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DEPARTMENT OF HOMELAND SECURITY

8 CFR Part 217

RIN 1601–AA54

Designation of Greece for the Visa Waiver Program

AGENCY: Office of the Secretary, DHS.

ACTION: Final rule; technical amendment.

SUMMARY: Citizens and eligible nationals of participating Visa Waiver Program countries may apply for admission to the United States at U.S. ports of entry as nonimmigrant aliens for a period of ninety days or less for business or pleasure without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements. On March 4, 2010, the Secretary of Homeland Security, in consultation with the Secretary of State, designated Greece as a country that is eligible to participate in the Visa Waiver Program. Accordingly, this rule updates the list of countries authorized to participate in the Visa Waiver Program by adding Greece.

DATES: This final rule is effective on April 5, 2010.

FOR FURTHER INFORMATION CONTACT: Gianfranco Corti, Department of Homeland Security, Office of Policy, (202) 282–8732.

SUPPLEMENTARY INFORMATION:

I. Background

A. The Visa Waiver Program

Pursuant to section 217 of the Immigration and Nationality Act (INA), 8 U.S.C. 1187, the Secretary of Homeland Security (the Secretary), in consultation with the Secretary of State, may designate certain countries as Visa Waiver Program (VWP) countries if certain requirements are met. Those requirements include, without limitation: (1) Meeting the statutory rate of nonimmigrant visa refusal for nationals of the country; (2) a government certification that it issues machine-readable passports that comply with internationally accepted standards; (3) a U.S. government determination that the country's designation would not negatively affect U.S. law enforcement and security interests; (4) an agreement to report, or make available through other designated means, to the U.S. government information about the theft or loss of passports; (5) government acceptance for repatriation any citizen, former citizen, or national not later than three weeks after the issuance of a final order of removal; and (6) an agreement with the United States to share information regarding whether citizens or nationals of the country represent a threat to the security or welfare of the United States or its citizens.

The INA also sets forth requirements for continued eligibility and, where appropriate, probation and/or termination of program countries.

The designated countries in the VWP include Andorra, Australia, Austria, Belgium, Brunei, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, New Zealand, Norway, Portugal, Republic of Korea, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom.[1] *See* 8 CFR 217.2(a).

Citizens and eligible nationals of VWP countries may apply for admission to the United States at U.S. ports of entry as nonimmigrant visitors for a period of ninety days or less for business or pleasure without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements. To travel to the United States under the VWP, an alien must be from a participating country and must satisfy the following:

(1) Be seeking entry as a tourist for ninety days or less;

(2) Be a national of a program country;

(3) Present an electronic passport or a machine-readable passport issued by a designated VWP participant country to the air or vessel carrier before departure;[2]

(4) Execute the required immigration forms;

(5) If arriving by air or sea, arrive on an authorized carrier;

(6) Not represent a threat to the welfare, health, safety or security of the United States;

(7) Have not violated U.S. immigration law during a previous admission under the VWP;

(8) Possess a round-trip ticket;

(9) Waive the right to review or appeal a decision regarding admissibility or to contest, other than on the basis of an application for asylum, any action for removal; and

(10) Obtain an approved travel authorization via the Electronic System for Travel Authorization (ESTA) in advance of travel. For more information about the ESTA, please see the interim final rule at 73 FR 32440 (June 9, 2008), and implementing notice at 73 FR 67354 (November 13, 2008). *See* Sections 217(a) and 217(b) of the Immigration and Nationality Act (INA), 8 U.S.C. 1187(a)–(b). *See also* 8 CFR part 217.

DHS, in consultation with the Department of State, has evaluated the country of Greece for VWP designation to ensure that it meets the requirements set forth in section 217 of the INA, as amended by section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act). The Secretary has determined that Greece has satisfied the statutory requirements to be a VWP country; therefore, the Secretary, in consultation with the Secretary of State, has designated Greece as a program country.[3]

This final rule adds Greece to the list of countries authorized to participate in

[1] The United Kingdom refers only to British citizens who have the unrestricted right of permanent abode in the United Kingdom (England, Scotland, Wales, Northern Ireland, the Channel Islands and the Isle of Man); it does not refer to British overseas citizens, British dependent territories' citizens, or citizens of British Commonwealth countries.

[2] For countries designated as VWP member countries prior to November 17, 2008, passports issued before October 26, 2006 [see 8 U.S.C. 1732(c)(2)], need not contain the electronic chip that includes the biographic and biometric information of the passport holder provided the passports comply with the International Civil Aviation Organization's machine-readable standards.

[3] The Secretary of State nominated Greece for participation in the VWP on August 31, 2007.

the VWP. Accordingly, beginning April 5, 2010, citizens and eligible nationals from Greece may apply for admission to the United States at U.S. ports of entry as nonimmigrant visitors for a period of ninety days or less for business or pleasure without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission under applicable statutory and regulatory requirements.

III. Statutory and Regulatory Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (5 U.S.C. 553(b)), an agency may waive the normal notice and comment requirements if it finds, for good cause, that they are impracticable, unnecessary, or contrary to the public interest. The final rule merely lists a country that the Secretary of Homeland Security, in consultation with the Secretary of State, has designated as a VWP eligible country in accordance with 8 U.S.C. 1187(c). This amendment is a technical change simply updating the list of VWP eligible countries. Therefore, notice and comment for this rule are unnecessary and contrary to the public interest because the rule has no substantive impact, is technical in nature, and relates only to management, organization, procedure, and practice. For the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

This final rule is also excluded from the rulemaking provisions of 5 U.S.C. 553 as a foreign affairs function of the United States, because it advances the President's foreign policy goals, involves a bilateral agreement that the United States has entered into with Greece, and directly involves relationships between the United States and its alien visitors. Accordingly, DHS is not required to provide public notice and an opportunity to comment before implementing the requirements under this final rule.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 603(b)), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996 (SBREFA), requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of a proposed rule on small entities (i.e., small businesses, small organizations, and small governmental jurisdictions) when the agency is required "to publish a general notice of proposed rulemaking for any proposed rule." Because this rule is being issued as a final rule, on the grounds set forth above, a regulatory flexibility analysis is not required under the RFA.

DHS has considered the impact of this rule on small entities and has determined that this rule will not have a significant economic impact on a substantial number of small entities. The individual aliens to whom this rule applies are not small entities as that term is defined in 5 U.S.C. 601(6). Accordingly, there is no change expected in any process as a result of this rule that would have a direct effect, either positive or negative, on a small entity.

C. 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 $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.

D. Executive Order 12866

This amendment does not meet the criteria for a "significant regulatory action" as specified in Executive Order 12866.

E. Executive Order 13132

The rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, DHS has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988 Civil Justice Reform

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

List of Subjects in 8 CFR Part 217

Air carriers, Aliens, Maritime carriers, Passports and visas.

Amendments to the Regulations

■ For the reasons stated in the preamble, DHS amends part 217 of title 8 of the Code of Federal Regulations (8 CFR part 217), as set forth below.

PART 217—VISA WAIVER PROGRAM

■ 1. The general authority citation for part 217 continues to read as follows:

Authority: 8 U.S.C. 1103, 1187; 8 CFR part 2.

* * * * *

■ 2. In section 217.2 the definition of the term "Designated country" in paragraph (a) is revised to read as follows:

§ 217.2 Eligibility.

(a) * * *

Designated country refers to Andorra, Australia, Austria, Belgium, Brunei, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Monaco, the Netherlands, New Zealand, Norway, Portugal, Republic of Korea, San Marino, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, and the United Kingdom. The United Kingdom refers only to British citizens who have the unrestricted right of permanent abode in the United Kingdom (England, Scotland, Wales, Northern Ireland, the Channel Islands and the Isle of Man); it does not refer to British overseas citizens, British dependent territories' citizens, or citizens of British Commonwealth countries. After May 15, 2003, citizens of Belgium must present a machine-readable passport in order to be granted admission under the Visa Waiver Program.

* * * * *

Janet Napolitano,

Secretary.

[FR Doc. 2010–7211 Filed 3–30–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Docket No. FAA–2009–0921; Airspace Docket No. 09–AWA–3]

RIN 2120–AA66

Revision of Prohibited Area P–49; Crawford, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Prohibited Area 49 (P–49) Crawford, TX. While the United States Secret Service (USSS) recognizes the ongoing security

requirement for this prohibited area, it considers reducing prohibited airspace area appropriate at this time. This action restores previously prohibited airspace to public use within the National Airspace System.

DATES: Effective date 0901 UTC, June 3, 2010.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace and Rules Group, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

History

On October 5, 2009, the Department of the Treasury, USSS, notified the FAA that while the security requirements for establishing P–49 Crawford, TX (66 FR 16391) remain valid, consideration of a modification of the existing prohibited area was appropriate. After a six-month security review of P–49, the USSS determined the dimensions (boundary and altitude) of the prohibited area could be reduced. This action responds to that notification.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 73 by revising the legal description for P–49 Crawford, TX. After conducting a security review of P–49, the USSS notified the FAA to reduce the boundary and altitude dimensions of the prohibited area. This action reduces the boundary from a 3 NM radius to a 2 NM radius of lat. 31°34′45″ N., 97°32′00″ W., and lowers the designated altitude from "Surface to but not including 5,000 feet MSL" to "Surface to but not including 2,000 feet MSL."

Because this action restores previously prohibited airspace to public use, I find that notice and public procedures under 5 U.S.C. 553(b) are unnecessary as it would only delay the return of the airspace to public use.

Section 73.89 of Title 14 CFR part 73 was republished in FAA Order 7400.8S, effective February 16, 2010.

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. Therefore, this regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) 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 the 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 amends prohibited airspace in Crawford, Texas.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with paragraph 311c, FAA Order 1050.1E, Environmental Impacts: Policies and Procedures. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

List of Subjects in 14 CFR Part 73

Airspace, Prohibited areas, Restricted areas.

Adoption of Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73 as follows:

PART 73—SPECIAL USE AIRSPACE

■ 1. The authority citation for part 73 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.

§ 73.89 [Amended]

■ 2. § 73.89 is amended as follows:

* * * * *

P–49 Crawford, TX [Revised]

Boundaries. That airspace within a 2 NM radius of lat. 31°34′45″ N., long. 97°32′00″ W.

Designated altitudes. Surface to 2,000 feet MSL.

Time of designation. Continuous.

Using agency. United States Secret Service, Washington, DC.

Issued in Washington, DC, on March 25, 2010.

Kelly Neubecker,

Acting Manager, Airspace and Rules Group.

[FR Doc. 2010–7242 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1119

Civil Penalty Factors

AGENCY: Consumer Product Safety Commission.

ACTION: Final interpretative rule.

SUMMARY: The Consumer Product Safety Improvement Act of 2008 ("CPSIA") requires the Consumer Product Safety Commission ("Commission") to issue a final rule providing its interpretation of the civil penalty factors found in the Consumer Product Safety Act ("CPSA"), the Federal Hazardous Substances Act ("FHSA"), and the Flammable Fabrics Act ("FFA"), as amended by section 217 of the CPSIA. These statutory provisions require the Commission to consider certain factors in determining the amount of any civil penalty to seek. The Commission published an interim final rule on September 1, 2009, providing its interpretation of the statutory factors and seeking public comment. The Commission is now issuing a final rule interpreting the statutory factors.

DATES: This rule is effective March 31, 2010.

FOR FURTHER INFORMATION CONTACT: Melissa V. Hampshire, Assistant General Counsel, Division of Enforcement and Information, Office of the General Counsel, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, Maryland 20814, telephone: 301–504–7631, e-mail: *mhampshire@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The CPSIA specified that the Commission, by August 14, 2009, issue a final regulation providing its interpretation of civil penalty factors in section 20(b) of the CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA.[1] The Commission issued an

[1] The Commission voted 4–1 to approve the Final Rule as amended. Chairman Tenenbaum, Commissioner Nord, Commissioner Adler, and Moore voted to approve the final rule as amended.

Continued

interim final rule providing its interpretation on September 1, 2009, and sought public comment. As a result of the comments received and review of the interim final rule, certain information and terms are clarified in this final rule. This rule interprets the factors in section 20(b) of the CPSA, section 5(c)(3) of the FHSA and section 5(e)(2) of the FFA, and describes other factors the Commission may consider in determining the amount of a civil penalty to be sought for knowing violations of section 19 of the CPSA, section 4 of the FHSA, and section 5 of the FFA. The statutory factors the Commission is required to consider in determining the amount of a civil penalty to seek are the following: The nature, circumstances, extent and gravity of the violation, including the nature of the product defect or of the substance, the severity of the risk of injury, the occurrence or absence of injury, the number of defective products distributed or the amount of substance distributed, the appropriateness of the penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses, and such other factors as appropriate.

The statutory factors the Commission is required to consider in determining the amount of a civil penalty to seek are the same factors identified in section 20(c) of the CPSA, section 5(c)(4) of the FHSA, and section 5(e)(3) of the FFA for determining whether a civil penalty may be compromised by the Commission. These statutory provisions instruct the Commission to consider the following factors in determining the amount of a compromised penalty, whether it should be remitted or mitigated by the Commission, and, in what amount: The nature, circumstances, extent and gravity of the violation, including the nature of the product defect,[2] the severity of the risk of injury, the occurrence or absence of injury, the number of defective products distributed,[3] the appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses, and such other factors as appropriate. The Commission will apply its interpretation to these statutory terms in determining whether and in what amounts any penalties may be compromised.

As set forth in section 217(a)(4) of the CPSIA, new penalty amounts specified in section 217(a) of the CPSIA became effective on August 14, 2009 (one year after the date of enactment of the CPSIA). Under the amendments, the maximum penalty amounts increase from $8,000 to $100,000 for each knowing violation under the CPSA, FHSA, and FFA. Maximum penalty amounts for any related series of violations increase from $1,825,000 to $15,000,000.

B. Prior Proposal on Civil Penalty Factors

On July 12, 2006, the Commission published a proposed interpretative rule (71 FR 39248) that identified additional factors to be considered in assessing and compromising civil penalties under sections 20(b) and (c) of the CPSA. The comment period closed August 11, 2006. The Commission received four comments.

C. CPSIA Requirements

The enactment of the CPSIA superseded the proposed rule by requiring that the Commission provide its interpretation of the enumerated statutory factors under section 20(b) of the CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA. The CPSIA also indicated that under the CPSA, FHSA, and FFA, the Commission should consider the nature, circumstances, extent, and gravity of the violation in determining the appropriate penalty amount. The statute provides examples of elements that should go into that consideration. The CPSIA modified the factor of appropriateness of the penalty in relation to the size of the business of the person charged by requiring that this factor include a consideration of how to mitigate undue adverse economic impacts on small businesses. This small business analysis element was added to the CPSA and FHSA but not added to the FFA factor. The Commission will consider the undue adverse economic impacts on small businesses as another appropriate factor under the FFA. The CPSIA also added to the CPSA, FHSA, and FFA a new catch-all statutory factor "other factors as appropriate." The effect of the CPSIA amendments was noted in the Fall 2008 Current Regulatory Plan and the Unified Agenda (RIN: 3041–AC40) by stating that the proposed July 2006 rule would be withdrawn. In the **Federal Register** of August 26, 2009 (74 FR 43084), the Commission withdrew the July 12, 2006, notice of proposed rulemaking (71 FR 39248).

On November 18, 2008, the Commission staff posted a notice on the Commission Web site inviting comment on information the Commission should address in considering the amended statutory factors under the CPSA, FHSA, and FFA. The Commission staff also invited comment on what other factors are appropriate to consider in penalty determinations including: (1) A previous record of compliance; (2) timeliness of response; (3) safety and compliance monitoring; (4) cooperation and good faith; (5) economic gain from noncompliance; (6) product failure rate; and (7) what information the Commission should consider in determining how to mitigate the adverse economic impact of a particular penalty on a small business. The Commission staff also invited comment on whether it should develop a formula or matrix for weighing any or all of the various factors and what criteria it should use in any weighting formula or matrix. The Commission received 16 comments in response to the 2008 Web site notice and considered the comments in issuing the interim final rule.

On September 1, 2009, the Commission published an interim final interpretative rule setting forth the Commission's interpretation of the statutory factors under the CPSA, FHSA, and FFA, for seeking and compromising civil penalties. The Commission sought comments on the interim final rule. The Commission received 10 comments in response to the September 1, 2009 notice. Some commenters responded on behalf of their trade or industry associations.

D. Statutory Discussion

1. What Are the Requirements for Imposition of Civil Penalties?

The determination of the amount of any civil penalty to seek and/or compromise should allow for maximum flexibility within an identified framework. The CPSIA requirement for the Commission to interpret the civil penalty factors gives transparency to the regulated community about the framework the Commission will use to guide its penalty calculations in the enforcement process and may provide incentives for greater compliance. The changes made by various CPSIA provisions to the CPSA, FHSA, and FFA, including those to the CPSA's prohibited acts and the addition of new prohibited acts, present the regulated community with many new compliance challenges and responsibilities.

Chairman Tenenbaum, Commissioner Moore and Adler issued a joint statement. Commissioners Nord and Northup each issued statements. All statements are available at *http://www.cpsc.gov/pr/statements.html.*

[2] This factor applies only to the CPSA. The FHSA factor is "the nature of the substance." The FFA has no comparable separate factor apart from the nature, circumstances, extent, and gravity of the violation.

[3] The FHSA factor is the "amount of the substance."

Any proposed civil penalty determination is based first on a violation of a prohibited act under the CPSA, FHSA, or FFA. Civil penalties may then be sought against any person who "knowingly violates" section 19 of the CPSA, section 4 of the FHSA, or a regulation or standard under section 4 of the FFA. The term "knowingly" is defined in section 20(d) of the CPSA, 15 U.S.C. 2069(d), section 5(c)(5) of the FHSA, 15 U.S.C. 1264(c)(5), and section 5(e)(1) of the FFA, 15 U.S.C. 1194(e)(1), to mean the having of actual knowledge or the presumed having of knowledge deemed to be possessed by a "reasonable man" who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Since its enactment in 1973, the CPSA always contained a civil penalty provision; however, until 1990, the FHSA and FFA did not contain comparable provisions for civil penalties. Under the FFA, the Commission had to seek civil penalties under the Federal Trade Commission Act, using the authorities under that act. The FHSA had no civil penalty provision. The Consumer Product Safety Improvement Act of 1990, Public Law 101–608, 104 Stat. 3110, November 16, 1990, amended section 5 of the FHSA and section 5 of the FFA giving the Commission authority to seek civil penalties for knowing violations of those acts. If a penalty settlement cannot be negotiated between the Commission and a person, the Commission may seek an action in Federal court to obtain a penalty. *See, Advance Machine Co.* v. *Consumer Product Safety Commission,* 666 F.2d 1166 (8th Cir. 1981); *Athlone Industries, Inc.* v. *Consumer Product Safety Commission,* 707 F.2d 1485 (DC Cir. 1983).

