and shall determine an individual's fitness to be granted authorization following an unfavorable termination or denial of authorization under this part, but may not be qualified to assess the fitness of an individual who may have experienced mental illness, significant emotional stress, or other mental or physical conditions that may cause impairment but are unrelated to substance abuse, unless the SAE has additional qualifications for addressing those fitness issues;

(2) A clinical psychologist may determine the fitness of an individual who may have experienced mental illness, significant emotional stress, or cognitive or psychological impairment from causes unrelated to substance abuse, but may not be qualified to assess the fitness of an individual who may have a substance abuse disorder, unless the psychologist is also an SAE;

(3) A psychiatrist may determine the fitness of an individual who is taking psychoactive medications consistently with one or more valid prescription(s), but may not be qualified to assess potential impairment attributable to substance abuse, unless the psychiatrist has had specific training to diagnose and treat substance abuse disorders;

(4) A physician may determine the fitness of an individual who may be ill, injured, fatigued, taking medications in accordance with one or more valid prescriptions, or using over-the-counter medications, but may not be qualified to assess the fitness of an individual who may have a substance abuse disorder, unless the physician is also an SAE; and

(5) As a physician with specialized training, the MRO may determine the fitness of an individual who may have engaged in substance abuse or may be ill, injured, fatigued, taking medications under one or more valid prescriptions, and/or using over-the-counter medications, but may not be qualified to assess an individual's fitness to be granted authorization following an unfavorable termination or denial of authorization under this part, unless the MRO is also an SAE.

(b) A determination of fitness must be made in at least the following circumstances:

(1) When there is an acceptable medical explanation for a positive, adulterated, substituted, or invalid test result, but there is a basis for believing that the individual could be impaired while on duty;

(2) Before making return-to-duty recommendations after an individual's authorization has been terminated unfavorably or denied under a licensee's or other entity's FFD policy;

(3) Before an individual is granted authorization when potentially disqualifying FFD information is identified that has not previously been evaluated by another licensee or entity who is subject to this subpart; and

(4) When potentially disqualifying FFD information is otherwise identified and the licensee's or other entity's reviewing official concludes that a determination of fitness is warranted under § 26.69.

(c) A determination of fitness that is conducted for cause (i.e., because of observed behavior or a physical condition) must be conducted through face-to-face interaction between the subject individual and the professional making the determination. Electronic means of communication may not be used.

(1) If there is neither conclusive evidence of an FFD policy violation nor a significant basis for concern that the individual may be impaired while on duty, then the individual must be determined to be fit for duty.

(2) If there is no conclusive evidence of an FFD policy violation but there is a significant basis for concern that the individual may be impaired while on duty, then the subject individual must be determined to be unfit for duty. This result does not constitute a violation of this part nor of the licensee's or other entity's FFD policy, and no sanctions may be imposed. However, the professional who made the determination of fitness shall consult with the licensee's or other entity's management personnel to identify the actions required to ensure that any possible limiting condition does not represent a threat to workplace or public health and safety. Licensee or other entity management personnel shall implement the required actions. When appropriate, the subject individual may also be referred to the EAP.

(d) Neither the individual nor licensees and other entities may seek a second determination of fitness if a determination of fitness under this part has already been performed by a qualified professional employed by or under contract to the licensee or other entity. After the initial determination of fitness has been made, the professional may modify his or her evaluation and recommendations based on new or additional information from other sources including, but not limited to, the subject individual, another licensee or entity, or staff of an education or treatment program. Unless the professional who made the initial determination of fitness is no longer employed by or under contract to the licensee or other entity, only that professional is authorized to modify the evaluation and recommendations. When reasonably practicable, licensees and other entities shall assist in arranging for consultation between the new professional and the professional who is no longer employed by or under contract to the licensee or other entity, to ensure continuity and consistency in the recommendations and their implementation.

Subpart I—Managing Fatigue

§ 26.201 Applicability.

The requirements in this subpart apply to the licensees and other entities identified in § 26.3(a), and, if applicable, (c) and (d). The requirements in §§ 26.203 and 26.211 apply to the individuals identified in § 26.4 (a) through (c). In addition, the requirements in § 26.205 through § 26.209 apply to the individuals identified in § 26.4(a).

§ 26.203 General provisions.

(a) *Policy*. Licensees shall establish a policy for the management of fatigue for all individuals who are subject to the licensee's FFD program and incorporate it into the written policy required in § 26.27(b).

(b) *Procedures*. In addition to the procedures required in § 26.27(c), licensees shall develop, implement, and maintain procedures that—

(1) Describe the process to be followed when any individual identified in § 26.4(a) through (c) makes a self-declaration that he or she is not fit to safely and competently perform his or her duties for any part of a working tour as a result of fatigue. The procedure must—

(i) Describe the individual's and licensee's rights and responsibilities related to self-declaration;

(ii) Describe requirements for establishing controls and conditions under which an individual may be permitted or required to perform work after that individual declares that he or she is not fit due to fatigue; and

(iii) Describe the process to be followed if the individual disagrees with the results of a fatigue assessment that is required under § 26.211(a)(2);

(2) Describe the process for implementing the controls required under § 26.205 for the individuals who are performing the duties listed in § 26.4(a);

(3) Describe the process to be followed in conducting fatigue assessments under § 26.211; and

(4) Describe the disciplinary actions that the licensee may impose on an individual following a fatigue assessment, and the conditions and considerations for taking those disciplinary actions.

(c) *Training and examinations*. Licensees shall add the following KAs to the content of the training that is required in § 26.29(a) and the comprehensive examination required in § 26.29(b):

(1) Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures; and

(2) Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace.

(d) *Recordkeeping*. Licensees shall retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of work hours for individuals who are subject to the work hour controls in § 26.205;

(2) Records of shift schedules and shift cycles of individuals who are subject to the work hour controls in § 26.205;

(3) The documentation of waivers that is required in § 26.207(a)(4), including the bases for granting the waivers;

(4) The documentation of work hour reviews that is required in § 26.205(e)(3) and (e)(4); and

(5) The documentation of fatigue assessments that is required in § 26.211(g).

(e) *Reporting*. Licensees shall include the following information in a standard format in the annual FFD program performance report required under § 26.717:

(1) A summary for each nuclear power plant site of all instances during the previous calendar year when the licensee waived the work hour controls specified in § 26.205(d)(1) through (d)(5)(i) for individuals described in § 26.4(a). The summary must include only those waivers under which work was performed. If it was necessary to waive more than one work hour control during any single extended work period, the summary of instances must include each of the work hour controls that were waived during the period. For each category of individuals specified in § 26.4(a), the licensee shall report—

(i) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), and (d)(3)(i) through (d)(3)(v) was waived for individuals not working on outage activities;

(ii) The number of instances when each applicable work hour control specified in § 26.205(d)(1)(i) through (d)(1)(iii), (d)(2)(i) and (d)(2)(ii), (d)(3)(i) through (d)(3)(v), and (d)(4) and (d)(5)(i) was waived for individuals working on outage activities; and

(iii) A summary that shows the distribution of waiver use among the individuals within each category of individuals identified in § 26.4(a) (e.g., a table that shows the number of individuals who received only one waiver during the reporting period, the number of individuals who received a total of two waivers during the reporting period).

(2) A summary of corrective actions, if any, resulting from the analyses of these data, including fatigue assessments.

(f) *Audits*. Licensees shall audit the management of worker fatigue as required by § 26.41.

§ 26.205 Work hours.

(a) *Individuals subject to work hour controls*. Any individual who performs duties identified in § 26.4(a)(1) through (a)(5) shall be subject to the requirements of this section.

(b) *Calculating work hours*. For the purposes of this section, a licensee shall calculate the work hours of individuals who are subject to this section as the amount of time the individuals perform duties for the licensee. Except as permitted by paragraphs (b)(1) through (b)(5) of this section, the calculated work hours must include all time performing duties for the licensee, including all within-shift break times and rest periods during which there are no reasonable opportunities or accommodations appropriate for restorative sleep.

(1) Shift turnover. Licensees may exclude shift turnover from the calculation of an individual's work hours. Shift turnover includes only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. Shift turnover activities may include, but are not limited to, discussions of the status of plant equipment, and the status of ongoing activities, such as extended tests of safety systems and components. Licensees may not exclude work hours worked during turnovers between individuals within a shift period due to rotations or relief within a shift. Activities that licensees may not exclude from work hours calculations also include, but are not limited to, shift holdovers to cover for late arrivals of incoming shift members; early arrivals of individuals for meetings, training, or pre-shift briefings for special evolutions; and holdovers for interviews needed for event investigations.

(2) Within-shift break and rest periods. Licensees may exclude from the calculation of an individual's work hours only that portion of a break or rest period during which there is a reasonable opportunity and accommodations for restorative sleep (e.g., a nap).

(3) Beginning or resuming duties subject to work hour controls. If an individual begins or resumes performing for the licensee any of the duties listed in § 26.4(a) during the calculation period, the licensee shall include in the calculation of the individual's work hours all work hours worked for the licensee, including hours worked performing duties that are not listed in § 26.4(a), and control the individual's work hours under the requirements of paragraph (d) of this section.

(4) Unannounced emergency preparedness exercises and drills. Licensees may exclude from the calculation of an individual's work hours the time the individual works unscheduled work hours for the purpose of participating in the actual conduct of an unannounced emergency preparedness exercise or drill.

(5) Incidental duties performed off site. Licensees may exclude from the calculation of an individual's work hours unscheduled work performed off site (e.g., technical assistance provided by telephone from an individual's home) provided the total duration of the work does not exceed a nominal 30 minutes during any single break period. For the purposes of compliance with the minimum break requirements of paragraph (d)(2) of this section and the minimum day off requirements of paragraph (d)(3) through (d)(5) of this section, such duties do not constitute work periods or work shifts.

(c) *Work hours scheduling.* Licensees shall schedule the work hours of individuals who are subject to this section consistent with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts.

(d) *Work hour controls.* Licensees shall control the work hours of individuals who are subject to this section.

(1) Except as permitted in § 26.207, licensees shall ensure that any individual's work hours do not exceed the following limits:

(i) 16 work hours in any 24-hour period;

(ii) 26 work hours in any 48-hour period; and

(iii) 72 work hours in any 7-day period.

(2) Licensees shall ensure that individuals have, at a minimum, the rest breaks specified in this paragraph. For the purposes of this subpart, a break is defined as an interval of time that falls between successive work periods, during which the individual does not perform any duties for the licensee other than one period of shift turnover at either the beginning or end of a shift but not both. Except as permitted in § 26.207, licensees shall ensure that individuals have, at a minimum—

(i) A 10-hour break between successive work periods or an 8-hour break between successive work periods when a break of less than 10 hours is necessary to accommodate a crew's scheduled transition between work schedules or shifts; and

(ii) A 34-hour break in any 9-day period.

(3) Licensees shall ensure that individuals have, at a minimum, the number of days off specified in this paragraph. For the purposes of this subpart, a day off is defined as a calendar day during which an individual does not start a work shift. For the purposes of calculating the average number of days off required in this paragraph, the duration of the shift cycle may not exceed 6 weeks.

(i) Individuals who are working 8-hour shift schedules shall have at least 1 day off per week, averaged over the shift cycle;

(ii) Individuals who are working 10-hour shift schedules shall have at least 2 days off per week, averaged over the shift cycle;

(iii) Individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(1) through (a)(3) shall have at least 2.5 days off per week, averaged over the shift cycle;

(iv) Individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(4) shall have at least 2 days off per week, averaged over the shift cycle; and

(v) Individuals who are working 12-hour shift schedules while performing the duties described in § 26.4(a)(5) shall have at least 3 days off per week, averaged over the shift cycle.

(4) During the first 60 days of a unit outage, licensees need not meet the requirements of paragraph (d)(3) of this section for individuals specified in § 26.4(a)(1) through (a)(4), while those individuals are working on outage activities. However, the licensee shall ensure that the individuals specified in § 26.4(a)(1) through (a)(3) have at least 3 days off in each successive (i.e., non-rolling) 15-day period and that the individuals specified in § 26.4(a)(4) have at least 1 day off in any 7-day period;

(5) During the first 60 days of a unit outage, security system outage, or increased threat condition, licensees shall control the hours worked by individuals specified in § 26.4(a)(5) as follows:

(i) During the first 60 days of a unit outage or a planned security system outage, licensees need not meet the requirements of paragraph (d)(3) of this section. However, licensees shall ensure that these individuals have at least 4 days off in each successive (i.e., non-rolling) 15-day period; and

(ii) During the first 60 days of an unplanned security system outage or increased threat condition, licensees need not meet the requirements of either paragraph (d)(3) or (d)(5)(i) of this section.

(6) The 60-day periods in paragraphs (d)(4) and (d)(5) of this section may be extended for each individual in 7-day increments for each non-overlapping 7-day period the individual has worked not more than 48 hours during the unit or security system outage or increased threat condition, as applicable.

(e) *Reviews.* Licensees shall evaluate the effectiveness of their control of work hours of individuals who are subject to this section. Licensees shall conduct the reviews once per calendar year. If any plant or security system outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee shall include in the review an evaluation of the control of work hours during the outages or increased threat conditions. Licensees shall complete the review within 30 days of the end of the review period. Licensees shall—

(1) Review the actual work hours and performance of individuals who are subject to this section for consistency with the requirements of § 26.205(c). At a minimum, this review must address—

(i) Individuals whose actual hours worked during the review period exceeded an average of 54 hours per week in any shift cycle while the individuals' work hours are subject to the requirements of § 26.205(d)(3);

(ii) Individuals who were granted more than one waiver during the review period; and

(iii) Individuals who were assessed for fatigue under § 26.211 during the review period.

(2) Review individuals' hours worked and the waivers under which work was performed to evaluate staffing adequacy for all jobs subject to the work hour controls of this section;

(3) Document the methods used to conduct the review and the results of the review; and

(4) Record, trend, and correct, under the licensee's corrective action program, any problems identified in maintaining control of work hours consistent with the specific requirements and performance objectives of this part.

§ 26.207 Waivers and exceptions.

(a) *Waivers.* Licensees may grant a waiver of the work hour controls in § 26.205(d)(1) through (d)(5)(i), as follows:

(1) To grant a waiver, the licensee shall meet both of the following requirements:

(i) An operations shift manager determines that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager determines that the waiver is necessary to maintain site security, or a site senior-level manager with requisite signature authority makes either determination; and

(ii) A supervisor assesses the individual face to face and determines that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver will be granted. The supervisor performing the assessment shall be trained as required by §§ 26.29 and 26.203(c) and shall be qualified to direct the work to be performed by the individual. If there is no supervisor on site who is qualified to direct the work, the assessment may be performed by a supervisor who is qualified to provide oversight of the work to be performed by the individual. At a minimum, the assessment must address the potential for acute and cumulative fatigue considering the individual's work history for at least the past 14 days, the potential for circadian degradations in alertness and performance considering the time of day for which the waiver will be granted, the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether any controls and conditions must be established under which the individual will be permitted to perform work.

(2) To the extent practicable, licensees shall rely on the granting of waivers only to address circumstances that could not have been reasonably controlled;

(3) Licensees shall ensure that the timing of the face-to-face supervisory assessment that is required by paragraph (a)(1)(ii) of this section supports a valid assessment of the potential for worker fatigue during the time the individual will be performing work under the waiver. Licensees may not perform the face-to-face assessment more than 4 hours before the individual begins performing any work under the waiver; and

(4) Licensees shall document the bases for individual waivers. The documented basis for a waiver must include a description of the circumstances that necessitate the waiver, a statement of the scope of work and time period for which the waiver is approved, and the bases for the determinations required in paragraphs (a)(1)(i) and (ii) of this section.

(b) *Force-on-force tactical exercises.* For the purposes of compliance with the minimum days off requirements of § 26.205(d)(3), licensees may exclude shifts worked by security personnel during the actual conduct of NRC-evaluated force-on-force tactical exercises when calculating the individual's number of days off.

(c) *Common defense and security.* When informed in writing by the NRC that the requirements of § 26.205, or any subset thereof, are waived for security personnel to ensure the common defense and security, licensees need not meet the specified requirements of § 26.205 for the duration of the period defined by the NRC.

(d) *Plant emergencies.* Licensees need not meet the requirements of § 26.205(c) and (d) during declared emergencies, as defined in the licensee's emergency plan.

§ 26.209 Self-declarations.

(a) If an individual is performing, or being assessed for, work under a waiver of the requirements contained in § 26.205(d)(1) through (d)(5)(i) and declares that, due to fatigue, he or she is unable to safely and competently perform his or her duties, the licensee shall immediately stop the individual from performing any duties listed in § 26.4(a), except if the individual is required to continue performing those duties under other requirements of this chapter. If the subject individual must continue performing the duties listed in § 26.4(a) until relieved, the licensee shall immediately take action to relieve the individual.

(b) Following a self-declaration, as described in paragraph (a) of this section, the licensee—

(1) May reassign the individual to duties other than those listed in § 26.4(a), but only if the results of a fatigue assessment, conducted under the requirements of § 26.211, indicate that the individual is fit to safely and competently perform those other duties; and

(2) Shall permit or require the individual to take a break of at least 10 hours before the individual returns to performing any duties listed in § 26.4(a).

§ 26.211 Fatigue assessments.

(a) Licensees shall ensure that fatigue assessments are conducted under the following conditions:

(1) For cause. In addition to any other test or determination of fitness that may be required under §§ 26.31(c) and 26.77, a fatigue assessment must be conducted in response to an observed condition of impaired individual alertness creating a reasonable suspicion that an individual is not fit to safely and competently perform his or her duties, except if the condition is observed during an individual's break period. If the observed condition is impaired alertness with no other behaviors or physical conditions creating a reasonable suspicion of possible substance abuse, then the licensee need only conduct a fatigue assessment. If the licensee has reason to believe that the observed condition is not due to fatigue, the licensee need not conduct a fatigue assessment;

(2) Self-declaration. A fatigue assessment must be conducted in response to an individual's self-declaration to his or her supervisor that he or she is not fit to safely and competently perform his or her duties for any part of a working tour because of fatigue, except if, following the self-declaration, the licensee permits or requires the individual to take a rest break of at least 10 hours before the individual returns to duty;

(3) Post-event. A fatigue assessment must be conducted in response to events requiring post-event drug and alcohol testing as specified in § 26.31(c). Licensees may not delay necessary medical treatment in order to conduct a fatigue assessment; and

(4) Followup. If a fatigue assessment was conducted for cause or in response to a self-declaration, and the licensee returns the individual to duty following a break of less than 10 hours in duration, the licensee shall reassess the individual for fatigue as well as the need to implement controls and conditions before permitting the individual to resume performing any duties.

(b) Only supervisors and FFD program personnel who are trained under §§ 26.29 and 26.203(c) may conduct a fatigue assessment. The fatigue assessment must be conducted face to face with the individual whose alertness may be impaired.

(1) In the case of a fatigue assessment conducted for cause, the individual who observed the condition of impaired alertness may not conduct the fatigue assessment.

(2) In the case of a post-event fatigue assessment, the individual who conducts the fatigue assessment may not have—

(i) Performed or directed (on site) the work activities during which the event occurred;

(ii) Performed, within 24 hours before the event occurred, a fatigue assessment of the individuals who were performing or directing (on site) the work activities during which the event occurred; and

(iii) Evaluated or approved a waiver of the limits specified in § 26.205(d)(1) through (d)(5)(i) for any of the individuals who were performing or directing (on site) the work activities during which the event occurred, if the event occurred while such individuals were performing work under that waiver.

(c) A fatigue assessment must provide the information necessary for management decisions and actions in response to the circumstance that initiated the assessment.

(1) At a minimum, the fatigue assessment must address the following factors:

(i) Acute fatigue;

(ii) Cumulative fatigue; and

(iii) Circadian variations in alertness and performance.

(2) Individuals shall provide complete and accurate information that may be required by the licensee to address the factors listed in paragraph (c)(1) of this section. Licensees shall limit any inquiries to obtaining from the subject individual only the personal information that may be necessary to assess the factors listed in paragraph (c)(1) of this section.

(d) The licensee may not conclude that fatigue has not or will not degrade the individual's ability to safely and competently perform his or her duties solely on the basis that the individual's work hours have not exceeded any of the limits specified in § 26.205(d)(1) or that the individual has had the minimum breaks required in § 26.205(d)(2) or minimum days off required in § 26.205(d)(3) through (d)(5), as applicable.

(e) Following a fatigue assessment, the licensee shall determine and implement the controls and conditions, if any, that are necessary to permit the individual to resume performing duties for the licensee, including the need for a break.

(f) Licensees shall document the results of any fatigue assessments conducted, the circumstances that necessitated the fatigue assessment, and any controls and conditions that were implemented.

(g) Licensees shall also prepare an annual summary for each nuclear power plant site of instances of fatigue assessments that were conducted during the previous calendar year for any individual identified in § 26.4(a) through (c). Each summary must include—

(1) The conditions under which each fatigue assessment was conducted (i.e., self-declaration, for cause, post-event, followup);

(2) A statement of whether or not the individual was working on outage activities at the time of the self-declaration or condition resulting in the fatigue assessment;

(3) The category of duties the individual was performing, if the individual was performing the duties described in § 26.4(a)(1) through (a)(5) at the time of the self-declaration or condition resulting in the fatigue assessment; and

(4) The management actions, if any, resulting from each fatigue assessment.

Subpart J—[Reserved]

Subpart K—FFD Program for Construction

§ 26.401 General.

(a) At the licensee's or other entity's discretion, a licensee or other entity in § 26.3(c) may establish, implement, and maintain an FFD program that meets the requirements of this subpart to apply to the individuals specified in § 26.4(f). If a licensee or other entity in § 26.3(c) does not elect to implement an FFD program that meets the requirements of this subpart, the individuals specified in § 26.4(f) shall be subject to an FFD program that meets the requirements of subparts A through H, N, and O of this part.

(b) Entities who intend to implement an FFD program under this subpart shall submit a description of the FFD program and its implementation as part of the license, permit, or limited work authorization application.

(c) Nothing in this subpart prohibits the licensees and other entities in § 26.3(c) from subjecting the individuals in § 26.4(f) to an FFD program that meets all of the requirements of this part or FFD program elements that meet all of the applicable requirements of this part.

§ 26.403 Written policy and procedures.

(a) Licensees and other entities who implement an FFD program under this subpart shall ensure that a clear, concise, written FFD policy statement is provided to individuals who are subject to the program. The policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and what consequences may result from a lack of adherence to the policy.

(b) Licensees and other entities shall develop, implement, and maintain written procedures that address the following topics:

(1) The methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the privacy of an individual who provides a specimen, procedures for protecting the integrity of the specimen, and procedures used to ensure that the test results are valid and attributable to the correct individual;

(2) The immediate and followup actions that will be taken, and the procedures to be used, in those cases in which individuals who are subject to the FFD program are determined to have—

(i) Been involved in the use, sale, or possession of illegal drugs;

(ii) Consumed alcohol to excess before or while constructing safety-or security-related SSCs, as determined by a test that accurately measures BAC;

(iii) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means;

(iv) Refused to provide a specimen for analysis; or

(v) Had legal action taken relating to drug or alcohol use.

(3) The process to be followed if an individual's behavior or condition raises a concern regarding the possible use, sale, or possession of illegal drugs on or off site; the possible use or possession of alcohol while constructing safety-or security-related SSCs; or impairment from any cause which in any way could adversely affect the individual's ability to safely and competently perform his or her duties.

§ 26.405 Drug and alcohol testing.

(a) To provide means to deter and detect substance abuse, licensees and other entities who implement an FFD program under this subpart shall perform drug and alcohol testing that complies with the requirements of this section.

(b) If the licensee or other entity elects to impose random testing for drugs and alcohol on the individuals identified in § 26.4(f), random testing must—

(1) Be administered in a manner that provides reasonable assurance that individuals are unable to predict the time periods during which specimens will be collected;

(2) Require individuals who are selected for random testing to report to the collection site as soon as reasonably practicable after notification, within the time period specified in the FFD program policy;

(3) Ensure that all individuals in the population that is subject to random

testing on a given day have an equal probability of being selected and tested; and

(4) Provide that an individual completing a test is immediately eligible for another random test.