2. How Do the CPSIA Amendments to the CPSA's Prohibited Acts Affect Civil Penalties?

In the past, the majority of civil penalties for prohibited acts were imposed either for a knowing failure to furnish information required by section 15(b) of the CPSA, or for regulatory violations under the CPSA, FHSA, or FFA. The interim final rule described how the CPSIA amended these three statutes to strengthen the Commission's enforcement ability and allow for more uniform enforcement under the CPSA.

The new amendments expand the acts prohibited under the CPSA and give the Commission the ability to enforce violations of the FHSA, FFA, and other acts enforced by the Commission as prohibited acts under the CPSA. Thus, the amended CPSA now prohibits the sale, offer for sale, distribution in commerce, or importation into the United States of any consumer product, or other product or substance that is regulated under the CPSA or any other act enforced by the Commission, that is not in conformity with an applicable consumer product safety rule under the CPSA, or any similar rule, regulation, standard, or ban under any other act enforced by the Commission. 15 U.S.C. 2068(a)(1).

The CPSA, as amended, adds a new prohibited act for the sale, manufacture, distribution, or importation of products subject to a voluntary corrective action taken by the manufacturer, in consultation with the Commission, and publicly announced by the Commission, or if the seller, distributor, or manufacturer knew or should have known of such voluntary corrective action. 15 U.S.C. 2068(a)(2)(B).

The CPSA, as amended, broadens the prohibited act for the sale, offer for sale, manufacture for sale, or distribution or importation of any consumer product or other product or substance subject to a section 15 mandatory recall order to include products subject to a section 12 order. A section 15 order is imposed in an adjudicative proceeding to declare a product a "substantial product hazard" under section 15 of the CPSA, 15 U.S.C. 2064. A section 12 order, which may include a mandatory order requiring notification to purchasers, and repair, replacement, or refund, is one imposed by a District Court after an "imminent hazard" proceeding under section 12 of the CPSA, 15 U.S.C. 2061.

The amended prohibited acts section of the CPSA is also broadened to include the sale, offer for sale, manufacture for sale, distribution in commerce, or importation into the United States of a banned hazardous substance under the FHSA as an act prohibited under the CPSA. 15 U.S.C. 2068(a)(2)(D).

The prohibited act in section 19(a)(6) of the CPSA relating to certification under section 14 of the CPSA is newly expanded to make the failure to furnish a certificate required by any other act enforced by the Commission a prohibited act under the CPSA. This prohibited act now also references a new tracking label requirement of CPSA section 14(a)(5) by specifying that the failure to comply with any requirement of section 14 includes the failure to comply with the requirement for tracking labels or any rule or regulation promulgated under section 14.

The CPSA statutory language has also been expanded to include a new prohibited act for the sale, offer for sale, distribution in commerce, or importation into the United States of any consumer product containing an unauthorized third-party certification mark. 15 U.S.C. 2068(a)(12).

Any misrepresentation to Commission officers or employees about the scope of consumer products subject to recall or material misrepresentation in the course of an investigation under any act enforced by the Commission also is a new prohibited act under the CPSA. 15 U.S.C. 2068(a)(13).

In addition, the CPSA now contains a new prohibited act for the exercise or attempt to exercise undue influence on a third-party conformity assessment body that tests products for compliance under laws administered by the Commission. *15 U.S.C. 2068(a)(14).*

The CPSIA adds to the Commission's export prohibition authority section 19(a)(15) of the CPSA, making it illegal to export from the United States for purposes of sale any consumer product or other product or substance (other than the export of a product or substance permitted by the Secretary of the Treasury under section 17(e) of the CPSA) that is subject to court- or Commission-ordered recall or that is banned under the FHSA or subject to a voluntary recall announced by the Commission. 15 U.S.C. 2068(a)(15).

The CPSIA also adds a new prohibited act that makes it illegal to violate a Commission order issued under new section 18(c) of the CPSA, which allows the Commission to prohibit export for sale of any consumer product not in conformity with an applicable consumer product safety rule. *15 U.S.C. 2068(a)(16).*

E. Discussion and Response to Comments on the Interim Final Rule

The comments that the Commission received on the Interim Final Rule and the Commission's responses are discussed in this section of the preamble.

1. Should Penalties Involving Actual Knowledge Be Higher Than Those Involving Presumed Knowledge?

Some commenters stated that the Commission should reserve seeking the highest penalties only for those violations involving actual knowledge where death or serious injury is likely. The commenters suggested that penalties involving presumed knowledge and circumstances where no injury or only minor injury occurred should result in lower or no penalties. Some commenters also suggested that technical violations should not involve a penalty at all. These commenters sought clarification of these concepts in the rule.

The CPSA, FHSA, and FFA define "knowingly" as the having of actual knowledge, or the presumed having of knowledge deemed to be possessed by a "reasonable man" who acts in the circumstances, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Thus, the knowledge requirements in the CPSA, FHSA, and FFA include presumed knowledge, as well as actual knowledge. Only in section 20(a)(2) is a distinction made and this limits the civil penalty liability of certain persons without actual knowledge to those who are not the manufacturer, private labeler or distributor of the products involved. Aside from this limitation, actual and presumed knowledge are treated equally under the statutes, and both could have the same consequence for civil penalty liability. Thus, the Commission declines to follow the commenters' suggestion to seek a higher penalty only where there is evidence of actual knowledge and serious injury or death, or a lower or no penalty where there is evidence of presumed knowledge. To follow the commenters' position would treat the "presumed knowledge" element differently than it is treated in the statute. However, the presence or absence of actual knowledge could reflect on a person's culpability and affect the size of the penalty. Moreover, the adoption of the distinction sought by the commenters would be a formulaic approach to penalty determinations. Almost all the commenters opposed the idea that the Commission adopt such a formulaic approach. However, the Commission has attempted to further clarify in the final rule its guidance about what factors may influence the Commission's determination under the various statutory and other factors. Importantly, in an individual case, the Commission would review the facts and circumstances surrounding the violations and the proposed assessment of penalties in light of the factors and framework described in the rule. Specific comments relating to each factor are discussed below. The CPSIA has greatly expanded the number of prohibited acts. Accordingly the Commission intends to use its civil penalty authority in a manner best designed to promote the underlying goals of the CPSA—specifically that of protecting the public against unreasonable risks of injury associated with consumer products. In so doing, the Commission may reserve the highest civil penalty for more serious or extensive violations.

2. In the Final Rule, How Does the Commission Interpret the Civil Penalty Factors?

Section 1119.1—Purpose

Section 1119.1 describes the purpose of new Part 1119 "Civil Penalty Factors," explaining that it is the Commission's interpretation of the statutory civil penalty factors set forth in the Consumer Product Safety Act (15 U.S.C. 2051–2089), the Federal Hazardous Substances Act (15 U.S.C. 1261–1278), and the Flammable Fabrics Act (15 U.S.C. 1191–1204). The Commission has revised the interim final rule's text in the final rule to add clarification on the underlying goals and policies of civil penalties.

Section 1119.2—Applicability

Section 1119.2 explains that the part applies to all civil penalty determinations that the Commission proposes to seek or compromise for knowing violations of the CPSA, the FHSA, or the FFA.

Section 1119.3—Definitions

Section 1119.3 defines certain terms used in the rule. The Commission has revised the definition of the term "product defect" from that in the interim final rule. The term is defined in the final rule to have the same meaning as the term "defect" referenced in the CPSA and the Commission's definition of "defect" at 16 CFR 1115.4. The term "violator" has been revised to reflect the statutory terminology that any "person" is subject to civil penalties. As noted in the rule, "person" includes any legally responsible party who committed a knowing violation of the CPSA, FHSA or FFA. The rule explains that the definitions apply for purposes of the rule.

Section 1119.4(a)(2)—Nature, Circumstances, Extent, and Gravity of the Violation

The Commission believes that this factor allows the Commission to consider the totality of the circumstances surrounding a violation while recognizing that depending upon the case, the significance and importance of each factor may vary. The Commission also believes that this particular factor allows for consideration of the seriousness and extent of a particular violation that may not otherwise be considered with respect to the other enumerated statutory factors. Therefore, in each case, the Commission will continue to look at the enumerated statutory factors, as well as other factors (described in section 1119.4(b) below) that the Commission may determine are appropriate, and consider all of the factors in determining the civil penalty amount.

Section 1119.4(a)(3)—Nature of the Product Defect

The interim final rule indicated that the Commission would consider, under this provision, where appropriate and applicable in each particular case, the nature of the hazard presented by the product for which a penalty is sought. The Commission construed this factor as applying broadly to products or substances that may in fact contain a defect which could create a substantial product hazard (as defined and explained in 16 CFR 1115.4), to products which present a hazard because of a violation of a rule, regulation, standard, or ban under the CPSA, FHSA, and FFA, as well as to any other violation and how the nature of those violations relate to the underlying products or substances.

A number of commenters addressed the definition of "product defect" in section 1119.3 of the interim final rule as overly broad and unnecessarily expansive and inconsistent with the Commission's interpretation of defect as used in 16 CFR 1115.4. The commenters pointed out that defining "product defect" beyond the definition in section 1115.4 as a product or substance "associated with a prohibited act" had no basis in the statutory language of the CPSA and that the definition should be clarified to refer only to the Commission's definition in 16 CFR 1115.4.

The Commission agrees that the definition of "product defect" in the interim final rule should be revised. The Commission agrees that certain CPSA violations may not involve a "product defect" or a "defective product." For example, failure to supply a required General Conformity Certification that a product complies with an applicable consumer product safety rule may not necessarily involve a product defect or a defective product. Thus, "product defect" may not be a relevant consideration in such a circumstance. Therefore, the Commission has revised the final rule to clarify that where "product defect" or "defective product" does not apply, in such circumstances, the other statutory factors will be considered.

Section 1119.4(a)(4)—Severity of the Risk of Injury

Several commenters noted that penalties should not be sought for violations where the products presented risks of minor or moderate injury.

The Commission declines to follow this suggestion. However, the Commission notes that minor or moderate injury is considered as a factor in the determination of the overall penalty. The Commission refers to the discussion of 16 CFR 1115.12 which specifies that severity of the risk includes a consideration of the likelihood of an injury occurring, the intended or reasonably foreseeable use or misuse of the product, and the population group exposed. The Commission retains these references in the final rule. The Commission also notes that the interim final rule has been modified in the final rule to further clarify that the Commission will consider "illness" along with injury and death as a consideration under this factor. The Commission believes that consideration of illness is consistent with the statutory direction which defines a "risk of injury" in section 3(a)(14) of the CPSA to mean a risk of death, personal injury, or serious or frequent illness.

Section 1119.4(a)(5)—The Occurrence or Absence of Injury

The Commission received several comments suggesting that it should not seek a penalty where the information the Commission evaluates reveals that the violation involved no injury or only minor injuries have occurred.

The Commission declines to follow this suggestion because a violative product, a product about which a person did not report as required, or another type of violation, may present a serious risk to consumers even though no injuries have occurred. However, the final rule is further clarified to state that the Commission would consider under this factor whether illnesses or deaths have occurred, in addition to considering whether injuries have or have not occurred. The rule is further clarified to explain that this consideration will also involve the number and nature of such injuries, illnesses, or deaths. Finally, the Commission has pointed out that both acute and the likelihood for chronic illness will be considered.

Section 1119.4(a)(6)—The Number of Defective Products Distributed

The Commission is required to consider the number of defective products or amount of substances distributed in commerce. The Commission recognizes, as some commenters pointed out, that the number of defective products in consumers' hands may be different from the number of defective products distributed. However, the statutory language makes no distinction between those defective products distributed in commerce that consumers received, and those defective products distributed in commerce that consumers have not received. Therefore both could be considered in appropriate cases. With respect to the number of defective products or amount of substances involved in a recall, the Commission clarifies in the rule that the Commission does not intend to penalize a person's decision to conduct a wider-than-necessary recall undertaken out of an abundance of caution. This would not include situations where such a recall is conducted due to a person's uncertainty concerning how many or which products may need to be recalled.

Section 1119.4(a)(7)—The Appropriateness of Such Penalty in Relation to the Size of the Business of the Person Charged, Including How To Mitigate Undue Adverse Economic Impacts on Small Businesses

The Commission is required to consider the size of a business in relation to the amount of the penalty. This factor reflects the relationship between the size of the business of the person charged and the deterrent effect of, and other policies underlying, civil penalties. In considering business "size," the Commission may look to several factors including but not limited to the number of employees, net worth, and annual sales. The Commission may be guided, where appropriate, by any relevant financial factors to help determine a person's ability to pay a penalty including but not limited to:

- Liquidity factors—factors that help measure a person's ability to pay its short-term obligations;
- Solvency factors—factors that help measure a person's ability to pay its long-term obligations; and
- Profitability factors— factors that measure a person's level of return on investment.

The Commission is aware that penalties may have adverse economic consequences on persons, including small businesses. The statute requires the Commission to consider how to mitigate the adverse economic consequences on small businesses only if those consequences would be "undue." What the Commission considers in determining what is "undue" may include, but is not limited to, the business's size and financial factors relating to its ability to pay. The interim final rule is modified in the final rule to explain that the burden to present clear, reliable, relevant, and sufficient evidence relating to a business's size and ability to pay rests on the business. When considering how to mitigate undue adverse economic consequences, the Commission will, as appropriate, follow its Small Business Enforcement Policy set forth at 16 CFR 1020.5. In determining a small business's ability to pay a proposed penalty, the Commission may be guided, where appropriate, by the financial factors set forth above. The Commission recognizes that on occasion its announced civil penalty amounts do not seem to reflect the seriousness of the violations due to the Commission's mitigation of the amount of the penalty based on ability to pay. While the Commission, unlike certain other federal agencies, has never publicized the amount it would have sought absent the mitigation, it acknowledges that it has that authority and may exercise that authority in appropriate circumstances.

Section 1119.4(b)—Other Factors as Appropriate

Some commenters suggested that the Commission should identify other factors that will be considered in penalty determinations. The factors the commenters suggested included previous record of compliance, good faith, efforts taken to respond to the violations, duration of the violations, and compliance with mandatory and/or voluntary standards. The Commission has determined that some of these factors would already be evaluated in the context of the enumerated statutory factors to consider, such as the nature, circumstances, extent, and gravity of the violation. Therefore, it is not necessary to separately enumerate these factors.

Congress clarified in the CPSIA that the Commission has the ability to consider factors in addition to the ones enumerated in the act in individual cases, as appropriate. However, the Commission retains the concept from the interim final rule in the final rule that in any penalty matter the Commission and the person are free to raise any other factors they believe are relevant in determining an appropriate civil penalty amount. Factors not identified below could therefore be raised in a penalty matter. The Commission has determined that the factors listed below should remain with changes and other clarifications as noted:

- *Safety/Compliance Program and/or System Relating to a Violation:* The Commission listed a number of factors relating to consideration of a safety/compliance program or system in the interim final rule. The Commission received comments seeking further definition of a safety or compliance program. The rule is intended to

provide examples of information that a person should consider, but not to provide one particular model of a program or system. The Commission intends to allow flexibility for the regulated community. However, the Commission has modified the final rule from the interim final rule in two important respects. First, the rule now makes explicit that the burden to present clear, reliable, relevant, and sufficient evidence of any such program and its relevance is on the person seeking consideration of this factor. Second, the rule makes explicit that any such program being asserted as relevant to a penalty matter must specifically relate to the violation or violations at issue and must be reasonable and effective. The Commission recognizes that the mere fact of a violation does not necessarily render a program ineffective.

• *History of Noncompliance:* Some commenters sought greater clarification on this factor and stated that the Commission should consider a history of compliance as well as noncompliance. The Commission declines to add "compliance" in the final rule because the factor by its nature is intended to address repeat violators. However, the Commission clarifies in the final rule that repeat violations of the same law or regulation, or prior violations of a different law or regulation enforced by the Commission, as well as the number of such violations, will be considerations.

• *Economic Gain from Noncompliance:* Some comments suggested that the Commission consider this factor after consideration of the statutory factors in determining a penalty amount. The Commission agrees that economic gain may be a consideration that should be factored in, where appropriate, with other factors.

• *Failure to respond in a timely and complete fashion to the Commission's requests for information or remedial action:* The Commission received a number of comments suggesting that this factor as written implied that a person may be penalized for exercising their legal rights to disagree and seek counsel on the Commission's requests for information or remedial action. The Commission agrees that a person has the legal right to decline to respond or act voluntarily and the legal right to seek advice on information and remedial action requests from the Commission and, therefore, is clarifying that it did not intend to impede such rights. This factor was intended to address egregious and dilatory tactics in response to the Commission's written requests for information or remedial action but not to impede any person's lawful rights. The rule is clarified to reflect this consideration.

Which additional factors the Commission considers in determining an appropriate penalty amount, including, but not limited to, those listed above, will be unique to each case.

A person will be notified of any factors beyond those enumerated in the statutes that the Commission relies on as aggravating factors for purposes of determining a civil penalty amount.

Section 1119.5—Enforcement Notification

Section 1119.5 of the rule sets forth a notification provision whereby, if it is believed that a person has violated the law and a penalty is sought, the person will be so advised. This provision has been informally followed by the Commission in determining the amount of a civil penalty to seek or compromise for knowing violations. The Commission has provided further clarification of this process in the rule.

F. Immediate Effective Date

The Commission issued an interim final rule, in accordance with the procedures set forth at 5 U.S.C. 553 of the Administrative Procedure Act, on September 1, 2009, providing its interpretation of the penalty factors in section 20(b) of the CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA. Maximum civil penalty amounts have increased for violations that occurred on or after August 14, 2009. This final rule is effective upon publication. The rule is interpretative and does not impose obligations on regulated parties beyond those imposed by the CPSA, FHSA, and FFA. Therefore, there is no need to provide a delayed effective date in order to allow for regulated parties to prepare for the rule.

G. Regulatory Flexibility Certification

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, directs agencies to consider the potential impact of regulations on small business and other small entities. However, the RFA does not apply to rulemaking that is not subject to the notice and comment requirement of the Administrative Procedure Act, 5 U.S.C. 553. Interpretative rules, such as the one issued by this notice, are not subject to the notice and comment requirement. Accordingly, neither an initial nor a final regulatory flexibility analysis is required for this rule.