(c) Individuals identified in § 26.4(f) shall be subject to drug and alcohol testing under the following conditions:

(1) Pre-assignment. Before assignment to construct safety-or security-related SSCs;

(2) For-cause. In response to an individual's observed behavior or physical condition indicating possible substance abuse or after receiving credible information that an individual is engaging in substance abuse, as defined in § 26.5;

(3) Post-accident. As soon as practical after an event involving a human error that was committed by an individual specified in § 26.4(f), where the human error may have caused or contributed to the accident. The licensee or other entity shall test the individual(s) who committed the error(s), and need not test individuals who were affected by the event but whose actions likely did not cause or contribute to the event. The individual(s) who committed the human error(s) shall be tested if the event resulted in—

(i) A significant illness or personal injury to the individual to be tested or another individual, which within 4 hours after the event is recordable under the Department of Labor standards contained in 29 CFR 1904.7, and subsequent amendments thereto, and results in death, days away from work, restricted work, transfer to another job, medical treatment beyond first aid, loss of consciousness, or other significant illness or injury as diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness; or

(ii) Significant damage, during construction, to any safety-or security-related SSC; and

(4) Followup. As part of a followup plan to verify an individual's continued abstinence from substance abuse.

(d) At a minimum, licensees and other entities shall test specimens for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol at the cutoff levels specified in this part, or comparable cutoff levels if specimens other than urine are collected for drug testing. Urine specimens collected for drug testing must be subject to validity testing.

(e) The specimen collection and drug and alcohol testing procedures of FFD programs under this subpart must protect the donor's privacy and the integrity of the specimen, and implement stringent quality controls to ensure that test results are valid and attributable to the correct individual. At the licensee's or other entity's discretion, specimen collections and alcohol testing may be conducted at a local hospital or other facility under the specimen collection and alcohol testing requirements of 49 CFR Part 40 and subsequent amendments thereto.

(f) Testing of urine specimens for drugs and validity, except validity screening and initial drug and validity tests that may be performed by licensee testing facilities, must be performed in a laboratory that is certified by HHS for that purpose, consistent with its standards and procedures for certification. Any initial drug test performed by a licensee or other entity subject to this subpart must use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. Urine specimens that yield positive, adulterated, substituted, or invalid initial validity or drug test results must be subject to confirmatory testing by the HHS-certified laboratory, except for invalid specimens that cannot be tested. Other specimens that yield positive initial drug test results must be subject to confirmatory testing by a laboratory that meets stringent quality control requirements that are comparable to those required for certification by the HHS.

(g) Licensees and other entities shall provide for an MRO review of positive, adulterated, substituted, and invalid confirmatory drug and validity test results to determine whether the donor has violated the FFD policy, before reporting the results to the individual designated by the licensee or other entity to perform the suitability and fitness evaluations required under § 26.419.

§ 26.406 Fitness monitoring.

(a) The requirements in this section apply only if a licensee or other entity does not elect to subject the individuals specified in § 26.4(f) to random testing for drugs and alcohol under § 26.405(b).

(b) Licensees and other entities shall implement a fitness monitoring program to deter substance abuse and detect indications of possible use, sale, or possession of illegal drugs; use or possession of alcohol while constructing safety-or security-related SSCs; or impairment from any cause that if left unattended may result in a risk to public health and safety or the common defense and security.

(c) Licensees and other entities shall establish procedures that monitors shall follow in response to the indications and actions specified in paragraph (b) of this section and train the monitors to implement the program.

(d) Licensees and other entities shall ensure that the fitness of individuals specified in § 26.4(f) is monitored effectively while the individuals are constructing safety- and security-related SSCs, commensurate with the potential risk to public health and safety and the common defense and security imposed by the construction activity. To achieve this objective, licensees and other entities shall consider the number and placement of monitors required, the necessary ratio of monitors to individuals specified in § 26.4(f), and the frequency with which the individuals specified in § 26.4(f) shall be monitored while constructing each safety- or security-related SSC.

§ 26.407 Behavioral observation.

While the individuals specified in § 26.4(f) are constructing safety- or security-related SSCs, licensees and other entities shall ensure that these individuals are subject to behavioral observation, except if the licensee or other entity has implemented a fitness monitoring program under § 26.406.

§ 26.409 Sanctions.

Licensees and other entities who implement an FFD program under this subpart shall establish sanctions for FFD policy violations that, at a minimum, prohibit the individuals specified in § 26.4(f) from being assigned to construct safety- or security-related SSCs unless or until the licensee or other entity determines that the individual's condition or behavior does not pose a potential risk to public health and safety or the common defense and security.

§ 26.411 Protection of information.

(a) Licensees and other entities who collect personal information about an individual for the purpose of complying with this subpart shall establish and maintain a system of files and procedures to protect the personal information. FFD programs must maintain and use such records with the highest regard for individual privacy.

(b) Licensees and other entities shall obtain a signed consent that authorizes the disclosure of the personal information collected and maintained under this subpart before disclosing the

personal information, except for disclosures to the individuals and entities specified in § 26.37(b)(1) through (b)(6), (b)(8), and persons deciding matters under review in § 26.413.

§ 26.413 Review process.

Licensees and other entities who implement an FFD program under this subpart shall establish and implement procedures for the review of a determination that an individual in § 26.4(f) has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts related to the determination that the individual has violated the FFD policy.

§ 26.415 Audits.

(a) Licensees and other entities who implement an FFD program under this subpart shall ensure that audits are performed to assure the continuing effectiveness of the FFD program, including FFD program elements that are provided by C/Vs, and the FFD programs of C/Vs that are accepted by the licensee or other entity.

(b) Each licensee and other entity shall ensure that these programs are audited at a frequency that assures their continuing effectiveness and that corrective actions are taken to resolve any problems identified. Licensees and entities may conduct joint audits, or accept audits of C/Vs conducted by others, so long as the audit addresses the relevant C/Vs' services.

(c) Licensees and other entities need not audit HHS-certified laboratories or the specimen collection and alcohol testing services that meet the requirements of 49 CFR Part 40, ''Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs'' (65 FR 41944; August 9, 2001), on which licensees and other entities may rely to meet the drug and alcohol testing requirements of this subpart.

§ 26.417 Recordkeeping and reporting.

(a) Licensees and other entities who implement FFD programs under this subpart shall ensure that records pertaining to the administration of the program, which may be stored and archived electronically, are maintained so that they are available for NRC inspection purposes and for any legal proceedings resulting from the administration of the program.

(b) Licensees and other entities shall make the following reports:

(1) Reports to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers any intentional act that casts doubt on the integrity of the FFD program and any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals who are subject to this subpart. These events must be reported under this subpart, rather than under the provisions of 10 CFR 73.71; and

(2) Annual program performance reports for the FFD program.

§ 26.419 Suitability and fitness evaluations.

Licensees and other entities who implement FFD programs under this subpart shall develop, implement, and maintain procedures for evaluating whether to assign individuals to construct safety- and security-related SSCs. These procedures must provide reasonable assurance that the individuals are fit to safely and competently perform their duties, and are trustworthy and reliable, as demonstrated by the avoidance of substance abuse.

Subpart L—[Reserved]

Subpart M—[Reserved]

Subpart N—Recordkeeping and Reporting Requirements

§ 26.709 Applicability.

The requirements of this subpart apply to the FFD programs of licensees and other entities specified in § 26.3, except for FFD programs that are implemented under subpart K of this part.

§ 26.711 General provisions.

(a) Each licensee and other entity shall maintain records and submit certain reports to the NRC. Records that are required by the regulations in this part must be retained for the period specified by the appropriate regulation. If a retention period is not otherwise specified, these records must be retained until the Commission terminates the facility's license, certificate, or other regulatory approval.

(b) All records may be stored and archived electronically, provided that the method used to create the electronic records meets the following criteria:

(1) Provides an accurate representation of the original records;

(2) Prevents the alteration of any archived information and/or data once it has been committed to storage; and

(3) Permits easy retrieval and re-creation of the original records.

(c) The licensees and other entities specified in § 26.3(a) and, as applicable, (c) and (d), shall inform each individual of his or her right to review information about the individual that is collected and maintained under this part to assure its accuracy. Licensees and other entities shall provide the individual with an opportunity to correct any inaccurate or incomplete information that is documented by licensees and other entities about the individual.

(d) Licensees and other entities shall ensure that only correct and complete information about individuals is retained and shared with other licensees and entities. If, for any reason, the shared information used for determining an individual's eligibility for authorization under this part changes or new information is developed about the individual, licensees and other entities shall correct or augment the shared information contained in the records. If the changed or developed information has implications for adversely affecting an individual's eligibility for authorization, a licensee and other entity specified in § 26.3(a) and, as applicable, (c) and (d), who has discovered the incorrect information, or develops new information, shall inform the reviewing official of any FFD program under which the individual is maintaining authorization of the updated information on the day of discovery. The reviewing official shall evaluate the information and take appropriate actions, which may include denial or unfavorable termination of the individual's authorization.

§ 26.713 Recordkeeping requirements for licensees and other entities.

(a) Each licensee and other entity who is subject to this subpart shall retain the following records for at least 5 years after the licensee or other entity terminates or denies an individual's authorization or until the completion of all related legal proceedings, whichever is later:

(1) Records of self-disclosures, employment histories, and suitable inquiries that are required under §§ 26.55, 26.57, 26.59, and 26.69 that result in the granting of authorization;

(2) Records pertaining to the determination of a violation of the FFD policy and related management actions;

(3) Documentation of the granting and termination of authorization; and

(4) Records of any determinations of fitness conducted under § 26.189, including any recommendations for treatment and followup testing plans.

(b) Each licensee and other entity who is subject to this subpart shall retain the following records for at least 3 years or until the completion of all related legal proceedings, whichever is later:

(1) Records of FFD training and examinations conducted under § 26.29; and

(2) Records of audits, audit findings, and corrective actions taken under § 26.41.

(c) Licensees and other entities shall ensure the retention and availability of records pertaining to any 5-year denial of authorization under § 26.75(c), (d), or (e)(2) and any permanent denial of authorization under § 26.75(b) and (g) for at least 40 years or until, on application, the NRC determines that the records are no longer needed.

(d) Licensees and other entities shall retain any superseded versions of the written FFD policy and procedures required under §§ 26.27, 26.39, and 26.203(b) for at least 5 years or until completion of all legal proceedings related to an FFD violation that may have occurred under the policy and procedures, whichever is later.

(e) Licensees and other entities shall retain written agreements for the provision of services under this part for the life of the agreement or until completion of all legal proceedings related to an FFD policy violation that involved those services, whichever is later.

(f) Licensees and other entities shall retain records of the background investigations, credit and criminal history checks, and psychological assessments of FFD program personnel, conducted under § 26.31(b)(1)(i), for the length of the individual's employment by or contractual relationship with the licensee or other entity, or until the completion of all related legal proceedings, whichever is later.

(g) If a licensee's or other entity's FFD program includes tests for drugs in addition to those specified in this part, as permitted under § 26.31(d)(1), or uses more stringent cutoff levels than those specified in this part, as permitted under § 26.31(d)(3), the licensee or other entity shall retain documentation certifying the scientific and technical suitability of the assays and cutoff levels used, as required under § 26.31(d)(1)(i) and (d)(3)(iii)(C), respectively, for the time the FFD program follows these practices or until the completion of all related legal proceedings, whichever is later.

§ 26.715 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services.

(a) Collection sites providing services to licensees and other entities who are subject to this subpart, licensee testing facilities, and HHS-certified laboratories shall maintain and make available documentation of all aspects of the testing process for at least 2 years or until the completion of all legal proceedings related to a determination of an FFD violation, whichever is later. This 2-year period may be extended on written notification by the NRC or by any licensee or other entity for whom services are being provided.

(b) Documentation that must be retained includes, but is not limited to, the following:

(1) Personnel files, including training records, for all individuals who have been authorized to have access to specimens, but are no longer under contract to or employed by the collection site, licensee testing facility, or HHS-certified laboratory;

(2) Chain-of-custody documents (other than forms recording specimens with negative test results and no FFD violations or anomalies, which may be destroyed after appropriate summary information has been recorded for program administration purposes);

(3) Quality assurance and quality control records;

(4) Superseded procedures;

(5) All test data (including calibration curves and any calculations used in determining test results);

(6) Test reports;

(7) Records pertaining to performance testing;

(8) Records pertaining to the investigation of testing errors or unsatisfactory performance discovered in quality control or blind performance testing, in the testing of actual specimens, or through the processing of appeals and MRO reviews, as well as any other errors or matters that could adversely reflect on the integrity of the testing process, investigation findings, and corrective actions taken, where applicable;

(9) Performance records on certification inspections;

(10) Records of preventative maintenance on licensee testing facility instruments;

(11) Records that summarize any test results that the MRO determined to be scientifically insufficient for further action;

(12) Either printed or electronic copies of computer-generated data;

(13) Records that document the dates, times of entry and exit, escorts, and purposes of entry of authorized visitors, maintenance personnel, and service personnel who have accessed secured areas of licensee testing facilities and HHS-certified laboratories; and

(14) Records of the inspection, maintenance, and calibration of EBTs.

§ 26.717 Fitness-for-duty program performance data.

(a) Licensees and other entities shall collect and compile FFD program performance data for each FFD program that is subject to this subpart.

(b) The FFD program performance data must include the following information:

(1) The random testing rate;

(2) Drugs for which testing is conducted and cutoff levels, including results of tests using lower cutoff levels, tests for drugs not included in the HHS panel, and any special analyses of dilute specimens permitted under § 26.163(a)(2);

(3) Populations tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);

(4) Number of tests administered and results of those tests sorted by population tested (i.e., individuals in applicant status, permanent licensee employees, C/Vs);

(5) Conditions under which the tests were performed, as defined in § 26.31(c);

(6) Substances identified;

(7) Number of subversion attempts by type;

(8) Summary of management actions; and

(9) The information required under § 26.203(e)(1) and (e)(2).

(c) Licensees and other entities who have a licensee-approved FFD program shall analyze the data at least annually and take appropriate actions to correct any identified program weaknesses. Records of the data, analyses, and corrective actions taken must be retained for at least 3 years or until the completion of any related legal proceedings, whichever is later.

(d) Any licensee or other entity who terminates an individual's authorization or takes administrative action on the basis of the results of a positive initial drug test for marijuana or cocaine shall also report these test results in the annual summary by processing stage (i.e., initial testing at the licensee testing facility, testing at the HHS-certified laboratory, and MRO determinations). The report must also include the number of terminations and administrative actions taken against individuals for the reporting period.

(e) Licensees and other entities shall submit the FFD program performance data (for January through December) to the NRC annually, before March 1 of the following year.

(f) Licensees and other entities may submit the FFD program performance data in a consolidated report, as long as the report presents the data separately for each site.

(g) Each C/V who maintains a licensee-approved drug and alcohol testing program is subject to the reporting requirements of this section and shall submit the required information either directly to the NRC or through the licensee's) or other entities to whom the C/V provided services during the year. Licensees, other entities, and C/Vs shall share information to ensure that the information is reported completely and is not duplicated in reports submitted to the NRC.

§ 26.719 Reporting requirements.

(a) *Required reports.* Each licensee and entity who is subject to this subpart shall inform the NRC of significant violations of the FFD policy, significant FFD program failures, and errors in drug and alcohol testing. These events must be reported under this section, rather than under the provisions of 10 CFR 73.71.

(b) *Significant FFD policy violations or programmatic failures.* The following significant FFD policy violations and programmatic failures must be reported to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation:

(1) The use, sale, distribution, possession, or presence of illegal drugs, or the consumption or presence of alcohol within a protected area;

(2) Any acts by any person licensed under 10 CFR parts 52 and/or 55 to operate a power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are authorized under this part, if such acts—

(i) Involve the use, sale, or possession of a controlled substance;

(ii) Result in a determination that the individual has violated the licensee's or other entity's FFD policy (including subversion as defined in § 26.5); or

(iii) Involve the consumption of alcohol within a protected area or while performing the duties that require the individual to be subject to the FFD program;

(3) Any intentional act that casts doubt on the integrity of the FFD program; and

(4) Any programmatic failure, degradation, or discovered vulnerability of the FFD program that may permit undetected drug or alcohol use or abuse by individuals within a protected area, or by individuals who are assigned to perform duties that require them to be subject to the FFD program.

(c) *Drug and alcohol testing errors.* (1) Within 30 days of completing an investigation of any testing errors or unsatisfactory performance discovered in performance testing at either a licensee testing facility or an HHS-certified laboratory, in the testing of quality control or actual specimens, or through the processing of reviews under § 26.39 and MRO reviews under § 26.185, as well as any other errors or matters that could adversely reflect on the integrity of the random selection or testing process, the licensee or other entity shall submit to the NRC a report of the incident and corrective actions taken or planned. If the error involves an HHS-certified laboratory, the NRC shall ensure that HHS is notified of the finding.

(2) If a false positive error occurs on a blind performance test sample submitted to an HHS-certified laboratory, the licensee or other entity shall notify the NRC within 24 hours after discovery of the error.

(3) If a false negative error occurs on a quality assurance check of validity screening tests, as required in § 26.137(b), the licensee or other entity shall notify the NRC within 24 hours after discovery of the error.

(d) *Indicators of programmatic weaknesses.* Licensees and other entities shall document, trend, and correct non-reportable indicators of FFD programmatic weaknesses under the licensee's or other entity's corrective action program, but may not track or trend drug and alcohol test results in a manner that would permit the identification of any individuals.

Subpart O—Inspections, Violations, and Penalties

§ 26.821 Inspections.

(a) Each licensee and other entity who is subject to this part shall permit duly authorized NRC representatives to inspect, copy, or take away copies of its records and to inspect its premises, activities, and personnel as may be necessary to accomplish the purposes of this part.

(b) Written agreements between licensees or other entities and their C/Vs must clearly show that—

(1) The licensee or other entity is responsible to the NRC for maintaining an effective FFD program under this part; and

(2) Duly authorized NRC representatives may inspect, copy, or take away copies of any licensee's, other entity's, or C/V's documents, records, and reports related to implementation of the licensee's or other entity's FFD program under the scope of the contracted activities.

§ 26.823 Violations.

(a) An injunction or other court order may be obtained to prohibit a violation of any provision of—

(1) The Atomic Energy Act of 1954, as amended;

(2) Title II of the Energy Reorganization Act of 1974; or

(3) Any regulation or order issued under these Acts.

(b) A court order may be obtained for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act of 1954, for violations of—

(1) Section 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Act;

(2) Section 206 of the Energy Reorganization Act of 1974;

(3) Any rule, regulation, or order issued under these sections;

(4) Any term, condition, or limitation of any license issued under these sections; or

(5) Any provisions for which a license may be revoked under section 186 of the Atomic Energy Act of 1954.

26.825 Criminal penalties.

(a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For the purposes of section 223, all of the regulations in Part 26 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section.

(b) The regulations in Part 26 that are not issued under sections 161b, 161i, or 161o for the purposes of section 223 are as follows: §§ 26.1, 26.3, 26.5, 26.7, 26.8, 26.9, 26.11, 26.51, 26.81, 26.121, 26.151, 26.181, 26.201, 26.823, and 26.825.

* * * * *

Dated at Rockville, Maryland, this 7th day of March, 2008.

For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

Note: This Appendix will not appear in The Code of Federal Regulations.

Appendix A to This Document—Derivation and Distribution Tables for Part 26.

TABLE 1.—DERIVATION TABLE FOR PART 26

New section	Based on
26.1	26.1 first sentence.
26.3(a)	26.2(a).
26.3(b)	26.1 (2nd sentence) and 26.2(a) (1st sentence).

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.3(c)	26.2(c).
26.3(d)	26.23(a)(1).
26.3(e)	26.2(b).
26.4(a)	26.2(a) and 26.2(d).
26.4(b)	26.2(a) and 26.2(d).
26.4(c)	26.2(a) and 26.2(d).
26.4(d)	26.2(a) and 26.2(d).
26.4(e)	NEW.
26.4(f)	NEW.
26.4(g)	NEW.
26.4(h)	NEW.
26.4(i)(1)	26.20(a).
26.4(i)(2)	26.2(b) first sentence.
26.4(i)(3)	26.2(b) first sentence.
26.4(i)(4)	NEW.
26.4(j)	NEW.
26.5	26.3 and Appendix A Subpart 1.2.
26.7	26.4.
26.8	26.8.
26.9	26.6.
26.11	NEW.
26.21	26.23(b).
26.23(a)	26.10(a).
26.23(b)	26.10(a).
26.23(c)	26.10(b).
26.23(d)	26.10(c).
26.23(e)	NEW.
26.27(a)	26.20 1st paragraph.
26.27(b)(1)	26.20(a).
26.27(b)(2)	NEW.
26.27(b)(3)	NEW.
26.27(b)(4)(i)	26.20(a)(1).
26.27(b)(4)(ii)	26.20(a)(2).
26.27(b)(5)	NEW.
26.27(b)(6)	26.20(a).
26.27(b)(7)	26.20(b).
26.27(b)(8)	26.20(d).
26.27(b)(9)	NEW.
26.27(b)(10)	NEW.
26.27(b)(11)	NEW.
26.27(c)(1)	26.20(c).
26.27(c)(2)	26.20(d).
26.27(c)(3)	26.20(e).
26.27(c)(4)	NEW.
26.27(d)	26.20(f).
26.29(a)	26.21(a)(1)–(5); 26.22(a)(1)–(5); 26.22(b).
26.29(b)	NEW.
26.29(c)	26.21(b) and 26.21(c).
26.31	26.24.
26.31(a)	26.24(a).
26.31(b)	Section 2.3 in Appendix A to Part 26.
26.31(b)(1)	First paragraph, Section 2.3 in Appendix A to Part 26.
26.31(b)(1)(i)	Section 2.3(2).
26.31(b)(1)(ii)	Section 2.3(1).
26.31(b)(1)(iii)	Section 2.3(1).
26.31(b)(1)(iv)	NEW.
26.31(b)(1)(v)	Section 2.3(3).
26.31(b)(2)	NEW.
26.31(c)	26.24(a)(1)–(4).
26.31(c)(1)	26.24(a)(1).
26.31(c)(2)	26.24(a)(3).
26.31(c)(3)	26.24(a)(3).
26.31(c)(4)	26.24(a)(4).
26.31(c)(5)	26.24(a)(2).

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.31(d)	NEW.
26.31(d)(1)	Section 2.1(a) in Appendix A to Part 26.
26.31(d)(1)(i)(A)	26.24(c).
26.31(d)(1)(i)(B)	26.24(c).
26.31(d)(1)(i)(C)	Section 2.1(c).
26.31(d)(1)(i)(D)	26.31(d)(1)(i)(C).
26.31(d)(1)(ii)	Section 2.1(b) and 26.31(d)(1)(i)(D).
26.31(d)(1)(iii)	NEW.
26.31(d)(2)	26.24(a).
26.31(d)(3)	NEW.
26.31(d)(3)(i)	Appendix A Subpart A 1.1(3); 26.24(f); Appendix A Subpart B 2.8(e); 2.8(a) and (b).
26.31(d)(3)(ii)	26.24(d)(1).
26.31(d)(3)(iii)	Sections 2.7(e)(1) and (f)(2).
26.31(d)(3)(iii)(A)	26.24(b).
26.31(d)(3)(iii)(B)	NEW.
26.31(d)(3)(iii)(C)	NEW.
26.31(d)(4)	26.24(g).
26.31(d)(5)	NEW.
26.31(d)(6)	Section 2.1(d).
26.33	26.22.
26.35	26.25.
26.37	26.29.
26.39	26.27.
26.41(a)	26.80(a).
26.41(b)	26.80(a).
26.41(c)	26.80(a); Appendix A Subpart B 2.7(m).
26.41(d)	Section 2.7(m).
26.41(e)	26.80(b).
26.41(f)	26.80(c).
26.41(g)	26.80(a).
26.51	26.1.
26.53	NEW.
26.55(a)	NEW.
26.55(b)	NEW.
26.57(a)	NEW.
26.57(b)	NEW.
26.59	NEW.
26.61	26.27(a)(1).
26.61(a)	NEW.
26.61(b)	NEW.
26.61(c)	NEW.
26.61(d)	26.27(a)(4).
26.63	26.27(a)(2).
26.63(a)	NEW.
26.63(b)	NEW.
26.63(c)	NEW.
26.63(d)	NEW.
26.63(e)	NEW.
26.63(f)(1)	26.71(c) and 26.27(b)(2)(vii).
26.63(f)(2)	NEW.
26.63(f)(3)	NEW.
26.65	26.24(a)(1).
26.65(a)	NEW.
26.65(b)	NEW.
26.65(c)	NEW.
26.65(d)	NEW.
26.65(e)	NEW.
26.65(f)	NEW.
26.65(g)	NEW.
26.67(a)	NEW.
26.67(b)	NEW.