H. Paperwork Reduction Act

The rule does not impose any information collection requirements. Rather, it describes the statutory civil penalty factors and how the Commission interprets those factors. Accordingly, it is not subject to the Paperwork Reduction Act, 44 U.S.C. 3501–3520.

I. Environmental Considerations

The Commission's regulations at 16 CFR 1021.5(a) provide that there are no CPSC actions that ordinarily produce significant environmental effects. The rule does not fall within the categories in 16 CFR 1021.5(b) of CPSC actions that have the potential for producing environmental effects. The rule does not have any potential for adversely affecting the quality of the human environment. Council of Environmental Quality regulations at 40 CFR 1508.18(a) provide that agency actions subject to environmental review "do not include bringing judicial or administrative enforcement actions." Therefore, no environmental assessment or environmental impact statement is required.

List of Subjects in 16 CFR Part 1119

Administrative practice and procedure, Business and Industry, Consumer protection, Reporting and recordkeeping requirements.

■ Accordingly, the Commission revises 16 CFR Part 1119 to read as follows:

PART 1119—CIVIL PENALTY FACTORS

Sec.
1119.1 Purpose.
1119.2 Applicability.
1119.3 Definitions.
1119.4 Factors considered in determining civil penalties.
1119.5 Enforcement notification.

Authority: 15 U.S.C. 2058, 2063, 2064, 2067(b), 2068, 2069, 2076(e), 2084, 1261, 1263, 1264, 1270, 1273, 1278, 1191, 1192, 1193, 1194, 1195, 1196.

§ 1119.1 Purpose.

This part sets forth the Consumer Product Safety Commission's (Commission) interpretation of the statutory factors considered in determining the amount of civil penalties that the Commission may seek or compromise. The policies behind, and purposes of, civil penalties include the following: Deterring violations; providing just punishment; promoting respect for the law; promoting full compliance with the law; reflecting the seriousness of the violation; and protecting the public.

§ 1119.2 Applicability.

This part applies to all civil penalty determinations the Commission may seek or compromise under the Consumer Product Safety Act (CPSA) (15 U.S.C. 2051–2089), the Federal Hazardous Substances Act (FHSA) (15 U.S.C. 1261–1278), and the Flammable Fabrics Act (FFA) (15 U.S.C. 1191–1204). Any person who knowingly violates section 19 of the CPSA, section 4 of the FHSA, or section 5(e) of the FFA, is subject to a civil penalty.

§ 1119.3 Definitions.

For purposes of this rule, the following definitions apply:

(a) *Product defect* means a defect as referenced in the CPSA and defined in Commission regulations at 16 CFR 1115.4.

(b) *Violation* means a violation committed knowingly, as the term "knowingly" is defined in section 19 of the CPSA, section 4 of the FHSA, or section 5 of the FFA.

(c) *Person* means any manufacturer (including importer), distributor, or retailer, as those terms are defined in the CPSA, FHSA, or FFA, and any other legally responsible party.

§ 1119.4 Factors considered in determining civil penalties.

(a) *Statutory Factors.* (1) Section 20(b) of the CPSA, section 5(c)(3) of the FHSA, and section 5(e)(2) of the FFA, specify factors considered by the Commission in determining the amount of a civil penalty to be sought upon commencing an action for knowing violations of each act. These factors are:

(i) *CPSA (15 U.S.C. 2069(b)).* The nature, circumstances, extent, and gravity of the violation, including:

(A) The nature of the product defect;

(B) The severity of the risk of injury;

(C) The occurrence or absence of injury;

(D) The number of defective products distributed;

(E) The appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses; and

(F) Such other factors as appropriate.

(ii) *FHSA (15 U.S.C. 1264 (c)(3)).* The nature, circumstances, extent, and gravity of the violation, including:

(A) The nature of the substance;

(B) Severity of the risk of injury;

(C) The occurrence or absence of injury;

(D) The amount of substance distributed;

(E) The appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses; and

(F) Such other factors as appropriate.

(iii) *FFA (15 U.S.C. 1194 (e)(2)).* The nature, circumstances, extent, and gravity of the violations:

(A) The severity of the risk of injury;

(B) The occurrence or absence of injury;

(C) The appropriateness of such penalty in relation to the size of the business of the person charged; and

(D) Such other factors as appropriate.

(2) *The nature, circumstances, extent, and gravity of the violation.* Under this factor, the Commission will consider the totality of the circumstances and all other facts concerning a violation. The Commission will consider the enumerated statutory factors, as well as the factors described in paragraph (b) of this section.

(3) *Nature of the product defect.* The Commission will consider the nature of the product defect associated with a CPSA violation. This consideration will include, for example, whether the defect arises from the product's design, composition, contents, construction, manufacture, packaging, warnings, or instructions, and will include consideration of conditions or circumstances in which the defect arises. The Commission will also consider the nature of the substance associated with an FHSA violation. Two of the statutory factors in the CPSA civil penalty factors include the terms "product defect" or "defective products." However, certain violations of the CPSA, for example, failing to supply a required certificate that the product complies with an applicable consumer product safety rule, do not necessarily require that there be a product defect or defective product. The terms "product defect" or "defective products" would not apply to such situation. In such cases, however, the other civil penalty factors would still be considered.

(4) *Severity of the risk of injury.* Consistent with its discussion of severity of the risk at 16 CFR 1115.12, the Commission will consider, among other factors, the potential for serious injury, illness, or death (and whether any injury or illness required medical treatment including hospitalization or surgery); the likelihood of injury; the intended or reasonably foreseeable use or misuse of the product; and the population at risk (including vulnerable populations such as children, the elderly, or those with disabilities).

(5) *The occurrence or absence of injury.* The Commission will consider whether injuries, illnesses, or deaths have or have not occurred with respect to any product or substance associated with a violation, and, if so, the number and nature of injuries, illnesses, or deaths. Both acute illnesses and the likelihood of chronic illnesses will be considered.

(6) *The number of defective products distributed.* The Commission will consider the number of defective products or amount of substance distributed in commerce. The statutory language makes no distinction between those defective products distributed in commerce that consumers received and those defective products distributed in commerce that consumers have not received. Therefore both could be considered in appropriate cases. This factor will not be used to penalize a person's decision to conduct a wider-than-necessary recall out of an abundance of caution. This would not include situations where such a recall is conducted due to a person's uncertainty concerning how many or which products may need to be recalled.

(7) The appropriateness of such penalty in relation to the size of the business of the person charged, including how to mitigate undue adverse economic impacts on small businesses.

(i) The Commission is required to consider the size of the business of the person charged in relation to the amount of the penalty. This factor reflects the relationship between the size of a business and the policies behind, and purposes of, a penalty (as noted above in § 1119.1). In considering business size, the Commission may look to several factors including, but not limited to, the number of employees, net worth, and annual sales. A business's size and a business's ability to pay a penalty are separate considerations. In some cases for small businesses, however, these two considerations may relate to each other. The Commission will be guided, where appropriate, by relevant financial factors to determine a small business's ability to pay a penalty, including, but not limited to, liquidity, solvency, and profitability. The burden to present clear, reliable, relevant, and sufficient evidence relating to a business's size and ability to pay rests on the business.

(ii) The statute requires the Commission to consider how to mitigate the adverse economic impacts on small businesses only if those impacts would be undue. What the Commission considers in determining what is undue may include, but is not limited to, the business's size and financial factors relating to its ability to pay. When considering how to mitigate undue

adverse economic impacts, the Commission will, as appropriate, also follow its Small Business Enforcement Policy set forth at § 1020.5.

(b) *Other factors as appropriate.* In determining the amount of any civil penalty to be sought for a violation of the CPSA, FHSA, or FFA, the Commission may consider, as appropriate, such other factors in addition to those listed in the statutes. Both the Commission and a person may raise any factors they believe are relevant in determining an appropriate penalty amount. A person will be notified of any factors beyond those enumerated in the statutes that the Commission relies on as aggravating factors for purposes of determining a civil penalty amount. Additional factors that may be considered in a case include, but are not limited to, the following:

(1) *Safety/compliance program and/or system relating to a violation.* The Commission may consider, when a safety/compliance program and/or system as established is relevant to a violation, whether a person had at the time of the violation a reasonable and effective program or system for collecting and analyzing information related to safety issues. Examples of such information would include incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns. The Commission may also consider whether a person conducted adequate and relevant premarket and production testing of the product at issue; had a program in place for continued compliance with all relevant mandatory and voluntary safety standards; and other factors as the Commission deems appropriate. The burden to present clear, reliable, relevant, and sufficient evidence of such program, system, or testing rests on the person seeking consideration of this factor.

(2) *History of noncompliance.* The Commission may consider whether or not a person's history of noncompliance with the CPSA, FHSA, FFA, and other laws that the CPSC enforces, and the regulations thereunder, should increase the amount of the penalty. A person's history of noncompliance may be indicated by, for example, multiple violations of one or more laws or regulations that the CPSC enforces, including repeated violations of the same law or regulation. History of noncompliance may include the number of previous violations or how recently a previous violation occurred.

(3) *Economic gain from noncompliance.* The Commission may consider whether a person benefitted economically from a failure to comply, including a delay in complying, with the CPSA, FHSA, FFA, and other laws that the CPSC enforces, and the regulations thereunder.

(4) Failure to respond in a timely and complete fashion to the Commission's requests for information or remedial action. The Commission may consider whether a person's failure to respond in a timely and complete fashion to requests from the Commission for information or for remedial action should increase a penalty. This factor is intended to address a person's dilatory and egregious conduct in responding to written requests for information or remedial action sought by the Commission, but not to impede any person's lawful rights.

§ 1119.5 Enforcement notification.

A person will be informed in writing if it is believed that the person has violated the law and if the Commission intends to seek a civil penalty. Any person who receives such a writing will have an opportunity to submit evidence and arguments that it should not pay a penalty or should not pay a penalty in the amount sought by the Commission.

Dated: March 24, 2010.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2010–6940 Filed 3–30–10; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF LABOR

Employment and Training Administration

20 CFR Part 655

Temporary Employment of Foreign Workers in the United States

CFR Correction

In Title 20 of the Code of Federal Regulations, Part 500 to End, revised as of April 1, 2009, on page 466, remove § 655.0 and correctly reinstate it to read as follows:

§ 655.0 Scope and purpose of part.

(a) *Subparts A, B, and C*—(1) *General.* Subparts A, B, and C of this part set out the procedures adopted by the Secretary to secure information sufficient to make factual determinations of: (i) Whether U.S. workers are available to perform temporary employment in the United States, for which an employer desires to employ nonimmigrant foreign workers, and (ii) whether the employment of aliens for such temporary work will adversely affect the wages or working conditions of similarly employed U.S. workers. These factual determinations (or a determination that there are not sufficient facts to make one or both of these determinations) are required to carry out the policies of the Immigration and Nationality Act (INA), that a nonimmigrant alien worker not be admitted to fill a particular temporary job opportunity unless no qualifed U.S. worker is available to fill the job opportunity, and unless the employment of the foreign worker in the job opportunity will not adversely affect the wages or working conditions of similarly employed U.S. workers.

(2) *The Secretary's determinations.* Before any factual determination can be made concerning the availability of U.S. workers to perform particular job opportunities, two steps must be taken. First, the minimum level of wages, terms, benefits, and conditions for the particular job opportunities, below which similarly employed U.S. workers would be adversely affected, must be established. (The regulations in this part establish such minimum levels for wages, terms, benefits, and conditions of employment.) Second, the wages, terms, benefits, and conditions offered and afforded to the aliens must be compared to the established minimum levels. If it is concluded that adverse effect would result, the ultimate determination of availability within the meaning of the INA cannot be made since U.S. workers cannot be expected to accept employment under conditions below the established minimum levels. *Florida Sugar Cane League, Inc.* v. *Usery,* 531 F. 2d 299 (5th Cir. 1976).

Once a determination of no adverse effect has been made, the availability of U.S. workers can be tested only if U.S. workers are actively recruited through the offer of wages, terms, benefits, and conditions at least at the minimum level or the level offered to the aliens, whichever is higher. The regulations in this part set forth requirements for recruiting U.S. workers in accordance with this principle.

(3) *Construction.* This part and its subparts shall be construed to effectuate the purpose of the INA that U.S. workers rather than aliens be employed wherever possible. *Elton Orchards, Inc.* v. *Brennan,* 508 F. 2d 493, 500 (1st Cir. 1974), *Flecha* v. *Quiros,* 567 F. 2d 1154 (1st Cir. 1977). Where temporary alien workers are admitted, the terms and conditions of their employment must not result in a lowering of the terms and conditions of domestic workers similarly employed, *Williams* v. *Usery,* 531 F. 2d 305 (5th Cir. 1976); *Florida Sugar Cane League, Inc.* v. *Usery,* 531 F.

2d 299 (5th Cir. 1976), and the job benefits extended to any U.S. workers shall be at least those extended to the alien workers.

(b) *Subparts D and E.* Subparts D and E of this part set forth the process by which health care facilities can file attestations with the Department of Labor for the purpose of employing or otherwise using nonimmigrant registered nurses under H–1A visas.

(c) *Subparts F and G.* Subparts F and G of this part set forth the process by which employers can file attestations with the Department of Labor for the purpose of employing alien crewmembers in longshore work under D-visas and enforcement provisions relating thereto.

(d) *Subparts H and I of this part.* Subpart H of this part sets forth the process by which employers can file labor condition applications (LCAs) with, and the requirements for obtaining approval from, the Department of Labor to temporarily employ the following three categories of nonimmigrants in the United States: (1) H–1B visas for temporary employment in specialty occupations or as fashion models of distinguished merit and ability; (2) H–1B1 visas for temporary employment in specialty occupations of nonimmigrant professionals from countries with which the United States has entered into certain agreements identified in section 214(g)(8)(A) of the INA; and (3) E–3 visas for nationals of the Commonwealth of Australia for temporary employment in specialty occupations. Subpart I of this part establishes the enforcement provisions that apply to the H–1B, H–1B1, and E–3 visa programs.

(e) *Subparts J and K of this part.* Subparts J and K of this part set forth the process by which employers can file attestations with the Department of Labor for the purpose of employing nonimmigrant alien students on F-visas in off-campus employment and enforcement provisions relating thereto.

[43 FR 10312, Mar. 10, 1978, as amended at 52 FR 20507, June 1, 1987; 55 FR 50510, Dec. 6, 1990; 56 FR 24667, May 30, 1991; 56 FR 54738, Oct. 22, 1991; 56 FR 56875, Nov. 6, 1991; 57 FR 1337, Jan. 13, 1992; 57 FR 40989, Sept. 8, 1992; 69 FR 68226, Nov. 23, 2004; 73 FR 19947, Apr. 11, 2008]

[FR Doc. 2010–7380 Filed 3–30–10; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA–2003–N–0446] (formerly Docket No. 2003N–0324)

New Animal Drugs; Removal of Obsolete and Redundant Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is removing portions of a regulation that required sponsors to submit data regarding the subtherapeutic use of certain antibiotic, nitrofuran, and sulfonamide drugs administered in animal feed as these regulations have been determined to be obsolete or redundant. The portions of the regulation being removed are provisions listing certain feed use combinations for oxytetracycline and neomycin in the tables contained in that regulation. This rule does not finalize the provisions of the proposed rule regarding removing the remainder of the regulation.

DATES: This rule is effective April 30, 2010.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–50), 7519 Standish Pl., Rockville, MD 20855, 240–276–9090, e-mail: *william.flynn@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 8, 2003 (68 FR 47272), FDA published a notice of proposed rulemaking to remove 21 CFR 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (§ 558.15 (21 CFR 558.15)) on the grounds that these regulations were obsolete or redundant. The proposed rule explained the nature and purpose of § 558.15, and noted that most of the products and use combinations subject to the listings in that section had approvals that were already codified in part 558, subpart B (21 CFR part 558, subpart B).

In the same issue of the **Federal Register** as the proposed rule, FDA's Center for Veterinary Medicine (CVM) published a Notice of Opportunity for Hearing (NOOH), which announced CVM's findings of effectiveness for nine products and use combinations that were listed in § 558.15, but which were subject to the Drug Efficacy Study Implementation (DESI) program (68 FR 47332). CVM proposed to withdraw the new animal drug applications (NADAs) for those nine products and use combinations lacking substantial evidence of effectiveness, following an opportunity to supplement the NADAs with labeling conforming to the relevant findings of effectiveness. For applications proposed to be withdrawn, the agency provided an opportunity for hearing.

FDA received hearing requests regarding two products owned by Pennfield Oil Co. (Pennfield). One is a bacitracin methylene disalicylate (BMD) Type A medicated article, NADA 141–137, that is listed in the table in § 558.15(g)(1). This listing is under Fermenta Animal Health Co., which is a predecessor in interest to Pennfield. The other is a two-way, fixed-combination Type A medicated article containing oxytetracycline and neomycin sulfate, NADA 138–939, that is listed in the table in § 558.15(g)(2).

The agency received only one set of comments on the 2003 proposed rule, from Pennfield. The comment objected to the removal of § 558.15 until the issues in the NOOH are addressed. It argued that the BMD listing in § 558.15 provides evidence of Pennfield's approval, and that removal of that section, without updating the BMD listing in part 558, subpart B, would result in a lack of recognition in the regulations of the approval that Pennfield currently has.

In 2006, FDA finalized portions of the 2003 proposed rule. In that final rule (71 FR 16219, March 31, 2006), FDA removed from the tables in § 558.15(g) products and use combinations that were not approved, and products and use combinations whose approval was reflected in part 558, subpart B. FDA retained only the listings for NADA 141–137 and NADA 138–939 in those tables. In addition, FDA retained § 558.15(a) through (f). FDA stated it intended to finalize the proposed rule to remove all of § 558.15 once, as part of the DESI program, either the approvals for NADA 141–137 and NADA 138–939 have been withdrawn or part 558, subpart B has been amended to reflect their approvals.

Subsequently, Pennfield filed a supplement to NADA 138–939 for its fixed-combination oxytetracycline/neomycin Type A medicated articles. The supplemental NADA, which provided labeling conforming to the relevant findings of effectiveness announced in the NOOH, was approved on July 2, 2009, and the regulations were amended in § 558.455 of subpart B to reflect that approval (74 FR 40723, August 13, 2009).