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.67(c)	NEW.
26.69	26.27(b)(4).
26.69(a)	NEW. 26.27(b)(2).
26.69(b)(1)	NEW.
26.69(b)(2)	NEW. 26.27(b)(2).
26.69(b)(3)	26.27(b)(4).
26.69(b)(4)	26.27(b)(2).
26.69(b)(5)	NEW.
26.69(b)(6)	26.27(b)(4).
26.69(b)(7)	NEW.
26.69(c)(1)	NEW.
26.69(c)(2)	NEW.
26.69(c)(3)	NEW.
26.69(c)(4)	NEW.
26.69(c)(5)	NEW.
26.69(d)	NEW.
26.69(e)	NEW.
26.69(f)	26.27(a)(2).
26.71	NEW.
26.73	NEW.
26.75(a) (1st sentence).	NEW.
26.75(a) (2nd sentence).	26.27(b) (1st sentence).
26.75(b)	NEW.
26.75(c)	26.27(b)(3).
26.75(d)	26.27(c).
26.75(e)	26.27(b)(2).
26.75(f)	26.27(b)(5).
26.75(g)	26.27(b)(4).
26.75(h)	26.24(d)(2).
26.75(i)	26.24(d)(2).
26.77	26.26(b)(1).
26.77(a)	NEW.
26.77(b)(1)	26.27(b)(1).
26.77(b)(2)	NEW.
26.77(b)(3)	NEW.
26.77(c)	26.27(d).
26.83(b)	26.24(b).
26.85(a)	Appendix A Subpart B 2.2(d).
26.85(b)	NEW.
26.85(c)	Appendix A Subpart B 2.2(d)(2) (last sentence).
26.85(d)	Appendix A Subpart B 2.7(o)(5).
26.85(e)	NEW.
26.87(a)	Appendix A Subpart B 2.4(a).
26.87(b)	Appendix A Subpart B 2.4(f) (1st sentence).
26.87(c)	Appendix A Subpart B 2.7(m).
26.87(d)	Appendix A Subpart B 2.4(c).
26.87(d)(1)	Appendix A Subpart B 2.4(e).
26.87(d)(2)	Appendix A Subpart B 2.4(c) (2nd sentence).
26.87(d)(3)	Appendix A Subpart B 2.4(c).
26.87(e)	NEW.
26.87(e)(2)	Appendix A Subpart B 2.4(g)(1) (2nd sentence).
26.87(e)(3)	NEW.
26.87(f)(1)	Appendix A Subpart B 2.4(c)(1).

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.87(f)(2)	Appendix A Subpart B 2.4(g)(10) (3rd sentence).
26.87(f)(3)	Appendix A Subpart B 2.4(g)(10) (2nd sentence).
26.87(f)(4)	Appendix A Subpart B 2.4(g)(10) and new material.
26.87(f)(5)	Appendix A Subpart B 2.4(c)(2).
26.89(a)	Appendix A Subpart B 2.4(g)(3).
26.89(b)	Appendix A Subpart B 2.4(g)(2).
26.89(b)(1)	Appendix A Subpart B 2.4(g)(2).
26.89(b)(2)	Appendix A Subpart B 2.4(g)(2).
26.89(b)(3)	NEW.
26.89(b)(4)	Appendix A Subpart B 2.4(g)(4) and (g)(23)(ii).
26.89(c)	NEW.
26.89(d)	Appendix A Subpart B 2.4(e).
26.91(a)	Appendix A Subpart B 2.7(o)(3)(ii).
26.91(b)	Appendix A Subpart B 2.7(o)(3)(ii).
26.91(c)	NEW.
26.91(d)	NEW.
26.91(e)	NEW.
26.93	Appendix A Subpart B 2.4(g)(18) and new material.
26.95	Appendix A Subpart B 2.4(g)(18) and new material.
26.97	NEW.
26.99	26.24(g) and Appendix A Subpart B 2.7(e)(1).
26.101	Appendix A Subpart B 2.4(g)(18) and new material.
26.103	26.24(g), Appendix A Subpart B 2.7(f)(2), and new material.
26.105(a)	Appendix A Subpart B 2.4(g)(5).
26.105(b)	NEW.
26.105(c)	Appendix A Subpart B 2.4(g)(6).
26.105(d)	Appendix A Subpart B 2.4(g)(7).
26.105(e)	NEW.
26.107	Appendix A Subpart B 2.4(g) and new material.
26.109	Appendix A Subpart B 2.4 and new material.
26.111(a)	Appendix A Subpart B 2.4(g)(13) and (g)(14).
26.111(b)	Appendix A Subpart B 2.4(g)(15).
l26.111(c)	NEW.
26.111(d)	Appendix A Subpart B 2.4(g)(16).

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.111(e)	NEW.
26.111(f)	NEW.
26.113(a)	NEW.
26.113(b)	Appendix A Subpart B 2.4(g)(20) and 2.7(j).
26.113(c)	NEW.
26.115(a)(1)	Appendix A Subpart B 2.4(f)(2).
26.115(a)(2)	Appendix A Subpart B 2.4(f)(1) and (g)(14).
26.115(a)(3)	Appendix A Subpart B 2.4(f)(3).
26.115(a)(4)	Appendix A Subpart B 2.4(f)(4).
26.115(b)	Appendix A Subpart B 2.4(g)(25).
26.115(c)	NEW.
26.115(d)	NEW.
26.115(e)	Appendix A Subpart A 1.2 and Subpart B 2.4.
26.115(f)	NEW.
26.117(a)	Appendix A Subpart B 2.4(g)(20).
26.117(b)	Appendix A Subpart B 2.4(g)(21).
26.117(c)	Appendix A Subpart B 2.4(g)(22).
26.117(d)	Appendix A Subpart B 2.4(g)(23).
26.117(e)	Appendix A Subpart B 2.4(g)(26).
26.117(f)	Appendix A Subpart B 2.4(g)(27).
26.117(g)	Appendix A Subpart B 2.4(g)(28).
26.117(h)	Appendix A Subpart B 2.4(c)(2).
26.117(i)	Appendix A Subpart B 2.7(i).
26.117(j)	Appendix A Subpart B 2.4(1) and 2.7(c).
26.117(k)	Appendix A Subpart B 2.4(h).
26.119	NEW.
26.121	NEW.
26.123	Appendix A Subpart B 2.7(l)(2).
26.125(a)	Appendix A Subpart B 2.6(a).
26.125(b)	Appendix A Subpart B 2.6(b).
26.125(c)	Appendix A Subpart B 2.6(c).
26.127(a)	Appendix A Subpart B 2.2 1st paragraph.
26.127(b)	Appendix A Subpart B 2.7(a)(2) and 2.4(d).
26.127(c)	Appendix A Subpart B 2.7(o)(1).
26.127(d)	Appendix A Subpart B 2.7(o)(3)(iii).
26.127(e)	Appendix A Subpart B 2.7(o)(4).
26.129(a)	Appendix A Subpart B 2.7(a)(1).

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.129(b)	Appendix A Subpart B 2.2(b)(1).
26.129(c)	Appendix A Subpart B 2.7(b)(2).
26.129(d)	Appendix A Subpart B 2.7(a)(2).
26.129(e)	Appendix A Subpart B 2.7(d) 1st sentence.
26.129(f)	Appendix A Subpart B 2.7(c).
26.129(g)	Appendix A Subpart B 2.4(i).
26.129(h)	Appendix A Subpart B 2.4(i).
26.131	NEW.
26.133	Appendix A Subpart B 2.7(e)(1).
26.135(a)	Appendix A Subpart B 2.7(j).
26.135(b)	Appendix A Subpart B 2.7(j).
25.135(c)	Appendix A Subpart B 2.7(h).
26.137	Appendix A Subpart B 2.8(a).
26.137(e)(4–5)	Appendix A Subpart B 2.8(b).
26.137(e)(6–7)	Appendix A Subpart B 2.8(c).
26.137(f)	NEW.
26.137(g)	Appendix A Subpart B 2.7(o)(3)(i).
26.137(h)	Appendix A Subpart B 2.7(o)(2).
26.139(a)	Appendix A Subpart B 2.7(g)(2).
26.139(b)	26.24(d)(1).
26.139(c)	Appendix A Subpart B 2.7(o)(5).
26.139(d)	Appendix A Subpart B 2.7(g)(6).
26.139(e)	Appendix A Subpart B 2.7(g)(7).
26.139(f)	NEW.
26.151	NEW.
26.153(a)	26.24(f), Appendix A Subpart A 1.1(3) and Subpart D 4.1(a).
26.153(b)	Appendix A Subpart B 2.7(l)(2).
26.153(c)	Appendix A Subpart B 2.7(k).
26.153(d)	Appendix A Subpart D 4.1(b).
26.153(e)	Appendix A Subpart B 2.7(m).
26.153(f)(1)	Appendix A Subpart B 2.7(l)(1).
26.153(f)(2)	Appendix A Subpart B 2.7(o)(5).
26.153(f)(3)	Appendix A Subpart C 3.1.
26.153(f)(4)	Appendix A Subpart C 3.2.
26.153(f)(5)	NEW.
26.153(f)(6)	Appendix A Subpart B 2.7(m).
26.153(g)	NEW.

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.155	Appendix A Subpart B 2.5.
26.157(a)	Appendix A Subpart B 2.2 1st paragraph.
26.157(b)	Appendix A Subpart B 2.4(d) and 2.7(a)(2).
26.157(c)	Appendix A Subpart B 2.7(o)(1).
26.157(d)	Appendix A Subpart B 2.2(o)(3)(iii).
26.157(e)	Appendix A Subpart B 2.7(o)(4).
26.159(a)	Appendix A Subpart B 2.7(a)(1).
26.159(b)	Appendix A Subpart B 2.7(b)(1).
26.159(c)	Appendix A Subpart B 2.7(b)(2).
26.159(d)	Appendix A Subpart B 2.7(a)(2).
26.159(e)	Appendix A Subpart B 2.7(a)(2).
26.159(f)	Appendix A Subpart B 2.4(i).
26.159(g)	Appendix A Subpart B 2.4(i).
26.159(h)	NEW.
26.159(i)	Appendix A Subpart B 2.7(h).
26.159(j)	NEW.
26.161	NEW.
26.163(a)	Appendix A Subpart B 2.7(e).
26.163(a)(2)	NEW.
26.163(b)	Appendix A Subpart B 2.7(f).
26.165(a)	26.24(f) and Appendix A Subpart B 2.7(j).
26.165(b)	Appendix A Subpart B 2.7(j) and new material.
26.165(c)	Appendix A Subpart B 2.7(i).
26.165(c)(1)	NEW.
26.165(c)(2)	Appendix A Subpart B 2.7(i).
26.165(c)(3)	NEW.
26.165(c)(4)	Appendix A Subpart B 2.7(j) (last sentence).
26.165(d)	NEW.
26.165(e)	NEW.
26.165(f)	NEW.
26.167(a)	Appendix A Subpart B 2.8(a) and (d).
26.167(b)	Appendix A Subpart B 2.8(c) and (d) and new material.
26.167(c)	NEW.
26.167(d)(1)	Appendix A Subpart B 2.7(e)(1).
26.167(d)(2)	NEW.
26.167(d)(3)	Appendix A Subpart B 2.8(c).
26.167(e)	Appendix A Subpart B 2.7(f)(2) and 2.8(d).

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.167(f)	Appendix A Subpart B 2.8(e)(4)–(e)(6).
26.167(g)	Appendix A Subpart B 2.7(o)(3)(i).
26.167(h)	Appendix A Subpart B 2.7(o)(2).
26.168	Appendix A Subpart B 2.8(e) and new material.
26.169	Appendix A Subpart B 2.7(g) (substantially revised).
26.181	NEW.
26.183(a)	26.3 and Appendix A Subpart A 1.2 and Appendix A Subpart B 2.9(b).
26.183(b)	Appendix A Subpart B 2.9(b).
26.183(c)	26.3 and Appendix A Subparts A 1.2, B 2.4(j), B 2.9(a), and B 2.9(b).
26.183(d)	NEW.
26.185(a)	Appendix A Subpart B 2.9(a).
26.185(b)	Appendix A Subpart B 2.9(b).
26.185(c)	Appendix A Subpart B 2.9(c).
26.185(d)	NEW.
26.185(e)	NEW.
26.185(f)	NEW.
26.185(g)	NEW.
26.185(h)	NEW.
26.185(i)	NEW.
26.185(j)(1)	Appendix A Subpart B 2.9(d).
26.185(j)(2)	Appendix A Subpart B 2.9(d).
26.185(j)(3)	NEW.
26.185(j)(4)	NEW.
26.185(j)(5)	NEW.
26.185(j)(6)	NEW.
26.185(k)	Appendix A Subpart B 2.9(f).
26.185(l)	Appendix A Subpart B 2.9(e).
26.185(m)	Appendix A Subpart B 2.9(g).
26.185(n)	NEW.
26.185(o)	NEW.
26.185(p)	26.24(e).
26.187	NEW.
26.189	NEW.
26.201	NEW.
26.203	NEW.
26.205	NEW.
26.207	NEW.
26.209	NEW.
26.211	NEW.
26.401	26.2(c).
26.403	26.2(c).
26.405	26.2(c).
26.407	26.2(c).
26.409	26.2(c).
26.411	26.2(c).
26.413	26.2(c).
26.415	26.2(c).
26.417	26.2(c).
26.419	26.2(c).