This oxytetracycline/neomycin use combination is listed in the table in § 558.15(g)(2) and is the only use combination listed in this provision. Because this use combination's approval is now reflected in § 558.455, FDA is removing § 558.15(g)(2) as obsolete or redundant. As in the 2006 final rule, FDA is retaining the sole listing in the table in § 558.15(g)(1) for NADA 141–137 as well as § 558.15(a) through (f), and intends to continue to finalize the proposed rule to remove all of § 558.15.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–602), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

FDA proposed the removal of § 558.15 on August 8, 2003, because it was obsolete or redundant. The original purpose of § 558.15, requiring the submission of the results of studies on the long-term administration of then-marketed antimicrobial drugs in animal feed on the occurrence of multiple drug-resistant bacteria associated with these animals, was obsolete as FDA had a new strategy and concept for assessing the safety of antimicrobial new animal drugs, including subtherapeutic use of antimicrobials in animal feed, with regard to their microbiological effects on bacteria of human health concern. This final rule would delete the only animal drug use combination listed in § 558.15(g)(2) which is redundant because its approved conditions of use are now listed in § 558.455.

A. Benefits

Only one set of comments on the proposal was received by FDA. Because these comments did not question the benefits as described in the proposed rule, we retain the benefits for the final rule. This final rule is expected to provide greater clarity in the regulations for new animal drugs for use in animal feeds by deleting obsolete provisions in § 558.15. We do not expect this final rule to result in any direct human or animal health benefit. Rather, this final rule would remove regulations that are no longer necessary.

B. Compliance Costs

We do not expect the final rule that revokes § 558.15(g)(2) to have a substantive effect on any approved new animal drugs, or to cause any approved new animal drug to lose its marketing ability or experience a loss of sales.

C. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA has determined that this final rule does not impose compliance costs on the sponsors of any products that are currently marketed. Further, it does not cause any drugs that are currently marketed to lose their marketing ability. We therefore certify that this final rule would not have a significant economic effect on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

FDA concludes that this rule does not have information collection requirements.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 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.

§ 558.15 [Amended]

■ 2. In § 558.15, remove and reserve paragraph (g)(2).

Dated: March 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7108 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0959]

RIN 1625–AA09

Drawbridge Operation Regulation; Chehalis River, Aberdeen, WA, Schedule Change

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulations that govern the operation of the U.S. Highway 101 bascule bridge across the Chehalis River, mile 0.1, at Aberdeen, Washington. At least one-hour notice by telephone will be required at all times for draw openings. The change is necessary to allow the bridge owner to reduce the staffing requirements of the bridge in light of the infrequent openings requested for the bridge.

DATES: This rule is effective April 30, 2010.

ADDRESSES: Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2009–0959 and are available online by going to *http://www.regulations.gov.*, inserting USCG–2009–0959 in the "Keyword" box, and then clicking "Search". This material is also available for inspection or copying at the Docket Management Facility (M–60), 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or

e-mail Austin Pratt, Chief, Bridge Section, Waterways Management Branch, 13th Coast Guard District; telephone 206–220–7282, e-mail *william.a.pratt@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On December 4, 2009, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Chehalis River, Aberdeen, WA, Schedule Change in the **Federal Register** (74 FR 63695). We received no comments on the proposed rule. No public meeting was requested and none was held.

Background and Purpose

This rule enables the Washington State Department of Transportation, the owner of the Chehalis River Bridge, to operate the draw only if at least one-hour notice is provided at all times. This notice will be given by telephone to 360–533–9360. A marine radio will also be maintained at the bridge, but will only be monitored when a draw tender is present. Previously, one-hour notice was only required between 9 p.m. and 5 a.m.

Over the years ship traffic has dwindled on this reach of the Chehalis River. From June through September 2009 the draw did not open for large oceangoing vessels. The former ship traffic is now focused seaward of the bridge following the recent closure of timber terminals above the bridge. The bridge averages only seven openings a month during those daylight hours when a draw operator is present. The Washington State Department of Transportation requested this change to reduce unnecessary staffing of the drawbridge in light of the infrequent openings requested for the bridge.

Discussion of Comments and Changes

No comments were received on the proposed rule and no changes were made to the proposed rule.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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 Coast Guard has made this determination based on the fact that vessel operators will not be significantly impacted since they will still be able to transit under the bridge by giving one-hour notice.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities because all vessel operators will not be significantly impacted since they will still be able to transit under the bridge by giving one-hour notice.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding this 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 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 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 Information and Regulatory Affairs has not designated this 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 Department of Homeland Security Management Directive 023–01, and 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 this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required.

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 § 117.1031 to read as follows:

§ 117.1031 Chehalis River.

The draw of the U.S. 101 highway bridge, mile 0.1, at Aberdeen shall open on signal if at least one-hour notice is given at all times by telephone to the Washington State Department of Transportation.

Dated: March 11, 2010.

G.T. Blore,

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

[FR Doc. 2010–7166 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0185]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Albemarle and Chesapeake Canal, Chesapeake, VA

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 regulations governing the operation of the SR170 Centerville Turnpike Bridge across the Atlantic Intracoastal Waterway, Albemarle and Chesapeake Canal, mile 15.7, at Chesapeake, VA. The deviation is necessary to facilitate structural repairs to the swing span. This deviation allows the drawbridge to remain in the closed to navigation position.

DATES: This deviation is effective from 8 a.m. on April 10, 2010 to 6 p.m. on April 18, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket USCG–2010–0185 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0185 in the "Keyword" box, and then clicking "Search". This material is also available for inspection or copying 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Bill H. Brazier, Bridge Management Specialist, Fifth Coast Guard District; telephone (757) 398–6422, e-mail *Bill.H.Brazier@uscg.mil.* If you have questions on reviewing the docket, call Renee V. Wright, Program Manager, Docket Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION: The City of Chesapeake, who owns and operates this swing-type bridge, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.997(i), to facilitate structural repairs.

The SR170 Centerville Turnpike Bridge has a vertical clearance in the closed position to vessels of four feet above mean high water.

Under this temporary deviation, the drawbridge will be maintained in the closed to navigation position to facilitate repairs to structural support stringers on two separate closures. The first closure period will begin at 8 a.m. April 10, 2010, until and including 6 p.m. April 11, 2010; and the second closure period scheduled to begin at 8 a.m. on April 17, 2010, until and including 6 p.m. on April 18, 2010. Openings will be provided during the closure periods at the following times: on Saturdays at 8 a.m., 10 a.m., noon, 2 p.m., 4 p.m., 6 p.m., 8 p.m., and 10 p.m., and on Sundays at midnight, 2 a.m., 4 a.m., 6 a.m., 8 a.m., 10 a.m., noon, 2 p.m., 4 p.m., and 6 p.m.

The Atlantic Intracoastal Waterway caters to a variety of vessels from tug and barge traffic to recreational vessels traveling from Florida to Maine. The Coast Guard has carefully coordinated the restrictions with commercial and recreational waterway users. Additionally, the Coast Guard will inform unexpected users of the waterway through our local and broadcast Notices to Mariners of the closure periods for the bridge so that vessels can arrange their transits to minimize any impacts caused by the temporary deviation. The Atlantic Ocean is the alternate route for vessels and the bridge will be able to open in the event of an emergency.

In accordance with 33 CFR 117.35(e), the draw must return to its original 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 17, 2010.

Waverly W. Gregory, Jr.,

Chief, Bridge Administration Branch, Fifth Coast Guard District.

[FR Doc. 2010–7244 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0840]

RIN 1625–AA09

Drawbridge Operation Regulation; Port of Coos Bay Railroad Bridge, Coos Bay, North Bend, OR

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the drawbridge operation regulation for the Coos Bay Railroad Bridge, Coos Bay, mile 9.0, at North Bend, Oregon to delete the requirement for special sound signals used in foggy weather and to change the name of the owner. The change is necessary to make the sound signals used at the bridge consistent with other bridges in the area and to eliminate the unnecessary special sound signals.

DATES: This rule is effective April 30, 2010.

ADDRESSES: Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in this docket are part of docket USCG–2009–0840 and are available online by going to *http://www.regulations.gov*, inserting USCG–2009–0840 in the "Keyword" box, and then clicking "Search". This material is also available for inspection or copying at 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 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Austin Pratt, Chief, Bridge Section, Waterways Management Branch, 13th Coast Guard; telephone 206–220–7282, e-mail *william.a.pratt@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On November 16, 2009, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Port of Coos Bay Railroad Bridge, Coos Bay, North Bend, OR, in the **Federal Register** (74 FR 58931). No comments were received on the proposed rule. No public meeting was requested and none was held.

Background and Purpose

This rule will remove the requirements at the Port of Coos Bay Railroad Bridge, Coos Bay, mile 9.0, at North Bend, Oregon for a bell to be rung continuously in foggy weather and that a siren be sounded in foggy weather when the swingspan is closed. The movable span is normally kept in the open position except for the passage of trains or maintenance work. The rule will also change the regulation to reflect the bridge's current owner as the Port of Coos Bay.

The bell and siren at this drawbridge are not standard requirements at drawbridges and there is nothing specific to this bridge that currently warrants the continuance of these signals. Vessel traffic through the swingspan includes tugs and tows and a variety of recreational craft. Oceangoing ship traffic has diminished greatly in recent decades.

The operating regulations currently in effect for the bridge are found at 33 CFR 117.871. These state that the bridge be maintained normally in the open position except for the passage of trains or maintenance. The aforementioned sound signals are also prescribed.

Discussion of Comments and Changes

No comments on the proposed rule were received and no changes were made to it.

Regulatory Analyses

We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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 Coast Guard has made this finding based on the fact that the rule will have no known impact on the maritime public.

Small Entities

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

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities because it will have no known impact on any vessel traffic.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the proposed rule so that they can better evaluate its effects on them and participate in the rulemaking process.

Collection of Information

This 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 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 Information and Regulatory Affairs has not designated this 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 Department of Homeland Security Management Directive 023–01 and 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 this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist 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.

■ 2. Revise § 117.871 to read as follows:

§ 117.871 Coos Bay.

The draw of the Port of Coos Bay railroad bridge, mile 9.0 at North Bend, shall be maintained in the fully open position, except for the crossing of trains or maintenance.

Dated: March 11, 2010.

G.T. Blore,

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

[FR Doc. 2010–7159 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0152]

Drawbridge Operation Regulation; Sacramento River, Sacramento, CA

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 I Street Drawbridge across the Sacramento River, mile 59.4, at Sacramento, CA. The deviation is necessary to allow the bridge owner to make bridge repairs.

DATES: This deviation is effective from 8 a.m. to 6 p.m. on March 30, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of the docket USCG–2010–0152 and are available online by going to *http://www.regulations.gov*, inserting USCG–2010–0152 in the "Keyword" box and then clicking "Search". They are also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, e-mail *David.H.Sulouff@uscg.mil* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: Union Pacific Railroad Company requested a temporary change to the operation of the I Street Drawbridge, mile 59.4, over Sacramento River, at Sacramento, CA. The I Street Drawbridge navigation span provides 109 feet vertical clearance above Mean High Water in the full open-to-navigation position, and 30 feet vertical clearance above Mean High Water when closed. The draw opens on signal from May 1 through October 31 from 6 a.m. to 10 p.m. and from November 1 through April 30 from 9 a.m. to 5 p.m. At all other times the draw shall open on signal if at least four hours notice is given, as required by 33

CFR 117.189(a). Navigation on the waterway is commercial and recreational.

The drawspan will be secured in the closed-to-navigation position from 8 a.m. to 6 p.m. on March 30, 2010, to allow the bridge owner to remove and replace the oil in the operating machinery for the drawspan. This temporary deviation has been coordinated with waterway users. There are no scheduled river boat cruises or anticipated levee maintenance during this deviation period. No objections to the proposed temporary deviation were raised. The drawspan can be opened with 2 hours advance notice for emergencies requiring the passage of waterway traffic.

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 15, 2010.

S.P. Metruck,

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

[FR Doc. 2010–7249 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0686]

RIN 1625–AA09

Drawbridge Operation Regulation; Lower Grand River, Iberville Parish, LA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulation governing the operation of the LA 75 pontoon bridge, mile 38.4, in Iberville Parish, Louisiana. The Iberville Parish School Board requested that the operating regulation of the LA 75 pontoon bridge be changed to add an additional 30 minutes to the end of the morning scheduled closure period to provide more time for school buses to transit across the bridge. The additional time is needed as a result of school redistricting.

DATES: This rule is effective April 30, 2010.

ADDRESSES: Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2009–0686 and are available online by going to *http://www.regulations.gov,* inserting USCG–2009–0686 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at 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.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On November 10, 2009, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Lower Grand River, Iberville Parish, LA in the **Federal Register** (74 FR 57884). We received one comment on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The Iberville Parish School Board requested a change in the operation regulation for the LA 75 pontoon and the LA 77 swing bridge across the Lower Grand River, mile 38.4 and 47.0, respectively, in Iberville Parish, Louisiana. The change would add an additional 30 minutes to the end of each scheduled closure period to provide more time for school buses to transit across the bridge. Extra time is now needed because one of Iberville Parish's high schools has been closed. School bus lines have been rerouted, creating the need to have more time to transit the students over the bridges.

Presently, 33 CFR 117.478(a) and (b) states: The draw of the LA 75 bridge, mile 38.4 (Alternate Route) at Bayou Sorrel and the draw of the LA 77 bridge, mile 47.0 (Alternate Route) at Grosse Tete, shall open on signal; except that, from about August 15 to about June 5 (the school year), the draw of the LA 75 bridge need not be opened from 6 a.m. to 7:30 a.m. and from 3 p.m. to 4:30 p.m. and the draw of the LA 77 bridge need not be opened from 6 a.m. to 8 a.m. and from 2:30 p.m. to 4:30 p.m., Monday through Friday except Federal holidays. The draws shall open on signal at any time for an emergency aboard the vessel.

Concurrent with the publication of the notice of proposed rulemaking, a test deviation [USCG–2009–0686] was issued to allow the Iberville Parish School Board to test the proposed schedule and to obtain data and public comments. The test deviation allowed the bridges to operate as follows: The draw of the LA 75 bridge, mile 38.4 (Alternate Route) at Bayou Sorrel and the draw of the LA 77 bridge, mile 47.0 (Alternate Route) at Grosse Tete, shall open on signal; except that, from about August 15 to about June 5 (the school year), the draw of the LA 75 bridge need not be opened from 6 a.m. to 8 a.m. and from 3 p.m. to 5 p.m. and the draw of the LA 77 bridge need not be opened from 6 a.m. to 8:30 a.m. and from 2:30 p.m. to 5 p.m., Monday through Friday except Federal holidays. The draws shall open on signal at any time for an emergency aboard the vessel. The test period was in effect from November 25, 2009 until December 28, 2009.

One comment was received on November 11, 2009, before the test deviation went into effect, from a mariner expressing concern about the curfew changes. He is concerned because he believes there is already a congestion problem on the waterway during the closure periods and the additional 30 minutes would make the congestion worse. We did not receive any comments during or after the test deviation.

The Coast Guard has reviewed bridge tender logs from before, during, and after the test deviation became effective. The logs do not indicate an appreciable difference in the number of openings with the additional 30 minute closure period. The Coast Guard also reviewed the school buses crossing the bridges during the test deviation. The report indicated that the only time extension needed for the school buses is the morning closure for LA 75 pontoon bridge at Bayou Sorrel. Based on the research and data that was reviewed and the comment that was received, the Coast Guard has determined that the permanent change to the operating regulation for the Bayou Sorrel, LA 75 pontoon bridge morning closure period is warranted. The LA 75 pontoon bridge at Bayou Sorrel afternoon bridge closure and the LA 77 swing bridge at Grosse Tete morning and afternoon closures will remain as they are presently regulated.

Discussion of Comments and Changes

The Coast Guard received one comment from a mariner on November 11, 2009. Although he recognizes the importance of getting children to school at the proper times, he is worried about the increase in the duration of time that the bridges would be closed because it would add to a current congestion issue during those periods of closure. The Coast Guard has analyzed the data and research on the impact of the time

adjustment on vessel traffic and has concluded that there is not a significant impact. Furthermore, the Coast Guard has analyzed the data and research on the impact the time adjustment has made on school bus traffic and has concluded that the only bridge closure in need of the time adjustment is the morning closure at the LA 75 pontoon bridge at Bayou Sorrel. Therefore, this is the only closure that will be permanently changed in the regulatory text.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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.

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. The changes have a minimal impact on maritime traffic transiting the bridge. Mariners can plan their trips in accordance with the scheduled bridge openings. The changes to the regulatory text published in the NPRM will be less restrictive than what was published. The afternoon closure at the LA 75 pontoon bridge at Bayou Sorrel and both the morning and afternoon closures at the LA 77 swing bridge at Grosse Tete will remain unchanged to what is currently published in the operating regulations.

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 rule will affect the following entities, some of which might be small entities: The owners or operators of vessels that would be transiting the bridge during that 30 minute increment of time. Because the amount of time that would be added to the current bridge closure period is minimal, this rule will not affect a substantial number of small entities and therefore will not have a substantial economic impact.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM (SNPRM) 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.

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 (adjusted for inflation) 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 Department of Homeland Security

Management Directive 023–01 and 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 this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the Instruction, an environmental analysis checklist 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. In § 117.478 paragraph (a) is revised to read as follows:

§ 117.478 Lower Grand River.

(a) The draw of the LA 75 bridge, mile 38.4 (Alternate Route) at Bayou Sorrel, shall open on signal; except that from about August 15 to about June 5 (the school year), the draw need not be opened from 6 a.m. to 8 a.m. and from 3 p.m. to 4:30 p.m., Monday through Friday except holidays. The draw shall open on signal at any time for an emergency aboard a vessel.

* * * * *

Dated: March 15, 2010.

Mary E. Landry,

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

[FR Doc. 2010–7167 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2010–0167]

Drawbridge Operation Regulations; Acushnet River, New Bedford and Fairhaven, MA, Event—Road Race

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 6 New Bedford Fairhaven Bridge across the Acushnet River, mile 0.0, between New Bedford and Fairhaven, Massachusetts. This temporary deviation is necessary to facilitate a public event, the Greater New Bedford Community Health Center 5K Road Race, by allowing the bridge to remain in the closed position for two hours during the running of the 5K Road Race.

DATES: This deviation is effective from 10 a.m. through 12 p.m. on May 30, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket are part of docket USCG–2010–0167 and are available online at *http://www.regulations.gov*, inserting USCG–2009–0001 in the "Keyword" and then clicking "Search". They are also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. John McDonald, Project Officer, First Coast Guard District, telephone (617) 223–8364, *john.w.mcdonald@uscg.mil*. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

The Route 6 New Bedford Fairhaven Bridge, across the Acushnet River at mile 0.0, between New Bedford and Fairhaven, Massachusetts, has a vertical clearance in the closed position of 6 feet at mean high water and 10 feet at mean low water. The Drawbridge Operation Regulations are listed at 33 CFR 117.585. The bridge opens on the hour from 6 a.m. through 10 a.m. and at a quarter past the hour between 11:15 a.m. and 6:15 p.m. The bridge opens on signal at all other times.