TABLE 1.—DERIVATION TABLE FOR PART 26—Continued

New section	Based on
26.709	NEW.
26.711	NEW.
26.713(a)(1)	26.71(a).
26.713(a)(2)	26.71(b).
26.713(a)(3)	NEW.
26.713(a)(4)	NEW.
26.713(b)	26.21(b); 26.22(c); 26.80(c).
26.713(c)	26.71(c).
26.713(d)	26.20.
26.713(e)	26.23(a).
26.713(f)	NEW.
26.713(g)	NEW.
26.715(a)	Appendix A, Section 2.7(n).
26.715(b)(1)–(14)	NEW.
26.717	26.71(d).
26.719(a)–(b)	26.73.
26.719(c)(1)	Appendix A Subpart B 2.8(e)(4).
26.719(c)(2)	Appendix A Subpart B 2.8(e)(5).
26.719(c)(3)	NEW.
26.719(d)	NEW.
26.821	26.70.
26.823	26.90.
26.825	26.91.

TABLE 2.—DISTRIBUTION TABLE FOR PART 26

Former section	Replaced by
26.1 (from beginning to ''programs'').	26.1.
26.1 (following ''programs'').	Deleted.
26.2(a) (first clause)	26.3(a).
26.2(a) (balance of 1st sentence).	26.3(b) first clause.
26.2(a) (2nd sentence).	26.21 (1st sentence).
26.2(a) (3rd sentence to end).	26.4(a), (b), (c), and (d).
26.2(b) (1st sentence)	26.4(i) (2) and (3).
26.2(b) (2nd sentence to end).	26.3(e).
26.2(c) (1st sentence)	26.3(c); Subpart K.
26.2(c) (from ''shall implement'' to end).	Subpart K.
26.2(d)	26.3(c).
26.3	26.5.
26.4	26.7.
26.6	26.9.
26.8	26.13.
26.10(a) (from beginning through ''manner'').	26.23(a).
26.10(a) (balance of 1st sentence).	26.23(b).
26.10(b)	26.23(c).
26.10(c)	26.23(d).
26.20 (introductory paragraph, 1st sentence).	26.27(a).
26.20 (introductory paragraph, 2nd sentence).	26.713(d).

TABLE 2.—DISTRIBUTION TABLE FOR PART 26—Continued

Former section	Replaced by
26.20 (introductory paragraph, final sentence).	26.27(b) (sentence before ''(1)'').
26.20(a)	26.27(b).
26.20(b)	26.27(b)(7).
26.20(c)	26.27(c)(1).
26.20(d)	26.27(c)(2).
26.20(e)	26.27(c)(3).
26.20(f)	26.27(d).
26.21(a)	26.29(a).
26.21(b)	26.29(c).
26.21(b) (last sentence).	26.713(b)(1).
26.22	Deleted.
26.23(a)	26.3(d) and 26.21.
26.23(b)	26.21.
26.24(a) (first sentence to ''(1)'').	26.31(a).
26.24(a)(1)–(4)	26.31(c) (substantially revised).
26.24(b)	Subparts E, F, and G.
26.24(c)	26.31(d).
26.24(d)	Subparts E, F, and G.
26.24(e)	Subpart H.
26.24(f)	26.31(d)(2) and requirements in Subpart G.
26.24(g)	26.31(d)(4) and Subparts E, F, and G.
26.25	26.35.
26.27(a)	Subpart C.
26.27(b)	Subpart D.
26.27(c)	Subpart D.
26.27(d)	26.77(c).
26.28	26.39.
26.29	26.37.
26.70	26.721.
26.71	26.711, 26.713, and 26.715.
26.73	26.719 (substantially revised).
26.80	26.41 (substantially revised).
26.90	26.723.
26.91	26.725.
Appendix A Subpart A, 1.1(1).	26.3.
Appendix A Subpart A, 1.1(3).	Subparts F and G.
Appendix A Subpart A, 1.2.	26.5, and 26.115(e).
Appendix A Subpart B, 2.1(a).	26.31(d)(1).
Appendix A Subpart B, 2.1(b).	26.31(d)(1)(ii).
Appendix A Subpart B.2.1(c).	Subparts E, F, and G.
Appendix A Subpart B.2.1(d).	26.31(d)(6).
Appendix A Subpart B.2.1(e).	26.31.
Appendix A Subpart B.2.2 (Initial paragraph).	Subparts F and G.
Appendix A Subpart B.2.2 (a), (b), and (c).	26.115, 26.117, 26.129, 26.159, 26.169.
Appendix A Subpart B.2.2 (d)(1), (2), and (3).	26.85 and 26.157(b).

TABLE 2.—DISTRIBUTION TABLE FOR PART 26—Continued

Former section	Replaced by
Appendix A Subpart B.2.2(d)(4).	Deleted.
Appendix A Subpart B.2.3.	26.31(b), and requirements in Subparts E, F, and G.
Appendix A Subpart B.2.4(a).	26.87(a).
Appendix A Subpart B.2.4(b).	26.85 and 26.115(e).
Appendix A Subpart B.2.4(c).	26.87 (d) and (f), 26.117(h).
Appendix A Subpart B 2.4(d).	26.117 and 26.127(b).
Appendix A Subpart B 2.4(e).	26.87(d)(1).
Appendix A Subpart B 2.4(f) 1st sentence.	26.87(b).
Appendix A Subpart B 2.4(f)(1) through (f)(4).	26.95 through 26.115 and Subparts Fand G.
Appendix A Subpart B 2.4(g)(1) through (g)(25).	Subparts E, F, and G.
Appendix A Subpart B 2.4(h) (1st sentence).	26.87(f)(5).
Appendix A Subpart B 2.4(h) (balance of section).	26.129(d) and 26.157.
Appendix A Subpart B 2.4(i).	26.117(j), 26.129(h) and 26.159.
Appendix A Subpart B 2.4(j) (first two sentences).	26.115 and 26.185.
Appendix A Subpart B 2.4(j) (final sentence).	Deleted.
Appendix A Subpart B 2.5(a).	26.155(a).
Appendix A Subpart B 2.5(b).	26.153(c) and 26.155(c).
Appendix A Subpart B 2.5(c).	26.155(c).
Appendix A Subpart B 2.5(d).	26.155(d).
Appendix A Subpart B 2.5(e).	26.155(e).
Appendix A Subpart B 2.5(f).	26.155(f).
Appendix A Subpart B 2.6(a).	26.125(a).
Appendix A Subpart B 2.6(b).	26.125(b).
Appendix A Subpart B 2.6(c).	26.125(c).
Appendix A Subpart B 2.7(a).	26.127, 26.129, 26.157, and 26.159.
Appendix A Subpart B 2.7(b).	26.129(b) and 26.159.
Appendix A Subpart B 2.7(c).	26.117(j), 26.129(f) and 26.159(h).
Appendix A Subpart B 2.7(d).	26.157 and 26.159.

TABLE 2.—DISTRIBUTION TABLE FOR PART 26—Continued

Former section	Replaced by
Appendix A Subpart B 2.7(e).	Validity screening and initial validity test requirements in 26.131 and 26.161 and initial cutoff levels in 26.133 and 26.163(a).
Appendix A Subpart B 2.7(f).	26.103, 26.115(a), 26.163(b), 26.167 and 26.169.
Appendix A Subpart B 2.7(g)(1) through (5).	26.169.
Appendix A Subpart B 2.7(g)(6) and (7).	Requirement for annual summary in 26.169(h).
Appendix A Subpart B 2.7(g)(8).	26.215.
Appendix A Subpart B 2.7(h).	26.159(i) and by 26.135(c).
Appendix A Subpart B 2.7(i).	26.117(i) and Subparts F and G.
Appendix A Subpart B 2.7(j).	26.113, 26.135, 26.165.
Appendix A Subpart B 2.7(k).	26.153(c).
Appendix A Subpart B 2.7(l).	26.123 and 26.153.
Appendix A Subpart B 2.7(m).	26.87(c), 26.153 and 26.221.
Appendix A Subpart B 2.7(n).	26.215(a).
Appendix A Subpart B 2.7(o)(1).	26.127(c) and 26.157(c).
Appendix A Subpart B 2.7(o)(2), (o)(3), and (o)(4).	26.91, 26.127, 26.137, 26.157 and 26.167.
Appendix A Subpart B 2.7(o)(5).	26.85(d), 26.139(c) and 26.153(f)(2).
Appendix A Subpart B 2.8(a).	26.137(a) and 26.167(a).
Appendix A Subpart B 2.8(b).	26.137.
Appendix A Subpart B 2.8(c).	26.167.
Appendix A Subpart B 2.8(d).	26.137 and 26.167.
Appendix A Subpart B 2.8(e)(1) to (e)(3).	26.137 and 26.167.
Appendix A Subpart B 2.8(e)(4), (e)(5), and (e)(6).	26.137, 26.167, and 26.219.
Appendix A Subpart B 2.9 (a) and (b) (through ''contract employee'').	26.183.
Appendix A Subpart B 2.9(b) (balance of section), (c), (d), (e), (f), and (g).	26.185.
Appendix A Subpart C 3.1.	26.37(e) and 26.153(f)(3).
Appendix A Subpart C 3.2.	26.75(l)(4), 26.153(f)(4), and 26.165(f).
Appendix A Subpart D 4.1.	26.153(d).

[FR Doc. E8–4998 Filed 3–28–08; 8:45 am]

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Federal Register

Monday,
March 31, 2008

Part III

Department of Housing and Urban Development

24 CFR Part 200
Changes in Maximum Mortgage Limits for Multifamily Housing; Final Rule

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 200

[Docket No. FR–5197–F–01]

RIN 2502–A162

Changes in Maximum Mortgage Limits for Multifamily Housing

AGENCY: Office of Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Final rule.

SUMMARY: This rule conforms HUD's regulations to a recent statutory increase in the amount by which HUD may increase the dollar amount limitations on insured mortgages for multifamily housing.

DATES: *Effective Date:* April 30, 2008.

FOR FURTHER INFORMATION CONTACT: Joe Sealey, Director, Technical Support Division, Office of Housing, 451 Seventh Street, SW., Room 6150, Washington, DC 20410–8000; telephone (202) 708–2866. This is not a toll-free number. Persons with hearing or speech impairments may access these numbers toll-free through TTY by calling the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Background

Title II of the National Housing Act (12 U.S.C. 1707 *et seq.*) authorizes the Secretary to make exceptions to the maximum mortgage amounts in certain Federal Housing Administration (FHA) multifamily mortgage insurance programs. Until recently, Title II provided for exceptions in amounts of up to a 140 percent increase on a geographical basis and up to a 170 percent increase on a project-by-project basis. For example, section 207(c)(3) of the National Housing Act, after listing the maximum mortgage limits for the program, states that:

> [T]he Secretary may, by regulation, increase any of the dollar amount limitations in subparagraph (A) (as such limitations may have been adjusted in accordance with section 1712a of this title) by not to exceed 140 percent in any geographical area where the Secretary finds that cost levels so require and by not to exceed 140 percent, or 170 percent in high cost areas, where the Secretary determines it necessary on a project-by-project basis * * *

(12 U.S.C. 1713(c)(3)(B)). Similar language provided the same exceptions to maximum mortgage limits in other FHA multifamily insurance programs. (*See* 12 U.S.C. 1715e(b)(2)(B)(i), 1715k(d)(3)(B)(iii)(II), 1715l(d)(3)(ii)(II), 1715l(d)(4)(ii)(II), 1715v(c)(2)(B), and 1715y(e)(3)(B).)

Section 200.15 of HUD's regulations (24 CFR 200.15) provides that the FHA Commissioner, acting under authority delegated by the Secretary, may increase the dollar amount limitations specified in law for insured mortgages ''(a) By not to exceed 140 percent in any geographic area in which the Commissioner finds that cost levels so require; and (b) By not to exceed 140 percent, or 170 percent in high cost areas, where the Commissioner determines it necessary on a project-by-project basis.''