The owner of the bridge, Massachusetts Department of Transportation, requested this temporary deviation to facilitate a public event, the Greater New Bedford Community Health Center 5K Road Race.

Under this deviation, the Route 6 New Bedford Fairhaven Bridge may remain in the closed position between 10 a.m. and 12 p.m. on May 30, 2010. The 10 a.m. and 11:15 a.m. openings will be missed as a result of this temporary deviation. Vessels able to pass under the closed draw may do so at any time.

In accordance with 33 CFR 117.35(e), the bridge 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 16, 2010.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2010–7246 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[USCG–2010–0029]

Drawbridge Operation Regulations; Hackensack River, Jersey City, NJ, Maintenance

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 1 & 9 (Lincoln Highway) Bridge, mile 1.8, across the Hackensack River at Jersey City, New Jersey. This deviation allows the bridge owner to require a two hour advance notice for bridge openings April through September and several bridge closures to facilitate bridge painting operations. Vessels that can pass under the draw without a bridge opening may do so at all times.

DATES: This deviation is effective from April 1, 2010 through September 15, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2010–0029 and are available online at *http://www.regulations.gov.* They are also available for inspection or copying at 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 First Coast Guard District, Bridge Branch Office, 408 Atlantic Avenue, Boston,

Massachusetts 02110, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule call Joe Arca, Project Officer, First Coast Guard District, at (212) 668–7165. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION: The Route 1 & 9 (Lincoln Highway) Bridge across the Hackensack River at mile 1.8, at Jersey City, New Jersey, has a vertical clearance in the closed position of 35 feet at mean high water and 40 feet at mean low water. The bridge opens on signal as required by 33 CFR 117.723(a)(5).

The bridge owner, the New Jersey Department of Transportation, requested a temporary deviation to require at least a two hour advance notice for bridge openings to allow workers sufficient time to clear painting equipment from the lift span in order to provide bridge openings.

In addition, several bridge closures will be necessary during the effective time period for this temporary deviation in order to facilitate various phases of this bridge painting project that must be completed with the bridge closed.

The exact times and dates for the bridge closures could not be determined prior to publication of this temporary deviation. They will be announced in the Local Notice to Mariners two weeks prior to their implementation. A broadcast notice to mariners will also be initiated twenty four hours in advance to further inform mariners of the proposed bridge closures.

Under this deviation the Route 1 & 9 (Lincoln Highway) Bridge shall require at least a two hour advance notice for bridge openings from April 1, 2010 through September 15, 2010. In addition, several bridge closures to be announced as stated above, will occur during the effective period of this temporary deviation from April 1, 2010 and September 15, 2010.

Vessels able to pass under the closed draw may do so at all times.

The waterway is primarily used by deep draft tankers, tugs and barge units. Waterway users were advised of the requested bridge closure period and offered no objection.

In accordance with 33 CFR 117.35(e), the bridge 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 16, 2010.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. 2010–7238 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2010–0198]

RIN 1625–AAOO

Safety Zone; Red River, MN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard Captain of the Port (COTP), Marine Safety Unit Duluth, MN is establishing a temporary safety zone on the waters of the Red River, MN. This safety zone is being established to ensure the safety of the public. The safety zone will prevent individuals from entering all navigable waters of the Red River in the State of Minnesota north of a line drawn across latitude 46°20′00″ N, including those portions of the river in Wilkin, Clay, Norman, Polk, Marshall and Kittson counties, to the United States-Canada international border.

DATES: *Effective Date:* This rule is effective in the CFR from March 31, 2010 until 5 p.m. on April 24, 2010. This rule is effective with actual notice for purposes of enforcement beginning 12 p.m. March 19, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2010–0198 and are available online by going to *http://www.regulations.gov,* inserting USCG–2010–0198 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at 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.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Aaron L. Gross, Chief of Port Operations, Marine Safety Unit Duluth, Coast Guard; telephone 218–720–5286 ext 111, e-mail *Aaron.L.Gross@uscg.mil.* If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because immediate action is necessary to provide for the safety of life and property on navigable waters.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register.** Good cause for making this rule effective less than 30 days after publication exists because delaying the effective date would be contrary to public interest because of the dangers associated with emergency flooding conditions on the Red River.

Background and Purpose

Flooding conditions along the Red River have created serious dangers to the boating public. The strong currents and floating debris associated with the flooding of the Red River necessitate the Coast Guard limiting access to the portions of the river affected by this rule in order to protect the public.

This temporary safety zone is necessary to ensure the safety of the public from hazards involved with the flooding of the Red River. Restricted access to the Red River by the public will help ensure the safety of persons and property along the Red River.

Discussion of Rule

The Coast Guard is establishing a temporary safety zone to encompass certain waters of the Red River in the Duluth Captain of the Port (COTP) Zone. The safety zone will prevent individuals from entering all navigable waters of the Red River in the State of Minnesota north of a line drawn across latitude 46°20′00″ N, including those portions of the river in Wilkin, Clay, Norman, Polk, Marshall and Kittson counties, to the United States-Canada international border.

The COTP may stop enforcement of this safety zone before 5 p.m. on April

24, 2010 if river conditions change such that enforcement of the safety zone is no longer necessary for the public's safety. COTP will notify the public via a Broadcast Notice to Mariners.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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.

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 rule will affect the following entities, some of which may be small entities: The owners or operators of vessels intending to transit or anchor in the portions of the Red River affected by this safety zone.

This safety zone will not have a significant economic impact on a substantial number of small entities for the following reasons: Few small business entities operate on the affected portion of the river and this rule will be enforced for a limited time, only until the Red River is deemed safe to transit.

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 (adjusted for inflation) 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 cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Energy Effects

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

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 Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and

have concluded this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2–1, paragraph (34)(g), of the Instruction. This rule involves the establishment of a temporary safety zone to protect the public from dangerous water conditions. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Pub. L. 107–295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0198 to read as follows:

§ 165.T09–0198 Safety zone; Red River, MN.

(a) *Location.* The following area is a temporary safety zone: All navigable waters of the Red River in the State of Minnesota north of a line drawn across latitude 46°20′00″ N, including those portions of the river in Wilkin, Clay, Norman, Polk, Marshall and Kittson counties, to the United States-Canada international border.

(b) *Enforcement period.* This rule is effective from 12 p.m. on March 19, 2010 until 5 p.m. on April 24, 2010. If the river conditions change such that enforcement of the safety zone is unnecessary prior to 5 p.m. on April 24, 2010, the COTP will notify the public via a Broadcast Notice to Mariners.

(c) *Regulations.* (1) In accordance with the general regulations in section 165.23 of this part, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Duluth, or his designated on-scene representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the Captain of the Port Duluth or his designated on-scene representative.

(3) The "on-scene representative" of the Captain of the Port is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port to act on his behalf. The on-scene representative of the Captain of the Port will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port Duluth or his on-scene representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port Duluth or his on-scene representative.

March 19, 2010.

M.P. Lebsack,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2010–7158 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[EPA–HQ–OAR–2004–0014: FRL–9131–9; 2060–AP73]

Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Inclusion of Fugitive Emissions; Final Rule; Stay

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In this final action, EPA is issuing a stay for 18 months of the inclusion of fugitive emissions requirements in the federal Prevention of Significant Deterioration (PSD) program published in the **Federal Register** on December 19, 2008, in the final rule entitled, "Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NSR): Reconsideration of Fugitive Emissions" ("Fugitive Emissions Rule"). The Fugitive Emissions Rule under the federal PSD program requires that fugitive emissions be included in determining whether a physical or operational change results in a major modification only for sources in industries that have been designated through rulemaking under section 302(j) of the Clean Air Act (Act or CAA). The existing stay is in effect for 3 months; that is, from December 31, 2009 until March 31, 2010. This action puts in place an additional stay for 18 months, which we believe will allow for sufficient time for EPA to propose, take public comment on, and issue a final action concerning the inclusion of fugitive emissions in the federal PSD program.

DATES: The amendments to 40 CFR parts 51 and 52 in this rule are effective from April 1, 2010 through October 3, 2011. Effective April 1, 2010, the following Code of Federal Regulations sections are administratively stayed until October 3, 2011: 40 CFR 51.165(a)(1)(v)(G), (a)(1)(vi)(C)(3), (a)(1)(ix), (a)(1)(xxviii)(B)(2), (a)(1)(xxviii)(B)(4), (a)(1)(xxxv)(A)(1), (a)(1)(xxxv)(B)(1), (a)(1)(xxxv)(C), (a)(1)(xxxv)(D), (a)(2)(ii)(B), (a)(6)(iii), (a)(6)(iv), and (f)(4)(i)(D); 40 CFR 51.166, (a)(7)(iv)(b), (b)(2)(v), (b)(3)(iii)(c), (b)(3)(iii)(d), (b)(20), (b)(40)(ii)(b), (b)(40)(ii)(d), (b)(47)(i)(a), (b)(47)(ii)(a), (b)(47)(iii), (b)(47)(iv), (r)(6)(iii) and (r)(6)(iv), and (w)(4)(i)(d); 40 CFR part 51, Appendix S, paragraphs II.A.5(vii), II.A.6(iii), II.A.9, II.A.24(ii)(b), II.A.24(ii)(d), II.A.30(i)(a), II.A.30(ii)(a), II.A.30(iii), II.A.30(iv), IV.I.1(ii), IV.J.3, IV.J.4, and IV.K.4(i)(d); and 40 CFR 52.21, (a)(2)(iv)(b), (b)(2)(v), (b)(3)(iii)(b), (b)(3)(iii)(c), (b)(20), (b)(41)(ii)(b), (b)(41)(ii)(d), (b)(48)(i)(a), (b)(48)(ii)(a), (b)(48)(iii), (b)(48)(iv), (r)(6)(iii), (r)(6)(iv), and (aa)(4)(i)(d).

ADDRESSES: *Docket:* All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., confidential business information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at the EPA Docket Center, Public Reading Room, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC 20460. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1742, and the telephone number for the Air Docket is (202) 566–1744.

FOR FURTHER INFORMATION CONTACT: Ms. Carrie Wheeler, Air Quality Policy Division, (C504–03), U.S. Environmental Protection Agency, Research Triangle Park, NC 27711; telephone number (919) 541–9771; fax

number (919) 541–5509; or e-mail address: *wheeler.carrie@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially affected by this action include sources in all industry groups. The majority of sources potentially affected are expected to be in the following groups.

Industry group	SIC [a]	NAICS [b]
Electric Services	491	221111, 221112, 221113, 221119, 221121, 221122.
Petroleum Refining	291	324110.
Industrial Inorganic Chemicals	281	325181, 325120, 325131, 325182, 211112, 325998, 331311, 325188.
Industrial Organic Chemicals	286	325110, 325132, 325192, 325188, 325193, 325120, 325199.
Miscellaneous Chemical Products	289	325520, 325920, 325910, 325182, 325510.
Natural Gas Liquids	132	211112.
Natural Gas Transport	492	486210, 221210.
Pulp and Paper Mills	261	322110, 322121, 322122, 322130.
Paper Mills	262	322121, 322122.
Automobile Manufacturing	371	336111, 336112, 336211, 336992, 336322, 336312, 336330, 336340, 336350, 336399, 336212, 336213.
Pharmaceuticals	283	325411, 325412, 325413, 325414.
Mining	211, 212, 213	21.
Agriculture, Fishing and Hunting	111, 112, 113, 115	11.

[a] Standard Industrial Classification.
[b] North American Industry Classification System.

Entities potentially affected by the subject rule for this proposed action also include state, local, and tribal governments.

B. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this final rule is also be available on the World Wide Web in the regulations and standards section of our NSR home page located at *http://www.epa.gov/nsr.*

C. How is this preamble organized?

I. General Information
A. Does this action apply to me?
B. Where can I get a copy of this document and other related information?
C. How is this preamble organized?
II. This Action
A. Background
B. Final Rule
C. Comments and Responses
D. Basis for Making This Rule Effective on the Date of Publication
III. Statutory and Executive Order Review
A. Executive Order 12866: Regulatory Planning and Review
B. Paperwork Reduction Act
C. Regulatory Flexibility Act
D. Unfunded Mandates Reform Act
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations
K. Determination Under Section 307(d)
L. The Congressional Review Act
M. Basis for Making This Rule Effective on the Date of Publication
IV. Statutory Authority

II. This Action

A. Background

On December 19, 2008, the EPA ("we") issued a final rule revising our requirements of the major NSR programs regarding the treatment of fugitive emissions ("Fugitive Emissions Rule"). 73 FR 77882. The final rule required fugitive emissions to be included in determining whether a physical or operational change results in a major modification only for sources in industries that have been designated through rulemaking under section 302(j) of the CAA. The final rule amended all portions of the major NSR program regulations: Permit requirements, the PSD program, and the emission offset interpretive ruling.

On February 17, 2009, the Natural Resources Defense Council submitted a petition for reconsideration of the December 2008 final rule as provided for in CAA 307(d)(7)(B).[1]

On April 24, 2009, we responded to the February 17, 2009 petition by letter indicating that we were convening a reconsideration proceeding for the inclusion of fugitive emissions challenged in the petition and granting a 3-month administrative stay of the rule contained in the federal PSD program at 40 CFR parts 51 and 52. The letter also indicated that we would publish a notice of proposed rulemaking "in the near future" to address the specific issues for which we are granting reconsideration.[2]

The administrative stay of the Fugitive Emissions Rule became effective on September 30, 2009. *See* 74 FR 50115, FR Doc. E9–23503. As noted above, our authority under section 307(d)(7)(B) to stay a rule or portion thereof solely under the Administrator's discretion is limited to 3 months. An interim final determination was made to provide an additional stay for 3 months. This additional stay became effective on December 31, 2009. *See* 74 FR 65692.

B. Final Rule

In this final rule we are staying the Fugitive Emissions Rule for 18 months. As described above, the same provisions were administratively stayed for 3 months; however, that stay ended on December 30, 2009. To avoid a gap between the end of the stay and the proposed additional stay, an interim final determination was made to provide an additional stay for 3 months, ending on March 31, 2010. We believe the 18 month additional stay is needed and will provide adequate time for EPA to propose, take comment on, and issue a final action on issues that are associated with the inclusion of fugitive emissions. Therefore, we are issuing this stay of the final Fugitive Emissions Rule in the federal PSD program at 40 CFR 51

[1] John Walke, NRDC, EPA–HQ–OAR–2004–0014–0060.

[2] Lisa Jackson, U.S. EPA, EPA–HQ–OAR–2004–0014–0062.

and 52 for 18 months, until October 3, 2011.

C. Comments and Responses

When we proposed this stay on February 11, 2010, we did not take comment on any substantive issues concerning the inclusion of fugitive emissions in the NSR program as stated in the Fugitive Emissions Rule. Comments sought were to be limited to the issue of whether to establish this additional stay and how long this stay would be. [75 FR 6823 at 6825].

We received three comments on the proposal for this additional stay of the Fugitive Emissions Rule. The first commenter supported the additional stay for "18 months, 24 months, or however long it takes for the current administration to reverse the rule and return to EPA's longstanding, lawful, and more protective approach."

One industry coalition commenter opposed the additional 18 month stay to "take substantive action and facilitate resolution of this significant permit applicability issue." Further, the commenter suggested that any delay "makes compliance with already complex PSD and NSR rules just that more difficult." No additional detail is provided regarding the difficulties with compliance for these rules. We agree with the industry coalition commenter that EPA should take substantive action to facilitate resolution of this applicability issue. However, we believe that 18 months is necessary to allow EPA sufficient time to propose, take public comment on, and issue a final action concerning the inclusion of fugitive emissions in the federal PSD program. The commenter does not provide further details to demonstrate how this stay negatively impacts compliance. In our view, it is imperative the Fugitive Emissions Rule continue to be stayed while we undergo the reconsideration process to reduce confusion. If it is effective during this process and the Rule is ultimately changed, it would only further complicate compliance with PSD and NSR rules, an issue of concern for the commenter.

The final commenter did not comment specifically on the proposed additional stay, but instead stated that "further reconsideration is unnecessary." We believe this comment addresses the underlying substance of the Fugitive Emissions rule, which is beyond the scope of this action.

III. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review

This action is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the Executive Order.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq*. Burden is defined at 5 CFR 1320.3(b). This action only issues a stay of the Fugitive Emissions Rule for 18 months.

However, the Office of Management and Budget (OMB) has previously approved the information collection requirements contained in the existing regulations under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* and has assigned OMB control number 2060–0003 [EPA ICR No. 1230.21]. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. This final rule will not impose any new requirements on small entities. We have determined that small businesses will not incur any adverse impacts because EPA is taking this action to propose an additional stay to the regulations at 40 CFR parts 51 and 52 concerning the inclusion of fugitive emissions. No costs are associated with this amendment.

D. Unfunded Mandates Reform Act

This action does not contain a federal mandate under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for state, local, and tribal governments, in the aggregate, or the private sector in any one year. This action only proposes to put in place an additional stay of the regulations at 40 CFR parts 51 and 52 concerning the inclusion of fugitive emissions. Thus, this rule is not subject to the requirements of sections 202 or 205 of the Unfunded Mandates Reform Act (UMRA).

This final rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This final rule does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in EO 13132. This action only stays the regulations at 40 CFR parts 51 and 52 concerning the inclusion of fugitive emissions.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in EO 13175 (65 FR 67249, November 9, 2000). This action will not impose any new obligations or enforceable duties on tribal governments. Thus, EO 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

EPA interprets EO 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because this proposal only proposes to put in place an additional stay of the regulations at 40 CFR parts 51 and 52 concerning the inclusion of fugitive emissions.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a "significant regulatory action" under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the Executive Order.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 ("NTTAA"), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This final rulemaking does not involve technical standards. Therefore, EPA is not using any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority and/or low income populations. This rule stays the regulations at 40 CFR parts 51 and 52 concerning the inclusion of fugitive emissions.

K. Determination Under Section 307(d)

Pursuant to sections 307(d)(1)(J) and 307(d)(1)(V) of the CAA, the Administrator determines that this action is subject to the provisions of section 307(d). Section 307(d)(1)(V) provides that the provisions of section 307(d) apply to "such other actions as the Administrator may determine."

L. The Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2). This rule will be effective April 1, 2010.

M. Basis for Making This Rule Effective on the Date of Publication

Section 553(d) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b), generally provides that rules may not take effect earlier than 30 days after they are published in the **Federal Register**. However, EPA is issuing this final rule under section 307(d)(1) of the CAA, which states:

> "The provisions of section 553 through 557 * * * of Title 5 shall not, except as expressly provided in this section, apply to actions to which this subsection applies."

Thus, section 553(d) of the APA does not apply to this rule. EPA is nevertheless acting consistently with the policies underlying APA section 553(d) in making this rule effective on the date of publication. APA section 553(d)(3) provides an exception when the agency finds good cause exists for a period less than 30 days before effectiveness. We find good cause exists to make this rule effective upon publication. A gap between the current stay that ends on March 31, 2010 and the effective date of this stay could result in administrative and regulatory confusion if the stayed provisions came back into effect, only to be stayed again a short time later. In order to avoid this potential gap, this rule is effective upon publication.

IV. Statutory Authority

The statutory authority for this action is provided by section 301(a) of the CAA as amended (42 U.S.C. 7601(a)). This notice is also subject to section 307(d) of the CAA (42 U.S.C. 7407(d)).

List of Subjects

40 CFR Part 51

Administrative practices and procedures, Air pollution control, Carbon monoxide, Fugitive emissions, Intergovernmental relation, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Transportation, Volatile organic compounds.

40 CFR Part 52

Administrative practices and procedures, Air pollution control, Carbon monoxide, Fugitive emissions, Incorporation by reference, Intergovernmental relation, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Transportation, Volatile organic compounds.

Dated: March 24, 2010.

Lisa P. Jackson,

Administrator.

■ For the reasons discussed in the preamble, the EPA amends 40 CFR parts 51 and 52 as follows:

PART 51—[AMENDED]

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

§ 51.165 [Amended]

2. Effective April 1, 2010, 40 CFR 51.165(a)(1)(v)(G), (a)(1)(vi)(C)(3), (a)(1)(ix), (a)(1)(xxviii)(B)(2), (a)(1)(xxviii)(B)(*4*), (a)(1)(xxxv)(A)(*1*), (a)(1)(xxxv)(B)(*1*), (a)(1)(xxxv)(C), (a)(1)(xxxv)(D), (a)(2)(ii)(B), (a)(6)(iii), (a)(6)(iv), and (f)(4)(i)(D) are stayed until October 3, 2011.

3. Effective April 1, 2010 through October 3, 2011, amend 40 CFR 51.165 to add paragraph (a)(4) to read as follows:

§ 51.165 Permit requirements.

(a) * * *

(4) Each plan may provide that the provisions of this paragraph do not apply to a source or modification that would be a major stationary source or major modification only if fugitive emission to the extent quantifiable are considered in calculating the potential to emit of the stationary source or modification and the source does not belong to any of the following categories:

(i) Coal cleaning plants (with thermal dryers);

(ii) Kraft pulp mills;

(iii) Portland cement plants;

(iv) Primary zinc smelters;
(v) Iron and steel mills;
(vi) Primary aluminum ore reduction plants;
(vii) Primary copper smelters;
(viii) Municipal incinerators capable of charging more than 250 tons of refuse per day;
(ix) Hydrofluoric, sulfuric, or citric acid plants;
(x) Petroleum refineries;
(xi) Lime plants;
(xii) Phosphate rock processing plants;
(xiii) Coke oven batteries;
(xiv) Sulfur recovery plants;
(xv) Carbon black plants (furnace process);
(xvi) Primary lead smelters;
(xvii) Fuel conversion plants;
(xviii) Sintering plants;
(xix) Secondary metal production plants;
(xx) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
(xxi) Fossil-fuel boilers (or combination thereof) totaling more than 250 million British thermal units per hour heat input;
(xxii) Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;
(xxiii) Taconite ore processing plants;
(xxiv) Glass fiber processing plants;
(xxv) Charcoal production plants;
(xxvi) Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input;
(xxvii) Any other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the Act.

* * * * *

§ 51.166 [Amended]

■ 4. Effective April 1, 2010, 40 CFR 51.166(a)(7)(iv)(b), (b)(2)(v), (b)(3)(iii)(c), (b)(3)(iii)(*d*), (b)(20), (b)(40)(ii)(*b*), (b)(40)(ii)(d), (b)(47)(i)(*a*), (b)(47)(ii)(*a*), (b)(47)(iii), (b)(47)(iv), (r)(6)(iii) and (r)(6)(iv), and (w)(4)(i)(*d*) are stayed until March 31, 2010.

■ 5. Effective April 1, 2010 through October 3, 2011, amend 40 CFR 51.166 to add paragraph (i)(l)(ii) to read as follows:

§ 51.166 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(1) * * *

(ii) The source or modification would be a major stationary source or major modification only if fugitive emissions, to the extent quantifiable, are considered in calculating the potential to emit of the stationary source or modification and such source does not belong to any following categories:
(a) Coal cleaning plants (with thermal dryers);
(b) Kraft pulp mills;
(c) Portland cement plants;
(d) Primary zinc smelters;
(e) Iron and steel mills;
(f) Primary aluminum ore reduction plants;
(g) Primary copper smelters;
(h) Municipal incinerators capable of charging more than 250 tons of refuse per day;
(i) Hydrofluoric, sulfuric, or nitric acid plants;
(j) Petroleum refineries;
(k) Lime plants;
(l) Phosphate rock processing plants;
(m) Coke oven batteries;
(n) Sulfur recovery plants;
(o) Carbon black plants (furnace process);
(p) Primary lead smelters;
(q) Fuel conversion plants;
(r) Sintering plants;
(s) Secondary metal production plants;
(t) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
(u) Fossil-fuel boilers (or combination thereof) totaling more than 250 million British thermal units per hour heat input;
(v) Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;
(w) Taconite ore processing plants;
(x) Glass fiber processing plants;
(y) Charcoal production plants;
(z) Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input;
(aa) Any other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the Act; or

* * * * *

Appendix S to 40 CFR part 51 [Amended]

■ 6. Effective April 1, 2010, 40 CFR part 51, Appendix S, paragraphs II.A.5(vii), II.A.6(iii), II.A.9, II.A.24(ii)(*b*), II.A.24(ii)(*d*), II.A.30(i)(a), II.A.30(ii)(*a*), II.A.30(iii), II.A.30(iv), IV.I.1(ii), IV.J.3, IV.J.4, and IV.K.4(i)(*d*) are stayed until October 3, 2011.

■ 7. Effective April 1, 2010 through October 3, 2011, amend Appendix S to part 51 to add II.F to read as follows:

Appendix S to Part 51—Emission Offset Interpretative Ruling

* * * * *

II. * * *

F. *Fugitive emission sources.* Section IV.A. of this Ruling shall not apply to a source or modification that would be a major stationary source or major modification only if fugitive emissions, to the extent quantifiable, are considered in calculating the potential to emit of the stationary source or modification and such source does not belong to any following categories:
(1) Coal cleaning plants (with thermal dryers);
(2) Kraft pulp mills;
(3) Portland cement plants;
(4) Primary zinc smelters;
(5) Iron and steel mills;
(6) Primary aluminum ore reduction plants;
(7) Primary copper smelters;
(8) Municipal incinerators capable of charging more than 250 tons of refuse per day;
(9) Hydrofluoric, sulfuric, or nitric acid plants;
(10) Petroleum refineries;
(11) Lime plants;
(12) Phosphate rock processing plants;
(13) Coke oven batteries;
(14) Sulfur recovery plants;
(15) Carbon black plants (furnace process);
(16) Primary lead smelters;
(17) Fuel conversion plants;
(18) Sintering plants;
(19) Secondary metal production plants;
(20) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;
(21) Fossil-fuel boilers (or combination thereof) totaling more than 250 million British thermal units per hour heat input;
(22) Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;
(23) Taconite ore processing plants;
(24) Glass fiber processing plants;
(25) Charcoal production plants;
(26) Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input;
(27) Any other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the Act.

* * * * *

PART 52—[AMENDED]

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

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

§ 52.21 [Amended]

■ 9. Effective April 1, 2010, 40 CFR 52.21, (a)(2)(iv)(b), (b)(2)(v), (b)(3)(iii)(*b*), (b)(3)(iii)(*c*), (b)(20),(b)(41)(ii)(*b*), (b)(41)(ii)(*d*), (b)(48)(i)(*a*),(b)(48)(ii)(*a*), (b)(48)(iii), (b)(48)(iv), (r)(6)(iii), (r)(6)(iv), and (aa)(4)(i)(*d*) are stayed until October 3, 2011.

■ 10. Effective April 1, 2010 through October 3, 2011, amend 40 CFR 52.21 to add (i)(l)(vii) to read as follows:

§ 52.21 Prevention of significant deterioration of air quality.

* * * * *

(i) * * *

(1) * * *

(vii) The source or modification would be a major stationary source or major modification only if fugitive emissions, to the extent quantifiable, are considered in calculating the potential to emit of the stationary source or modification and the source does not belong to any of the following categories:

(a) Coal cleaning plants (with thermal dryers);

(b) Kraft pulp mills;

(c) Portland cement plants;

(d) Primary zinc smelters;

(e) Iron and steel mills;

(f) Primary aluminum ore reduction plants;

(g) Primary copper smelters;

(h) Municipal incinerators capable of charging more than 250 tons of refuse per day;

(i) Hydrofluoric, sulfuric, or nitric acid plants;

(j) Petroleum refineries;

(k) Lime plants;

(l) Phosphate rock processing plants;

(m) Coke oven batteries;

(n) Sulfur recovery plants;

(o) Carbon black plants (furnace process);

(p) Primary lead smelters;

(q) Fuel conversion plants;

(r) Sintering plants;

(s) Secondary metal production plants;

(t) Chemical process plants—The term chemical processing plant shall not include ethanol production facilities that produce ethanol by natural fermentation included in NAICS codes 325193 or 312140;

(u) Fossil-fuel boilers (or combination thereof) totaling more than 250 million British thermal units per hour heat input;

(v) Petroleum storage and transfer units with a total storage capacity exceeding 300,000 barrels;

(w) Taconite ore processing plants;

(x) Glass fiber processing plants;

(y) Charcoal production plants;

(z) Fossil fuel-fired steam electric plants of more than 250 million British thermal units per hour heat input;

(aa) Any other stationary source category which, as of August 7, 1980, is being regulated under section 111 or 112 of the Act; or

* * * * *

[FR Doc. 2010–7036 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0714; FRL–8816–3]

Cloquintocet-mexyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is amending 40 CFR 180.560 to add a reference to the active ingredient flucarbazone-sodium (wheat only) to the tolerance for the inert ingredient cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid) on wheat forage, wheat grain, wheat hay, and wheat straw. Arysta LifeScience North America, LLC requested this tolerance amendment under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective March 31, 2010. Objections and requests for hearings must be received on or before June 1, 2010, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0714. All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Karen Samek, Registration division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 347–8825; e-mail address: *samek.karen@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR cite at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2009–0714 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before June 1, 2010.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in

ADDRESSES. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2009–0714, by one of the following methods:

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

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Petition for Tolerance

EPA has received a petition from Arysta LifeScience North America, LLC, 15401 Weston Parkway, Cary, NC 27513, requesting an amendment to the existing tolerances for the inert ingredient (safener) (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinolinoxyacetic acid). For ease of reading this document, acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester will be referred to as cloquintocet-mexyl. EPA published two final rules to establish tolerances for the safener under 40 CFR 180.560 in the **Federal Register** of June 22, 2000 (65 FR 38757) (FRL–6592–4) and the **Federal Register** of December 16, 2005 (70 FR 74679) (FRL–7753–4). These tolerances establish tolerances for cloquintocet-mexyl when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients pinoxaden (wheat or barley) or clodinafop-propargyl (wheat only). In addition, a final rule that established tolerances for this safener was published in the **Federal Register** of March 5, 2008 (73 FR 11816) (FRL–8350–8). That final rule amended 40 CFR 180.560 by adding a reference to the active ingredient pyroxsulam (wheat only), and increased the existing tolerances for residues of cloquintocet-mexyl in or on wheat, forage and wheat, hay, and removed the specification of a 1:4 ratio inert ingredient safener to active ingredient from the tolerance expression.

In the **Federal Register** of October 7, 2009 (74 FR 51597) (FRL–8792–7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of the above-referenced pesticide petition (PP 9E7592) by Arysta LifeScience North America, LLC. The petition requested that 40 CFR 180.560 be amended by expanding the tolerance to cover cloquintocet-mexyl residues when used in formulation with the active ingredient flucarbazone-sodium on wheat. No numerical change to the tolerances for the specific wheat commodities was sought. That notice referenced a summary of the petition prepared by Arysta LifeScience North America, LLC, the registrant, which is available to the public in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

Consistent with section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the chemical. The Agency's decision document for this action is available on EPA's Electronic Docket at *http://www.regulations.gov/* under docket ID number EPA–HQ–OPP–2009–0714. For the full toxicity data and information on which this risk assessment is based, the reader is referred to the final rules establishing tolerances for cloquintocet-mexyl that published in in the **Federal Register** of March 5, 2008, December 16, 2005, and June 22, 2000.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by cloquintocet-mexyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rules published on March 5, 2008, December 16, 2005, and June 22, 2000. In these final rules, the Agency reviewed the available information on cloquintocet-mexyl submitted by the petitioners as well as additional information available to EPA. The toxicity database is sufficient for cloquintocet-mexyl and has not changed since the time of those publications. Therefore, only a brief summary is provided here.

Cloquintocet-mexyl has a low order of acute oral, dermal, and inhalation toxicity. It is slightly irritating to the eyes and non-irritating to the skin. Cloquintocet-mexyl is a skin sensitizer. The chemical is not genotoxic and is not a reproductive and developmental toxicant. There is no evidence of neurotoxicity in the available studies. Cloquintocet-mexyl is classified as "not likely to be a human carcinogen." The main metabolite for cloquintocet-mexyl is 5-chloro-8-quin-linoxyacetic acid, and testing on the metabolite is part of the toxicology database for cloquintocet-mexyl. For additional information on the human health toxicity data for cloquintocet-mexyl and its metabolite, see EPA's Electronic Docket at *http://www regulations.gov* and the **Federal Register** of March 5, 2008, December 16, 2005, and June 22, 2000.

B. Exposure Assessment

In examining aggregate exposure, the FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor

uses). In the 2008 rulemaking, EPA assessed human exposure to cloquintocet-mexyl from use on wheat and barley. EPA assumed that 100% of the wheat and barley crops were treated with cloquintocet-mexyl and that residues on all wheat and barley commodities were at the tolerance level. The Agency has determined that this assessment is sufficient for the current amendment to the cloquintocet-mexyl tolerance expression because no new crops are being added and the label requirements limit the total number of applications from all of the various cloquintocet-mexyl safener products to one application from this group of pesticides on a crop per growing season. For additional information on the exposure assessment for cloquintocet-mexyl, see the docket and the **Federal Register** of March 5, 2008.

C. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found cloquintocet-mexyl to share a common mechanism of toxicity with any other substances, and cloquintocet-mexyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that cloquintocet-mexyl does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA SF. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. There was no evidence of increased susceptibility of *in utero* or post-natal exposure to rats or rabbits in the prenatal developmental studies or in rats in the 2-generation reproduction study. NOAELs for maternal/parental toxicity were either less than or equal to the NOAELs for fetal or reproductive toxicity.

3. *Conclusion*. EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for cloquintocet-mexyl is complete, except for immunotoxicity and neurotoxicity studies. EPA began requiring these studies on December 26, 2009. In the absence of specific immunotoxicity studies, EPA has evaluated the available toxicity data for cloquintocet-mexyl and determined that an additional database uncertainty factor is not needed to account for potential immunotoxicity. EPA's determination is based on the following considerations.

There was some indication of possible immunotoxicity in the form of lymphoid hyperplasia of the thymus in male rats (without any histopathology changes in the study) at the LOAEL of 73.5 milligrams/kilogram/day (mg/kg/day) in the combined chronic/oncogenicity study in rats (with a NOAEL of 36.4 mg/kg/day). This effect was observed only in males. No blood parameters were affected. In addition, cloquintocet-mexyl does not belong to a class of chemicals that would be expected to be immunotoxic. A clear NOAEL was established for these effects (36.4 mg/kg/day), and the regulatory endpoint of 4.3 mg/kg/day (the NOAEL from the combined chronic/oncogenicity study) is nearly 10X below the NOAEL for the possible immunotoxic effect. Therefore, based on the considerations in this unit, EPA does not believe that conducting immunotoxicity testing will result in a NOAEL significantly less than the NOAEL of 4.3 mg/kg/day already established for cloquintocet-mexyl, and an additional factor (UFDB) for database uncertainties is not needed to account for potential immunotoxicity. A confirmatory immunotoxicity study will be required as a condition of the registration.

No acute and subchronic neurotoxicity studies are available, however, there is no evidence of neurotoxicity in the toxicology database on cloquintocet-mexyl. Therefore, based on the considerations in this unit, the Agency does not believe that conducting acute and subchronic neurotixicty studies will result in a NOAEL less than the NOAEL of 4.3 mg/kg/day. Therefore, there is no need for additional uncertainty factors (UF). Confirmatory acute and subchronic neurotoxicity studies will be required as a condition of registration.

ii. There is no indication of quantitative or qualitative increased susceptibility of rats or rabbits to *in utero* and/or postnatal exposure to cloquintocet-mexyl in the available toxicity database.

iii. There is no indication that cloquinocet-mexyl is a neurotoxic chemical and thus there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iv. The dietary (food and drinking water) exposure assessments will not underestimate the potential exposures for infants and children from the use of cloquintocet-mexyl (currently there are no proposed residential uses and therefore non-occupational exposure is not expected).

For additional information on the Safety Factor determination for infants and children for cloquintocet-mexyl, see the docket and the **Federal Register** of March 5, 2008.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate safty factors (SFs). EPA calculates the aPAD and cPAD by dividing the point of departure (POD) by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

In the 2005 and 2008 rulemakings for cloquintocet-mexyl, EPA concluded that aggregate risks from exposure to cloquintocet-mexyl did not exceed 1% of the aPAD or cPAD for the most exposed population groups. (73 FR 11819); (70 FR 74685). These findings are applicable to this tolerance amendment.

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to cloquintocet-mexyl and its acid metabolite (5-chloro-8-quinolinoxyacetic acid).

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Enviromental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; e-mail address: residuemethods@epa.gov. For the complete description of Analytical Methods for cloquintocet-mexyl, see the docket and the **Federal Register** of December 16, 2005.

B. International Residue Limits

There are no Codex tolerances for cloquintocet-mexyl.