These maximum mortgage amounts were recently revised by the Consolidated Appropriations Act, 2008 (Pub. L. 110–161, approved December 26, 2007) (FY2008 Appropriations Act) which appropriated fiscal year 2008 funds for the majority of federal agencies, including HUD. Section 221 of the General Provisions of Title II of Division K of the FY2008 Appropriations Act revises the statutory exceptions to maximum mortgage amounts for the FHA multifamily housing programs, listed in section 221 of the FY 2008 Appropriations Act, by (1) substituting 170 percent for the 140 percent exception for any geographical area, and (2) substituting 215 percent for 170 percent as the maximum exception allowed for a specific project. Accordingly, the statutory revision allows the Secretary to now grant exceptions to maximum mortgage limits for certain multifamily housing programs by (1) up to 170 percent in geographical areas where cost levels so require, and (2) up to 170 percent, or 215 in high cost areas, where necessary on a project-by-project basis.

This Final Rule

This final rule conforms HUD's regulation at 24 CFR 200.15 to the recent statutory changes made by FY2008 Appropriations Act. Because HUD is simply adopting the new statutory limits without change in order to conform its regulation to current law and is not exercising any regulatory discretion, public comment is unnecessary.

Findings and Certifications

Justification for Final Rulemaking

In general, the Department publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking, 24 CFR part 10. However, part 10 does provide for exceptions from that general rule where the agency finds good cause to omit advance notice and public participation. The good cause requirement is satisfied when prior public procedure is ''impracticable, unnecessary, or contrary to the public interest'' (24 CFR 10.1). In this case, public comment is unnecessary because HUD is only conforming its current rule to statutory change. HUD is not exercising its administrative discretion in this matter. Therefore, there would be no purpose served by accepting public comments on this rule.

Regulatory Flexibility Act

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this rule, and in so doing certified that this rule will not have a significant economic impact on a substantial number of small entities. This rule imposes no new obligation of any kind, but only raises the maximum mortgage limits for insured mortgages in HUD multifamily programs by percentage amounts.

Environmental Impact

This final rule is a statutorily required or discretionary establishment and review of loan limits, which does not constitute a development decision that affects the physical condition of specific project areas and building sites. Accordingly, under 24 CFR 50.19(c)(6), this rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 et seq.).

Executive Order 13132, Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits, to the extent practicable and permitted by law, an agency from promulgating a regulation that has federalism implications and either imposes substantial direct compliance costs on state and local governments and is not required by statute, or preempts state law, unless the relevant requirements of section 6 of the Executive Order are met. This final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive Order.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments, and on the private sector. This final rule does not impose any federal mandates on any state, local, or tribal government, or on

the private sector, within the meaning of UMRA.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers applicable to this rule are 14.112, 14.126, 14.127, 14.134, 14.135,14.138, 14.139, and 14.155.

List of Subjects in 24 CFR Part 200

Administrative practice and procedure, Claims, Equal employment opportunity, Fair housing, Home improvement, Housing standards, Lead poisoning, Loan programs—housing and community development, Mortgage insurance, Organization and functions (Government agencies), Penalties, Reporting and recordkeeping requirements, Social security, Unemployment compensation, Wages.

■ For the reasons stated in the preamble, HUD amends 24 CFR part 200 as follows:

PART 200—INTRODUCTION TO FHA PROGRAMS

■ 1. The authority citation for part 200 continues to read as follows:

Authority: 12 U.S.C. 1702–1715z–21; 42 U.S.C. 3535d.

■ 2. Revise § 200.15 to read as follows:

§ 200.15 Maximum mortgage.

Mortgages must not exceed either the statutory dollar amount or loan ratio limitations established by the section of the Act under which the mortgage is insured, except that the Commissioner may increase the dollar amount limitations:

(a) By not to exceed 170 percent, in any geographical area, in which the Commissioner finds that cost levels so require; and

(b) By not to exceed 170 percent, or 215 percent in high-cost areas, where the Commissioner determines it necessary on a project-by-project basis.

Dated: March 21, 2008.

Brian D. Montgomery,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. E8–6491 Filed 3–28–08; 8:45 am]

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LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.archives.gov/federal-register/laws.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html*. Some laws may not yet be available.

S. 2733/P.L. 110–198

Higher Education Extension Act of 2008 (Mar. 24, 2008; 122 Stat. 656)

Last List March 18, 2008

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CFR CHECKLIST

This checklist, prepared by the Office of the Federal Register, is published weekly. It is arranged in the order of CFR titles, stock numbers, prices, and revision dates.

An asterisk (*) precedes each entry that has been issued since last week and which is now available for sale at the Government Printing Office.

A checklist of current CFR volumes comprising a complete CFR set, also appears in the latest issue of the LSA (List of CFR Sections Affected), which is revised monthly.

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Title	Stock Number	Price	Revision Date
1	(869–062–00001–4)	5.00	[4] Jan. 1, 2007
2	(869–062–00002–2)	5.00	Jan. 1, 2007
3 (2006 Compilation and Parts 100 and 102)	(869–062–00003–1)	35.00	[1] Jan. 1, 2007
4	(869–064–00004–1)	13.00	Jan. 1, 2008
5 Parts:			
1–699	(869–062–00005–7)	60.00	Jan. 1, 2007
700–1199	(869–064–00006–8)	53.00	Jan. 1, 2008
1200–End	(869–062–00007–3)	61.00	Jan. 1, 2007
6	(869–062–00008–1)	10.50	Jan. 1, 2007
7 Parts:			
1–26	(869–064–00009–2)	47.00	Jan. 1, 2008
27–52	(869–064–00010–6)	52.00	Jan. 1, 2008
53–209	(869–064–00011–4)	40.00	Jan. 1, 2008
210–299	(869–062–00012–0)	62.00	Jan. 1, 2007
300–399	(869–064–00013–1)	49.00	Jan. 1, 2008
400–699	(869–062–00014–6)	42.00	Jan. 1, 2007
700–899	(869–062–00015–4)	43.00	Jan. 1, 2007
900–999	(869–062–00016–2)	60.00	Jan. 1, 2007
*1000–1199	(869–064–00017–3)	22.00	Jan. 1, 2008
1200–1599	(869–064–00018–1)	64.00	Jan. 1, 2008
1600–1899	(869–064–00019–0)	67.00	Jan. 1, 2008
*1900–1939	(869–064–00020–3)	31.00	Jan. 1, 2008
*1940–1949	(869–064–00021–1)	50.00	Jan. 1, 2008
1950–1999	(869–062–00022–7)	46.00	Jan. 1, 2007
2000–End	(869–062–00023–5)	50.00	Jan. 1, 2007
8	(869–062–00024–3)	63.00	Jan. 1, 2007
9 Parts:			
1–199	(869–062–00025–1)	61.00	Jan. 1, 2007
200–End	(869–064–00026–2)	61.00	Jan. 1, 2008
10 Parts:			
1–50	(869–062–00027–8)	61.00	Jan. 1, 2007
51–199	(869–062–00028–6)	58.00	Jan. 1, 2007
*200–499	(869–064–00029–7)	46.00	Jan. 1, 2008
500–End	(869–064–00030–1)	65.00	Jan. 1, 2008
11	(869–062–00031–6)	41.00	Jan. 1, 2007
12 Parts:			
1–199	(869–064–00032–7)	37.00	Jan. 1, 2008
200–219	(869–064–00033–5)	40.00	Jan. 1, 2008
220–299	(869–062–00034–1)	61.00	Jan. 1, 2007
*300–499	(869–064–00035–1)	47.00	Jan. 1, 2008
500–599	(869–064–00036–0)	42.00	Jan. 1, 2008
600–899	(869–064–00037–8)	59.00	Jan. 1, 2008
900–End	(869–064–00038–6)	53.00	Jan. 1, 2008
13	(869–064–00039–4)	58.00	Jan. 1, 2008
14 Parts:			
1–59	(869–062–00040–5)	63.00	Jan. 1, 2007
*60–139	(869–064–00041–6)	61.00	Jan. 1, 2008
140–199	(869–064–00042–4)	33.00	Jan. 1, 2008
200–1199	(869–062–00043–0)	50.00	Jan. 1, 2007
1200–End	(869–064–00044–1)	48.00	Jan. 1, 2008
15 Parts:			
0–299	(869–062–00045–6)	40.00	Jan. 1, 2007
300–799	(869–064–00046–7)	63.00	Jan. 1, 2008
800–End	(869–062–00047–2)	42.00	Jan. 1, 2007
16 Parts:			
0–999	(869–062–00048–1)	50.00	Jan. 1, 2007
1000–End	(869–064–00049–1)	63.00	Jan. 1, 2008
17 Parts:			
1–199	(869–062–00051–1)	50.00	Apr. 1, 2007
200–239	(869–062–00052–9)	60.00	Apr. 1, 2007
240–End	(869–062–00053–7)	62.00	Apr. 1, 2007
18 Parts:			
1–399	(869–062–00054–5)	62.00	Apr. 1, 2007
400–End	(869–062–00055–3)	26.00	Apr. 1, 2007
19 Parts:			
1–140	(869–062–00056–1)	61.00	Apr. 1, 2007
141–199	(869–062–00057–0)	58.00	Apr. 1, 2007
200–End	(869–062–00058–8)	31.00	Apr. 1, 2007
20 Parts:			
1–399	(869–062–00059–6)	50.00	Apr. 1, 2007
400–499	(869–062–00060–0)	64.00	Apr. 1, 2007
500–End	(869–062–00061–8)	63.00	Apr. 1, 2007
21 Parts:			
1–99	(869–062–00062–6)	40.00	Apr. 1, 2007
100–169	(869–062–00063–4)	49.00	Apr. 1, 2007
170–199	(869–062–00064–2)	50.00	Apr. 1, 2007
200–299	(869–062–00065–1)	17.00	Apr. 1, 2007
300–499	(869–062–00066–9)	30.00	Apr. 1, 2007
500–599	(869–062–00067–7)	47.00	Apr. 1, 2007
600–799	(869–062–00068–5)	17.00	Apr. 1, 2007
800–1299	(869–062–00069–3)	60.00	Apr. 1, 2007
1300–End	(869–062–00070–7)	25.00	Apr. 1, 2007
22 Parts:			
1–299	(869–062–00071–5)	63.00	Apr. 1, 2007
300–End	(869–062–00072–3)	45.00	Apr. 1, 2007
23	(869–062–00073–7)	45.00	Apr. 1, 2007
24 Parts:			
0–199	(869–062–00074–0)	60.00	Apr. 1, 2007
200–499	(869–062–00075–8)	50.00	Apr. 1, 2007
500–699	(869–062–00076–6)	30.00	Apr. 1, 2007
700–1699	(869–062–00077–4)	61.00	Apr. 1, 2007
1700–End	(869–062–00078–2)	30.00	Apr. 1, 2007
25	(869–062–00079–1)	64.00	Apr. 1, 2007
26 Parts:			
§§ 1.0–1–1.60	(869–062–00080–4)	49.00	Apr. 1, 2007
§§ 1.61–1.169	(869–062–00081–2)	63.00	Apr. 1, 2007
§§ 1.170–1.300	(869–062–00082–1)	60.00	Apr. 1, 2007
§§ 1.301–1.400	(869–062–00083–9)	47.00	Apr. 1, 2007
§§ 1.401–1.440	(869–062–00084–7)	56.00	Apr. 1, 2007
§§ 1.441–1.500	(869–062–00085–5)	58.00	Apr. 1, 2007
§§ 1.501–1.640	(869–062–00086–3)	49.00	Apr. 1, 2007
§§ 1.641–1.850	(869–062–00087–1)	61.00	Apr. 1, 2007
§§ 1.851–1.907	(869–062–00088–0)	61.00	Apr. 1, 2007
§§ 1.908–1.1000	(869–062–00089–8)	60.00	Apr. 1, 2007
§§ 1.1001–1.1400	(869–062–00090–1)	61.00	Apr. 1, 2007
§§ 1.1401–1.1550	(869–062–00091–0)	58.00	Apr. 1, 2007
§§ 1.1551–End	(869–062–00092–8)	50.00	Apr. 1, 2007
2–29	(869–062–00093–6)	60.00	Apr. 1, 2007
30–39	(869–062–00094–4)	41.00	Apr. 1, 2007
40–49	(869–062–00095–2)	28.00	[6] Apr. 1, 2007
50–299	(869–062–00096–1)	42.00	Apr. 1, 2007