V. Conclusions

Therefore, 40 CFR 180.560 is amended by establishing a tolerance for the combined residues of cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinlinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients flucarbazone-sodium (wheat only), pinoxaden (wheat or barley), clodinafop-propargyl (wheat only), or pyroxsulum (wheat only) in or on barley, grain at 0.1 ppm; barley, hay at 0.1 ppm; barley, straw at 0.1 ppm; wheat, forage at 0.2 ppm; wheat, grain at 0.1 ppm; wheat, hay at 0.5 ppm; and wheat, straw at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: March 22, 2010.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

■ Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

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

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.560, revise paragraph (a) to read as follows:

§ 180.560 Cloquintocet-mexyl; tolerances for residues.

(a) *General*. Tolerances are established for the combined residues of cloquintocet-mexyl (acetic acid [(5-chloro-8-quinolinyl) oxy]-, 1-methylhexyl ester; CAS Reg. No. 99607–70–2) and its acid metabolite (5-chloro-8-quinlinoxyacetic acid) when used as an inert ingredient (safener) in pesticide formulations containing the active ingredients, flucarbazone-sodium (wheat only), pinoxaden (wheat or barley), clodinafop-propargyl (wheat only), or pyroxsulum (wheat only) in or on the following food commodities:

Commodity	Parts per million
Barley, grain	0.1
Barley, hay	0.1
Barley, straw	0.1
Wheat, forage	0.2
Wheat, grain	0.1
Wheat, hay	0.5
Wheat, straw	0.1

* * * * *

[FR Doc. 2010–6890 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 0910131362–0087–02]

RIN 0648–XV61

Fisheries of the Exclusive Economic Zone Off Alaska; Pollock in the West Yakutat District of the Gulf of Alaska

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

ACTION: Temporary rule; modification of a closure.

SUMMARY: NMFS is opening directed fishing for pollock in the West Yakutat District of the Gulf of Alaska (GOA). This action is necessary to fully use the 2010 total allowable catch (TAC) of pollock in the West Yakutat District of the GOA.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), March 26, 2010, through 2400 hrs, A.l.t., December 31, 2010. Comments must be received at the following address no later than 4:30 p.m., A.l.t., April 12, 2010.

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–XV61, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal: *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. No comments will be posted to *http://www.regulations.gov* for public viewing until after the comment period has closed. Comment will generally be posted 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 (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Josh Keaton, 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.

NMFS closed directed fishing for pollock in the West Yakutat District of the GOA under § 679.20(d)(1)(iii) on March 23, 2010 (75 FR 14498, March 26, 2010).

As of March 25, 2010, NMFS has determined that approximately 681 metric tons of pollock remain in the directed fishing allowance for pollock in the West Yakutat District of the GOA. Therefore, in accordance with § 679.25(a)(1)(i), (a)(2)(i)(C), and (a)(2)(iii)(D), and to fully utilize the 2010 TAC of pollock in the West Yakutat District of the GOA, NMFS is terminating the previous closure and is reopening directed fishing for pollock in the West Yakutat District of the GOA. The Administrator, Alaska Region (Regional Administrator) considered the following factors in reaching this decision: (1) the current catch of pollock in the West Yakutat District of the GOA and, (2) the harvest capacity and stated intent on future harvesting patterns of vessels in participating in this fishery.

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 opening of pollock in the West Yakutat District 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, 2010.

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.

Without this inseason adjustment, NMFS could not allow the fishery for pollock in the West Yakutat District of the GOA to be harvested in an expedient manner and in accordance with the regulatory schedule. Under § 679.25(c)(2), interested persons are invited to submit written comments on this action to the above address until April 12, 2010.

This action is required by § 679.20 and § 679.25 and is exempt from review under Executive Order 12866.

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

Dated: March 26, 2010.

Emily H. Menashes,

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

[FR Doc. 2010–7231 Filed 3–26–10; 4:15 pm]

BILLING CODE 3510–22–S

Proposed Rules

Federal Register

Vol. 75, No. 61

Wednesday, March 31, 2010

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2009–0982; Directorate Identifier 2009–NE–19–AD]

RIN 2120–AA64

Airworthiness Directives; Turbomeca S.A. MAKILA 1A and 1A1 Turboshaft Engines

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) issued 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: The installation of TU250 CS boards, however, has resulted in a few occurrences of erratic engine behaviour, in the form of unexpected N1 variations and/or illumination of the "GOV" warning light. The conclusions from an investigation by Turboméca are that these malfunctions are due to a lapse of quality control in the varnishing process applied to the boards, and that only boards in a specific serial number range, as defined under "Applicability" and referred to below as the "suspect batch," are affected.

We are proposing this AD to prevent loss of automatic engine control during flight due to an uncommanded engine roll-back, which could result in the inability to continue safe flight.

DATES: We must receive comments on this proposed AD by April 30, 2010.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

Contact Turbomeca, 40220 Tarnos, France; telephone 33 05 59 74 40 00; fax 33 05 59 74 45 15, for the service information identified in this proposed AD.

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 the same as the Mail address provided in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Kevin Dickert, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *kevin.dickert@faa.gov;* telephone (781) 238–7117, fax (781) 238–7199.

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–2009–0982; Directorate Identifier 2009–NE–19–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 with FAA personnel concerning this proposed AD. Using the search function of the Web site, anyone can find and read the comments in any of our dockets, including, if provided, the name of the individual who sent the comment (or signed the comment 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).

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 2009–0090, dated April 28, 2009 (referred to after this as "the MCAI"), to correct an unsafe condition for the specified products. The MCAI states:

> The installation of TU250 CS boards, however, has resulted in a few occurrences of erratic engine behaviour, in the form of unexpected N1 variations and/or illumination of the "GOV" warning light. The conclusions from an investigation by Turbomeca are that these malfunctions are due to a lapse of quality control in the varnishing process applied to the boards, and that only boards in a specific serial number range, as defined under "Applicability" and referred to below as the "suspect batch," are affected.

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

Relevant Service Information

Turbomeca S.A. has issued Mandatory Service Bulletins No. 298 73 0809, Version A, dated February 12, 2008; and No. 298 73 0810, Version B, dated April 27, 2009. 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 France, and is approved for operation in the United States. Pursuant to our bilateral agreement with France, 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 provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

Based on the service information, we estimate that this proposed AD would affect about 10 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with this proposed AD. The average labor rate is $85 per work-hour. Required parts would cost about $3,500 per product. Based on these figures, we estimate the cost of the proposed AD on U.S. operators to be $35,850.

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, Incorporation by reference, 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:

Turbomeca S.A.: Docket No. FAA–2009–0982; Directorate Identifier 2009–NE–19–AD.

Comments Due Date

(a) We must receive comments by April 30, 2010.

Affected Airworthiness Directives (ADs)

(b) None.

Applicability

(c) This AD applies to Turbomeca S.A. Makila 1A and 1A1 turboshaft engines with a comparator/selector (CS) board, part number (P/N) 0 177 99 716 0, and a serial number (S/N) between 241EL and 1192EL (inclusive) installed. These engines are installed on, but not limited to, Eurocopter AS 332 C, AS 332 C1, AS 332 L, and AS 332 L1 helicopters.

Reason

(d) The EASA AD 2009–0090, dated April 28, 2009, states that this AD results from the following:

(1) The installation of TU250 CS boards, however, has resulted in a few occurrences of erratic engine behaviour, in the form of unexpected N1 variations and/or illumination of the "GOV" warning light. The conclusions from an investigation by Turboméca are that these malfunctions are due to a lapse of quality control in the varnishing process applied to the boards, and that only boards in a specific serial number range, as defined under "Applicability" and referred to below as the "suspect batch", are affected.

(2) We are issuing this AD to prevent loss of automatic engine control during flight due to an uncommanded engine roll-back, which could result in the inability to continue safe flight.

Actions and Compliance

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

(1) Within 50 operating hours from the effective date of this AD, replace any CS board, P/N 0 177 99 716 0, with an S/N from 241EL to 1192EL (inclusive), that has fewer than 200 hours-since-new (HSN). Use paragraph 2 of Turbomeca S.A. Mandatory Service Bulletin (MSB) No. 298 73 0809 Version A, dated February 12, 2008, to replace the boards.

(2) During the next 500-hour inspection, replace any CS board, P/N 0 177 99 716 0, with a S/N from 241EL to 1192EL (inclusive), that has 200 HSN or more. Use paragraph 2 of Turbomeca S.A. MSB No. 298 73 0810 Version B, dated April 27, 2009, to replace the boards.

FAA AD Differences

(f) This AD differs from the Mandatory Continuing Airworthiness Information (MCAI) and/or service information as follows:

(1) This AD requires replacing within 50 operating hours after the effective date of this AD, all comparator/selector boards, P/N 0 177 99 716 0, with an S/N from 241EL to 1192EL (inclusive) that have fewer than 200 HSN.

(2) This AD requires replacing at the next 500-hour routine inspection after the effective date of this AD, all comparator/selector boards, P/N 0 177 99 716 0, with a S/N from 241EL to 1192EL (inclusive) that have 200 HSN or more.

Other FAA AD Provisions

(g) *Alternative Methods of Compliance (AMOCs):* The Manager, Engine Certification Office, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19.

Related Information

(h) Refer to MCAI EASA Airworthiness Directive 2009–0090, dated April 28, 2009, and Turbomeca S.A. Mandatory Service Bulletins No. 298 73 0809, Version A, dated February 12, 2008; and No. 298 73 0810, Version B, dated April 27, 2009, for related information. Contact Turbomeca, 40220 Tarnos, France; telephone 33 05 59 74 40 00; fax 33 05 59 74 45 15, for a copy of this service information.

(i) Contact Kevin Dickert, Aerospace Engineer, Engine Certification Office, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; e-mail: *kevin.dickert@faa.gov;* telephone (781) 238–7117, fax (781) 238–7199, for more information about this AD.

Issued in Burlington, Massachusetts, on March 19, 2010.

Peter A. White,

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

[FR Doc. 2010–7160 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2010–0071; Airspace Docket No. 10–AAL–1]

RIN 2120–AA66

Proposed Amendment of Norton Sound Low and Control 1234L Offshore Airspace Areas; Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify the Norton Sound Low and Control 1234L Offshore Airspace Areas in Alaska. This action would lower the airspace floors to provide controlled airspace beyond 12 miles from the coast of the United States given that there is a requirement to provide Instrument Flight Rules (IFR) en route Air Traffic Control (ATC) services and within which the United States is applying domestic ATC procedures.

DATES: Comments must be received on or before May 17, 2010.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; telephone: (202) 366–9826. You must identify FAA Docket No. FAA–2010–0071 and Airspace Docket No. 10–AAL–1 at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ken McElroy, Airspace and Rules Group, Office of System Operations Airspace and AIM, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments 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 (FAA Docket No. FAA–2010–0071 and Airspace Docket No. 10–AAL–1) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2010–0071 and Airspace Docket No. 10–AAL–1." 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 action 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 NPRMs

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/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9 a.m. 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 Alaskan Service Center, Operations Support Group, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513.

Persons interested in being placed on a mailing list for future NPRMs should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to modify the Norton Sound Low and Control 1234L Offshore Airspace Areas in Alaska.

The Norton Sound Low Offshore Airspace Area would be modified by lowering the offshore airspace floor to 1,200 feet mean sea level (MSL) at the following airports; within 73 miles of Clarks Point, King Salmon, Kivalina, Kwethluk, Napakiak, Scammon Bay, Shaktooklik, and Tooksook Bay; within 74 miles of Elim and Manokotak, and within 72.5 miles of Red Dog.

The Control 1234L Offshore Airspace Area would be modified by lowering the offshore airspace floor to 1,200 feet above the surface within 73 miles of Nikolski, and Toksook Bay Airports.

Offshore airspace areas are published in paragraph 2003 of FAA Order 7400.9T dated August 27, 2009 and effective September 15, 2009, which is incorporated by reference in 14 CFR 71.1. The offshore airspace areas listed in this document will 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. Therefore, this proposed regulation: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) 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 proposed 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 the 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 offshore airspace areas in Alaska.

ICAO Considerations

As part of this proposal relates to navigable airspace outside the United States, this notice is submitted in accordance with the International Civil Aviation Organization (ICAO) International Standards and Recommended Practices.

The application of International Standards and Recommended Practices by the FAA, Office of System Operations Airspace and AIM, Airspace and Rules Group, in areas outside the United States domestic airspace, is governed by the Convention on International Civil Aviation. Specifically, the FAA is governed by Article 12 and Annex 11, which pertain to the establishment of necessary air navigational facilities and services to promote the safe, orderly, and expeditious flow of civil air traffic. The purpose of Article 12 and Annex 11 is to ensure that civil aircraft operations on international air routes are performed under uniform conditions.

The International Standards and Recommended Practices in Annex 11 apply to airspace under the jurisdiction of a contracting state, derived from ICAO. Annex 11 provisions apply when air traffic services are provided and a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting this responsibility may apply the International Standards and Recommended Practices that are consistent with standards and practices utilized in its domestic jurisdiction.

In accordance with Article 3 of the Convention, state-owned aircraft are exempt from the Standards and Recommended Practices of Annex 11. The United States is a contracting state to the Convention. Article 3(d) of the Convention provides that participating state aircraft will be operated in international airspace with due regard for the safety of civil aircraft. Since this action involves, in part, the designation of navigable airspace outside the United States, the Administrator is consulting with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, "Environmental Impacts: Policies and Procedures," prior to any FAA final regulatory action.

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, 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 FAA Order 7400.9T, Airspace Designations and Reporting Points, signed August 27, 2009, and effective September 15, 2009, is to be amended as follows:

Paragraph 6007 Offshore Airspace Areas.

* * * * *

Norton Sound Low, AK [Amended]

That airspace extending upward from 14,500 feet MSL within an area bounded by a line beginning at lat. 56°42′59″ N., long. 160°00′00″ W., north by a line 12 miles from and parallel to the U.S. coastline to the intersection with 164°00′00″ W., longitude near the outlet to Kotzebue Sound, then north to the intersection with a point 12 miles from the U.S. coastline, then north by a line 12 miles from and parallel to the shoreline to lat. 68°00′00″ N., to lat. 68°00′00″ N., long. 168°58′23″ W., to lat. 65°00′00″ N., long. 168°58′23″ W., to lat. 62°35′00″ N., long. 175°00′00″ W., to lat. 59°59′57″ N., long. 168°00′08″ W., to lat. 57°45′57″ N., long. 161°46′08″ W., to lat. 58°06′57″ N., long. 160°00′00″ W., to the point of beginning; and that airspace extending upward from 1,200 feet MSL north of the Alaska Peninsula and east of 160° W. longitude within 73 miles of the Port Heiden NDB/DME, AK, and north of the Alaska Peninsula and east of 160° W. longitude within an 81.2-mile radius of the Perryville Airport, AK, and north of the Alaska Peninsula and east of 160° W. longitude within a 72.8-mile radius of the Chignik Airport, AK, and within a 35-mile radius of lat. 60°21′17″ N., long. 165°04′01″ W., and within a 73-mile radius of the Chevak Airport, AK, and within a 73-mile radius of the Clarks Point Airport, AK, and within a 73-mile radius of the Elim Airport, AK, and within a 45-mile radius of the Hooper Bay Airport, AK, and within a 73-mile radius of the King Salmon Airport, AK, and within a 73-mile radius of the Kivalina Airport, AK, and within a 74-mile radius of the Kotzebue VOR/DME, AK, and within a 73-mile radius of the Kwethluk Airport, AK, and within a 74-mile radius of the Manokotak Airport, AK, and within a 73-mile radius of the Napakiak Airport, AK, and within a 77.4-mile radius of the Nome VORTAC, AK, and within a 71NM radius of the New Stuyahok Airport, AK, and within a 73-mile radius of the Noatak Airport, AK, and within a 72.5-mile radius of the Red Dog Airport, AK, and within a 73-mile radius of the Scammon Bay Airport, AK, and within a 73-mile radius of the Shaktoolik Airport, AK, and within a 74-mile radius of the Selawik Airport, AK, and within a 73-mile radius of the St. Michael Airport, AK, and within a 73-mile radius of the Toksook Bay Airport, AK, and within a 30-mile radius of lat. 66°09′58″ N., long. 166°30′03″ W., and within a 30-mile radius of lat. 66°19′55″ N., long. 165°40′32″ W., and that airspace extending upward from 700 feet MSL within 8 miles west and 4 miles east of the 339° bearing from the Port Heiden NDB/DME, AK, extending from the Port Heiden NDB/DME, AK, to 20 miles north of the Port Heiden NDB/DME, AK, and within a 25-mile radius of the Nome Airport, AK.