Title	Stock Number	Price	Revision Date
300–499	(869–062–00097–9)	61.00	Apr. 1, 2007
500–599	(869–062–00098–7)	12.00	[5] Apr. 1, 2007
600–End	(869–062–00099–5)	17.00	Apr. 1, 2007
27 Parts:			
1–39	(869–062–00100–2)	64.00	Apr. 1, 2007
40–399	(869–062–00101–1)	64.00	Apr. 1, 2007
400–End	(869–062–00102–9)	18.00	Apr. 1, 2007
28 Parts:			
0–42	(869–062–00103–7)	61.00	July 1, 2007
43–End	(869–062–00104–5)	60.00	July 1, 2007
29 Parts:			
0–99	(869–062–00105–3)	50.00	[8] July 1, 2007
100–499	(869–062–00106–1)	23.00	July 1, 2007
500–899	(869–062–00107–0)	61.00	[8] July 1, 2007
900–1899	(869–062–00108–8)	36.00	July 1, 2007
1900–1910 (§§ 1900 to 1910.999)	(869–062–00109–6)	61.00	July 1, 2007
1910 (§§ 1910.1000 to end)	(869–062–00110–0)	46.00	July 1, 2007
1911–1925	(869–062–00111–8)	30.00	July 1, 2007
1926	(869–062–00112–6)	50.00	July 1, 2007
1927–End	(869–062–00113–4)	62.00	July 1, 2007
30 Parts:			
1–199	(869–062–00114–2)	57.00	July 1, 2007
200–699	(869–062–00115–1)	50.00	July 1, 2007
700–End	(869–062–00116–9)	58.00	July 1, 2007
31 Parts:			
0–199	(869–062–00117–7)	41.00	July 1, 2007
200–499	(869–062–00118–5)	46.00	July 1, 2007
500–End	(869–062–00119–3)	62.00	July 1, 2007
32 Parts:			
1–39, Vol. I		15.00	[2] July 1, 1984
1–39, Vol. II		19.00	[2] July 1, 1984
1–39, Vol. III		18.00	[2] July 1, 1984
1–190	(869–062–00120–7)	61.00	July 1, 2007
191–399	(869–062–00121–5)	63.00	July 1, 2007
400–629	(869–062–00122–3)	61.00	July 1, 2007
630–699	(869–062–00123–1)	37.00	July 1, 2007
700–799	(869–062–00124–0)	46.00	July 1, 2007
800–End	(869–062–00125–8)	47.00	July 1, 2007
33 Parts:			
1–124	(869–062–00126–6)	57.00	July 1, 2007
125–199	(869–062–00127–4)	61.00	July 1, 2007
200–End	(869–062–00128–2)	57.00	July 1, 2007
34 Parts:			
1–299	(869–062–00129–1)	50.00	July 1, 2007
300–399	(869–062–00130–4)	40.00	July 1, 2007
400–End & 35	(869–062–00131–2)	61.00	July 1, 2007
36 Parts:			
1–199	(869–062–00132–1)	37.00	July 1, 2007
200–299	(869–062–00133–9)	37.00	July 1, 2007
300–End	(869–062–00134–7)	61.00	July 1, 2007
37	(869–062–00135–5)	58.00	July 1, 2007
38 Parts:			
0–17	(869–062–00136–3)	60.00	July 1, 2007
18–End	(869–062–00137–1)	62.00	July 1, 2007
39	(869–062–00138–0)	42.00	July 1, 2007
40 Parts:			
1–49	(869–062–00139–8)	60.00	July 1, 2007
50–51	(869–062–00140–1)	45.00	July 1, 2007
52 (52.01–52.1018)	(869–062–00141–0)	60.00	July 1, 2007
52 (52.1019–End)	(869–062–00142–8)	64.00	July 1, 2007
53–59	(869–062–00143–6)	31.00	July 1, 2007
60 (60.1–End)	(869–062–00144–4)	58.00	July 1, 2007
60 (Apps)	(869–062–00145–2)	57.00	July 1, 2007
61–62	(869–062–00146–1)	45.00	July 1, 2007
63 (63.1–63.599)	(869–062–00147–9)	58.00	July 1, 2007
63 (63.600–63.1199)	(869–062–00148–7)	50.00	July 1, 2007
63 (63.1200–63.1439)	(869–062–00149–5)	50.00	July 1, 2007
63 (63.1440–63.6175)	(869–062–00150–9)	32.00	July 1, 2007
63 (63.6580–63.8830)	(869–062–00151–7)	32.00	July 1, 2007
63 (63.8980–End)	(869–062–00152–5)	35.00	July 1, 2007
64–71	(869–062–00153–3)	29.00	July 1, 2007
72–80	(869–062–00154–1)	62.00	July 1, 2007
81–84	(869–062–00155–0)	50.00	July 1, 2007
85–86 (85–86.599–99)	(869–062–00156–8)	61.00	July 1, 2007
86 (86.600–1–End)	(869–062–00157–6)	61.00	July 1, 2007
87–99	(869–062–00158–4)	60.00	July 1, 2007
100–135	(869–062–00159–2)	45.00	July 1, 2007
136–149	(869–062–00160–6)	61.00	July 1, 2007
150–189	(869–062–00161–4)	50.00	July 1, 2007
190–259	(869–062–00162–2)	39.00	[7] July 1, 2007
260–265	(869–062–00163–1)	50.00	July 1, 2007
266–299	(869–062–00164–9)	50.00	July 1, 2007
300–399	(869–062–00165–7)	42.00	July 1, 2007
400–424	(869–062–00166–5)	56.00	[7] July 1, 2007
425–699	(869–062–00167–3)	61.00	July 1, 2007
700–789	(869–062–00168–1)	61.00	July 1, 2007
790–End	(869–062–00169–0)	61.00	July 1, 2007
41 Chapters:			
1, 1–1 to 1–10		13.00	[3] July 1, 1984
1, 1–11 to Appendix, 2 (2 Reserved)		13.00	[3] July 1, 1984
3–6		14.00	[3] July 1, 1984
7		6.00	[3] July 1, 1984
8		4.50	[3] July 1, 1984
9		13.00	[3] July 1, 1984
10–17		9.50	[3] July 1, 1984
18, Vol. I, Parts 1–5		13.00	[3] July 1, 1984
18, Vol. II, Parts 6–19		13.00	[3] July 1, 1984
18, Vol. III, Parts 20–52		13.00	[3] July 1, 1984
19–100		13.00	[3] July 1, 1984
1–100	(869–062–00170–3)	24.00	July 1, 2007
101	(869–062–00171–1)	21.00	July 1, 2007
102–200	(869–062–00172–0)	56.00	July 1, 2007
201–End	(869–062–00173–8)	24.00	July 1, 2007
42 Parts:			
1–399	(869–062–00174–6)	61.00	Oct. 1, 2007
400–413	(869–062–00175–4)	32.00	Oct. 1, 2007
414–429	(869–062–00176–2)	32.00	Oct. 1, 2007
430–End	(869–062–00177–1)	64.00	Oct. 1, 2007
43 Parts:			
1–999	(869–062–00178–9)	56.00	Oct. 1, 2007
1000–end	(869–062–00179–7)	62.00	Oct. 1, 2007
44	(869–062–00180–1)	50.00	Oct. 1, 2007
45 Parts:			
1–199	(869–062–00181–9)	60.00	Oct. 1, 2007
200–499	(869–060–00182–7)	34.00	[9] Oct. 1, 2007
500–1199	(869–062–00183–5)	56.00	Oct. 1, 2007
1200–End	(869–062–00184–3)	61.00	Oct. 1, 2007
46 Parts:			
1–40	(869–062–00185–1)	46.00	Oct. 1, 2007
41–69	(869–062–00186–0)	39.00	Oct. 1, 2007
70–89	(869–062–00187–8)	14.00	Oct. 1, 2007
90–139	(869–062–00188–6)	44.00	Oct. 1, 2007
140–155	(869–062–00189–4)	25.00	Oct. 1, 2007
156–165	(869–062–00190–8)	34.00	Oct. 1, 2007
166–199	(869–062–00191–6)	46.00	Oct. 1, 2007
200–499	(869–062–00192–4)	40.00	Oct. 1, 2007
500–End	(869–062–00193–2)	25.00	Oct. 1, 2007
47 Parts:			
0–19	(869–062–00194–1)	61.00	Oct. 1, 2007
20–39	(869–062–00195–9)	46.00	Oct. 1, 2007
40–69	(869–062–00196–7)	40.00	Oct. 1, 2007
70–79	(869–062–00197–5)	61.00	Oct. 1, 2007
80–End	(869–062–00198–3)	61.00	Oct. 1, 2007
48 Chapters:			
1 (Parts 1–51)	(869–062–00199–1)	63.00	Oct. 1, 2007
1 (Parts 52–99)	(869–062–00200–9)	49.00	Oct. 1, 2007
2 (Parts 201–299)	(869–062–00201–7)	50.00	Oct. 1, 2007
3–6	(869–062–00202–5)	34.00	Oct. 1, 2007

Title	Stock Number	Price	Revision Date
7–14	(869–062–00203–3)	56.00	Oct. 1, 2007
15–28	(869–062–00204–1)	47.00	Oct. 1, 2007
29–End	(869–062–00205–0)	47.00	Oct. 1, 2007
49 Parts:			
1–99	(869–062–00206–8)	60.00	Oct. 1, 2007
100–185	(869–062–00207–6)	63.00	Oct. 1, 2007
186–199	(869–062–00208–4)	23.00	Oct. 1, 2007
200–299	(869–062–00208–1)	32.00	Oct. 1, 2007
300–399	(869–062–00210–6)	32.00	Oct. 1, 2007
400–599	(869–062–00210–3)	64.00	Oct. 1, 2007
600–999	(869–062–00212–2)	19.00	Oct. 1, 2007
1000–1199	(869–062–00213–1)	28.00	Oct. 1, 2007
1200–End	(869–062–00214–9)	34.00	Oct. 1, 2007
50 Parts:			
1–16	(869–062–00215–7)	11.00	Oct. 1, 2007
17.1–17.95(b)	(869–062–00216–5)	32.00	Oct. 1, 2007
17.95(c)–end	(869–062–00217–3)	32.00	Oct. 1, 2007
17.96–17.99(h)	(869–062–00218–1)	61.00	Oct. 1, 2007
17.99(i)–end and 17.100–end	(869–062–00219–0)	47.00	[8] Oct. 1, 2007
18–199	(869–062–00226–3)	50.00	Oct. 1, 2007
200–599	(869–062–00221–1)	45.00	Oct. 1, 2007
600–659	(869–062–00222–0)	31.00	Oct. 1, 2007
660–End	(869–062–00223–8)	31.00	Oct. 1, 2007
CFR Index and Findings Aids	(869–062–00050–2)	62.00	Jan. 1, 2007
Complete 2007 CFR set		1,499.00	2008
Microfiche CFR Edition:			
Subscription (mailed as issued)		406.00	2008
Individual copies		4.00	2008
Complete set (one-time mailing)		332.00	2007
Complete set (one-time mailing)		332.00	2006

[1] Because Title 3 is an annual compilation, this volume and all previous volumes should be retained as a permanent reference source.

[2] The July 1, 1985 edition of 32 CFR Parts 1–189 contains a note only for Parts 1–39 inclusive. For the full text of the Defense Acquisition Regulations in Parts 1–39, consult the three CFR volumes issued as of July 1, 1984, containing those parts.

[3] The July 1, 1985 edition of 41 CFR Chapters 1–100 contains a note only for Chapters 1 to 49 inclusive. For the full text of procurement regulations in Chapters 1 to 49, consult the eleven CFR volumes issued as of July 1, 1984 containing those chapters.

[4] No amendments to this volume were promulgated during the period January 1, 2005, through January 1, 2006. The CFR volume issued as of January 1, 2005 should be retained.

[5] No amendments to this volume were promulgated during the period April 1, 2000, through April 1, 2007. The CFR volume issued as of April 1, 2000 should be retained.

[6] No amendments to this volume were promulgated during the period April 1, 2006 through April 1, 2007. The CFR volume issued as of April 1, 2006 should be retained.

[7] No amendments to this volume were promulgated during the period July 1, 2006, through July 1, 2007. The CFR volume issued as of July 1, 2006 should be retained.

[8] No amendments to this volume were promulgated during the period October 1, 2005, through October 1, 2007. The CFR volume issued as of October 1, 2005 should be retained.

[9] No amendments to this volume were promulgated during the period October 1, 2006, through October 1, 2007. The CFR volume issued as of October 1, 2006 should be retained.