* * * * *

Control 1234L, AK [Amended]

That airspace extending upward from 2,000 feet above the surface within an area bounded by a line beginning at lat. 58°06′57″ N., long. 160°00′00″ W., then south along 160°00′00″ W. longitude, until it intersects the Anchorage Air Route Traffic Control Center (ARTCC) boundary; then southwest, northwest, north, and northeast along the Anchorage ARTCC boundary to lat. 62°35′00″ N., long. 175°00′00″ W., to lat. 59°59′57″ N., long. 168°00′08″ W., to lat. 57°45′57″ N., long. 161°46′08″ W., to the point of beginning; and that airspace extending upward from 1,200 feet above the surface within a 26.2-mile radius of Eareckson Air Station, AK, within an 11-mile radius of Adak Airport, AK, and within 16 miles of Adak Airport, AK, extending clockwise from the 033° bearing to the 081° bearing from the Mount Moffett NDB, AK, and within a 10-mile radius of Atka Airport, AK, and within a 10.6-mile radius from Cold Bay Airport, AK, and within 9 miles east and 4.3 miles west of the 321° bearing from Cold Bay Airport, AK, extending from the 10.6-mile radius to 20 miles northwest of Cold Bay Airport, AK, and 4 miles each side of the 070° bearing from Cold Bay Airport, AK, extending from the 10.6-mile radius to 13.6 miles northeast of Cold Bay Airport, AK, and within a 26.2-mile radius of Eareckson Air Station, AK, and west of 160° W. longitude within an 81.2-mile radius of Perryville Airport, AK, and within a 73-mile radius of the Nikolski Airport, AK, within a 74-mile radius of the Manokotak Airport, AK, and within a 73-mile radius of the Clarks Point Airport, AK and west of 160° W. longitude within a 73-mile radius of the Port Heiden NDB/DME, AK, and within a 10-mile radius of St. George Airport, AK, and within a 73-mile radius of St. Paul Island Airport, AK, and within a 20-mile radius of Unalaska Airport, AK, extending clockwise from the 305° bearing from the Dutch Harbor NDB, AK, to the 075° bearing from the Dutch Harbor NDB, AK, and west of 160° W. longitude within a 25-mile radius of the

Borland NDB/DME, AK, and west of 160° W. longitude within a 72.8-mile radius of Chignik Airport, AK; and that airspace extending upward from 700 feet above the surface within a 6.9-mile radius of Eareckson Air Station, AK, and within a 7-mile radius of Adak Airport, AK, and within 5.2 miles northwest and 4.2 miles southeast of the 061° bearing from the Mount Moffett NDB, AK, extending from the 7-mile radius of Adak Airport, AK, to 11.5 miles northeast of Adak Airport, AK, and within a 6.5-mile radius of King Cove Airport, and extending 1.2 miles either side of the 103° bearing from King Cove Airport from the 6.5-mile radius out to 8.8 miles, and within a 6.4-mile radius of the Atka Airport, AK, and within a 6.3-mile radius of Nelson Lagoon Airport, AK, and within a 6.3-mile radius of the Nikolski Airport, AK, and within a 6.4-mile radius of Sand Point Airport, AK, and within 3 miles each side of the 172° bearing from the Borland NDB/DME, AK, extending from the 6.4-mile radius of Sand Point Airport, AK, to 13.9 miles south of Sand Point Airport, AK, and within 5 miles either side of the 318° bearing from the Borland NDB/DME, AK, extending from the 6.4-mile radius of Sand Point Airport, AK, to 17 miles northwest of Sand Point Airport, AK, and within 5 miles either side of the 324° bearing from the Borland NDB/DME, AK, extending from the 6.4-mile radius of Sand Point Airport, AK, to 17 miles northwest of the Sand Point Airport, AK, and within a 6.6-mile radius of St. George Airport, AK, and within an 8-mile radius of St. Paul Island Airport, AK, and 8 miles west and 6 miles east of the 360° bearing from St. Paul Island Airport, AK, to 14 miles north of St. Paul Island Airport, AK, and within 6 miles west and 8 miles east of the 172° bearing from St. Paul Island Airport, AK, to 15 miles south of St. Paul Island Airport, AK, and within a 6.4-mile radius of Unalaska Airport, AK, and within 2.9 miles each side of the 360° bearing from the Dutch Harbor NDB, AK, extending from the 6.4-mile radius of Unalaska Airport, AK, to 9.5 miles north of Unalaska Airport, AK; and that airspace extending upward from the surface within a 4.6-mile radius of Cold Bay Airport, AK, and within 1.7 miles each side of the 150° bearing from Cold Bay Airport, AK, extending from the 4.6-mile radius to 7.7 miles southeast of Cold Bay Airport, AK, and within 3 miles west and 4 miles east of the 335° bearing from Cold Bay Airport, AK, extending from the 4.6-mile radius to 12.2 miles northwest of Cold Bay Airport, AK.

Issued in Washington, DC, on March 24, 2010.

Kelly Neubecker,

Acting Manager, Airspace and Rules Group.

[FR Doc. 2010–7266 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2009–0282; FRL–9131–5]

Approval and Promulgation of State Implementation Plan Revisions; State of North Dakota; Air Pollution Control Rules, and Interstate Transport of Pollution for the 1997 $PM_{2.5}$ and 8-Hour Ozone NAAQS: "Significant Contribution to Nonattainment" and "Interference With Prevention of Significant Deterioration" Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of North Dakota on April 6, 2009. Specifically, EPA is proposing approval of revisions to the North Dakota air pollution control rules regarding prevention of significant deterioration of air quality, and partial approval of the SIP revision "Interstate Transport of Air Pollution" addressing the requirements of Clean Air Act section 110(a)(2)(D)(i) for the 1997 $PM_{2.5}$ and 8-hour ozone National Ambient Air Quality Standards (NAAQS). For the latter, EPA proposes approval of the North Dakota Interstate Transport SIP sections that address the requirements of section 110(a)(2)(D)(i) prohibiting a state's emissions from contributing significantly to any other state's nonattainment of the NAAQS, or from interfering with any other state's required measures to prevent significant deterioration of its air quality. EPA will act at a later date on the North Dakota Interstate Transport SIP sections that address the remaining two requirements of section 110(a)(2)(D)(i), prohibiting a state's emissions from interfering with any other state's maintenance of the NAAQS, or with any other state's required measures to protect visibility. This action is being taken under section 110 of the Clean Air Act.

DATES: Comments must be received on or before April 30, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2009–0282, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-mail: videtich.callie@epa.gov* and *mastrangelo.domenico@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail:* Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- *Hand Delivery:* Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2009–0282. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other

material, such as copyrighted material, will be publicly available only in hard copy. Publicly-available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Domenico Mastrangelo, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–6436, *mastrangelo.domenico@epa.gov.*

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *North Dakota* and *State* mean the State of North Dakota.

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I. General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. What Action Is EPA Proposing?

EPA is proposing approval of revisions to the State provisions on the prevention significant deterioration (PSD) of air quality in subsection 33–15–15–01.2 of the North Dakota Administrative Code (NDAC), and is also proposing partial approval of the North Dakota Interstate Transport of Air Pollution SIP for the 1997 $PM_{2.5}$ and 8-hour ozone National Ambient Air Quality Standards (NAAQS). The revisions to NDAC subsection 33–15–15–01.2, and the addition to the North Dakota SIP of section 7.8, "Interstate Transport of Air Pollution," were adopted by the State of North Dakota on April 1, 2009 and submitted to EPA on April 6, 2009. EPA is proposing to approve the revision of NDAC subsection 33–15–15–01.02, incorporating changes to 40 CFR 52.21 made by EPA through August 1, 2007. EPA also proposes to approve the language and demonstrations of the North Dakota Interstate Transport SIP that address two elements of section 110(a)(2)(D)(i): significant contribution to nonattainment of the NAAQS in any other state, element (1), and interference with required measures by any other state to prevent significant deterioration (PSD) of its air quality, element (3).

III. What Is the State Process To Submit This Material to EPA?

Section 110(k) of the CAA addresses EPA's rulemaking action on SIP submissions by states. The CAA requires states to observe certain procedural requirements in developing SIP revisions for submittal to EPA. Section 110(a)(2) of the CAA requires that each SIP revision be adopted after reasonable notice and public hearing. This must occur prior to the revision being submitted by a state to EPA.

The North Dakota Department of Health (NDDH) held a public hearing on October 7, 2008 for revisions to subsection 33–15–15–01.02 of the NDAC and for the addition to the North Dakota SIP of the Interstate Transport non-regulatory provisions. The NDDH adopted the provisions on April 1, 2009 and submitted them to EPA on April 6, 2009.

In a March 2, 2010 email, EPA requested that the North Dakota Air Quality Division clarify the State commitment, stated in the Interstate Transport SIP submitted to EPA April 6, 2009, to EPA's interim policy on the use of PM_{10} as surrogate for $PM_{2.5}$. In a March 8, 2010 letter to the Region 8 Air Program, the North Dakota Air Quality Division clarified its interpretation of EPA's Surrogate Policy. This correspondence is included in this action's supporting docket available for public review.

We have evaluated the submittal by the NDDH and have determined that the State met the requirements of section 110(a)(2) of the CAA for reasonable notice and public hearing.

IV. EPA's Review and Technical Information

A. Prevention of Significant Deterioration Provisions

The revisions to subsection 33–15–15–01.2 updated to August 1, 2007 the baseline date for incorporation by reference of the Federal requirements at 40 CFR 52.21. In addition, various administrative corrections and clarifications were made. As these revisions were made to make the PSD provisions consistent with Federal requirements, they are approvable.

B. Interstate Transport SIP

The interstate transport provisions at CAA section 110(a)(2)(D)(i), also referred to as the "good neighbor"

provisions, require that each state SIP contain adequate provisions prohibiting emissions that adversely affect another state's air quality through interstate transport of air pollutants. Section 110(a)(2)(D)(i) contains four requirements or elements: (1) Significant contribution to nonattainment of the NAAQS in any other state; (2) interference with maintenance of the NAAQS by any other state; (3) interference with any other state's required measures to prevent significant deterioration of its air quality; and (4) interference with any other state's required measures to protect visibility. On August 15, 2006, EPA issued guidance for SIP submissions addressing the section 110(a)(2)(D)(i) requirements for the 1997 $PM_{2.5}$ and 8-hour ozone standards.[1] In November 2005 (70 FR 71612) and May 2008 (43 FR 28321), EPA finalized regulations implementing Phase II of the 1997 8-hour ozone NAAQS, and the New Source Review (NSR) Program for the 1997 $PM_{2.5}$ NAAQS.

To demonstrate that its SIP satisfies the requirements for significant contribution to nonattainment, North Dakota relies on a combination of: (a) EPA modeling analysis results published in Federal Register notices as part of the Clean Air Interstate Rule (CAIR) rulemaking process;[2] (b) monitoring data gathered by states and reported to EPA in the Air Quality System (AQS) database; and (c) consideration of geographical and meteorological factors affecting the likelihood of significant pollution transport from North Dakota to the closest $PM_{2.5}$ and 8-hour ozone nonattainment areas or violating monitors in other states. In this action EPA also expands on the analysis of geographical and meteorological factors, and of ozone and $PM_{2.5}$ concentration levels reflecting AQS monitoring data. EPA deems that the North Dakota Interstate Transport SIP sections addressing requirements (1) and (3) of section 110(a)(2)(D)(i) are consistent with EPA's 2006 guidance and the referenced implementation rules for ozone and $PM_{2.5}$.

Significant Contribution Element—$PM_{2.5}$

Section 110(a)(2)(D)(i) provides that EPA cannot approve a state's SIP for a new or revised NAAQS unless it contains adequate measures to prohibit emissions from sources within the state from contributing significantly to nonattainment of the NAAQS in another state. EPA's August 15, 2006, guidance to states concerning section 110(a)(2)(D)(i) recommended various methods by which states might evaluate whether or not its emissions significantly contribute to violations of the 1997 $PM_{2.5}$ standards in another state. Among other methods, EPA recommended consideration of available EPA modeling conducted in conjunction with CAIR, or in the absence of such EPA modeling, consideration of other information such as the amount of emissions, the geographic location of violating areas, meteorological data, or various other forms of information that would be relevant to assessing the likelihood of significant contribution to violations of the NAAQS in another state. It should be noted that significant contribution to nonattainment is not restricted to impacts upon areas that are formally designated nonattainment. Consistent with EPA's approach in CAIR, this impact must be evaluated with respect to monitors showing a violation of the NAAQS (70 FR 25172, May 12, 2005, and 63 FR 57371, October 27, 1998). Furthermore, although relevant information other than modeling may be considered in assessing the likelihood of significant contribution to violations of the 1997 $PM_{2.5}$ standard in another state, EPA notes that no single piece of information in the following discussion is by itself dispositive of the issue. Instead, the total weight of all the evidence taken together supports the conclusion that emissions within North Dakota do not significantly contribute to violations in another state of the 1997 $PM_{2.5}$ standard.

Although significant contribution must be measured not just against nonattainment areas, but against areas with monitors showing violations of the NAAQS, nonattainment areas are a convenient starting point for the analysis. For the 1997 annual $PM_{2.5}$ standard, Libby, in Lincoln County, Montana, and Chicago, in Cook County, Illinois, are the designated nonattainment areas closest to the State of North Dakota. In 2005, EPA designated both areas nonattainment for violations of the 1997 annual $PM_{2.5}$ standards. See 70 FR 944 (January 5, 2005), and 40 CFR 81.314 and 81.327.

A number of considerations provide evidence that North Dakota emissions are unlikely to contribute significantly to the violations of the 1997 annual $PM_{2.5}$ standards in Libby. First, Libby is more than 650 miles straight west of Bismarck, and any impact from North Dakota emissions would have to rely on strong easterly winds that rarely occur in the State.[3] This substantial distance and the rarity of easterly surface winds, while not outcome determinative given the distances across which $PM_{2.5}$ can transport, support a conclusion that North Dakota emissions are unlikely to contribute significantly to violations of the 1997 annual $PM_{2.5}$ standard in Libby. Second, in the process of designating Libby nonattainment for these standards, EPA noted the predominantly local origins of $PM_{2.5}$ nonattainment in Libby.[4] While the predominance of local sources does not alone rule out the possibility of impacts from interstate transport, this fact in conjunction with the distance and the near absence of easterly winds in North Dakota supports a conclusion that North Dakota emissions are unlikely to contribute significantly to violations in Libby. Third, during the ten years for which monitoring data are available, from 1999 to 2008, annual $PM_{2.5}$ design values at all other monitors in Montana remained significantly below the 15 $\mu g/m^3$ nonattainment threshold. Annual $PM_{2.5}$ design values for most of these monitors remained at levels equal to, or less than, two thirds of the NAAQS. Even the three highest design values at these monitors were 20 percent lower than the level of the annual standard.[5]

The fact that monitors located between North Dakota and Libby are not registering violations of the NAAQS does not conclusively establish that emissions from North Dakota could not contribute in the aggregate to violations

[1] Memorandum from William T. Harnett entitled "Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards," (Aug. 15, 2006) ("2006 Guidance"). This EPA guidance document is one of the documents available for review in the docket document entitled: "Relevant Guidance and Supporting Documentation for the Proposed Rulemaking **Federal Register** Action Docket ID # EPA–R08–OAR–2009–0282."

[2] In this action the expression "CAIR" refers to the final rule published in the May 12, 2005 **Federal Register** and entitled "Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to NO_X SIP Call; Final Rule" (70 FR 25162).

[3] Distances from Bismarck, North Dakota, to areas in other states are intended to approximate the average transport distance of emissions from sources in North Dakota to such areas. For surface wind directions, *see* "Climate of North Dakota-Wind," USGS web page at *http://www.npwrc.usgs.gov/resource/habitat/climate/wind.htm,* visited February 10, 2010, and available for review in EPA's January 14, 2010 docket memorandum: "Relevant Guidance and Supporting Documentation for the Proposed Rulemaking **Federal Register** Action Docket ID # EPA–R08–OAR–2009–0282."

[4] "Technical Support for State and Tribal Air Quality Fine Particle ($PM_{2.5}$) Designations," Chapter 6, pp. 347–352, December 2004.

[5] In 2001, 2002 and 2006, design values for two monitors in Missoula County were 11.1, 11.4 and 11.8 $\mu g/m^3$. Computed from AQS monitoring data.

in Libby, but this fact combined with other relevant evidence such as the distance, wind direction, and localized nature of the violations in Libby again supports the North Dakota's Interstate Transport SIP conclusion on $PM_{2.5}$ contribution. Finally, by 2007–2008, the annual $PM_{2.5}$ design values for the Libby nonattainment area itself fell below the level of the NAAQS, a reduction attributed to an effective wood stove replacement program that decreased $PM_{2.5}$ emissions by approximately 59 percent.[6] In other words, were there emissions from North Dakota sources reaching Libby, they would no longer be significantly contributing to violations of the NAAQS in that location.

Similarly, available information indicates that North Dakota emissions are unlikely to contribute significantly to the violations of the 1997 annual $PM_{2.5}$ standards in Cook County Illinois. In its rulemaking process for CAIR, EPA determined which states should be subject to the rule due to their significant contribution to nonattainment of the 1997 $PM_{2.5}$ NAAQS in other states. This determination included a modeling analysis of the contributions by upwind states to a violating monitor in Cook County, which is approximately 750 miles southeast of Bismarck, North Dakota. According to modeling cited in the CAIR proposal of January 30, 2004 (69 FR 4566), EPA estimated that the maximum contribution by emissions from sources in North Dakota to downwind counties predicted to have violating monitors for the $PM_{2.5}$ annual standard in the 2010 base year was to Cook County. EPA estimated that the North Dakota annual average contribution to Cook County would be 0.12 μg/m³ (Table V–5, 69 FR 4608), an amount well below 0.20 μg/m³, the threshold set by EPA in CAIR for the initial determination of whether a state would be subject to the rule (70 FR 25188–91).[7] The CAIR modeling analysis thus provides support for the conclusion that emissions from North Dakota are not significantly contributing to violations of the 1997 annual $PM_{2.5}$ NAAQS in Cook County.[8]

As mentioned above, EPA must consider not only significant contribution to nonattainment areas, but also to areas with monitors showing violations of the NAAQS. A review of the AQS monitoring data for adjacent downwind states shows that it is highly unlikely that emissions from North Dakota contribute significantly to downwind areas that have monitors showing violations of the 1997 24-hour and annual $PM_{2.5}$ NAAQS. Between 1999 and 2008 there were no violations of the 1997 $PM_{2.5}$ NAAQS at any of the monitors in adjacent downwind states, such as Minnesota, South Dakota and Iowa.[9]

In South Dakota, monitors in Minnehaha and Brookings Counties had the highest design values for 1997 24-hour $PM_{2.5}$ standards during the 1999–2008 period. Their design values ranged, respectively, from 23 to 28 and from 21 to 26 μg/m³, as compared with the 1997 24-hour $PM_{2.5}$ NAAQS of 65 μg/m³. For annual $PM_{2.5}$, Codington and Minnehaha Counties had the monitors with the highest design values, ranging from 9.5 to 10.3 μg/m³, and from 9.3 to 10.4 μg/m³, respectively, as compared to the annual NAAQS of 15 μg/m³.

In Minnesota, during 1999–2008, the highest design values for 1997 24-hour $PM_{2.5}$ NAAQS occurred for monitors in the Twin Cities' Hennepin and Ramsey Counties, where they ranged, respectively, from 23 to 32 and from 26 to 36 μg/m³. The highest design values for annual $PM_{2.5}$ reflected $PM_{2.5}$ monitored levels also in these two counties, and ranged, respectively, from 8.9 to 11.9 μg/m³ and from 10.7 to 13.8 μg/m³. It must be noted that the highest design value of 13.8 μg/m³, for a monitor in Ramsey County, reflected annual $PM_{2.5}$ concentrations registered during the 1999–2001 time span. After 2001, $PM_{2.5}$ concentrations in Ramsey County decreased steadily, and between 2006 and 2008 the highest design value for any of the Minnesota monitoring stations was 11.2 μg/m³, significantly below the annual NAAQS.

In Iowa, the highest 24-hour $PM_{2.5}$ design values during the 1999–2008 years reflected pollutant concentrations registered at monitors in Clinton and Muscatine Counties. In these counties, design values ranged, respectively, from 28 to 36 and from 34 to 38 μg/m³, as compared with the 1997 24-hour $PM_{2.5}$ NAAQS of 65 μg/m³. The highest annual $PM_{2.5}$ design values occurred in the same counties, and ranged from 11.7 to 14.1 μg/m³ in Clinton County, and from 12.5 to 13.3 μg/m³ in Muscatine County.

The data and weight of evidence analysis presented above support the conclusion of the North Dakota Interstate Transport SIP (adopted April 1, 2009 and submitted April 6, 2009) that emissions from North Dakota do not contribute significantly to nonattainment in any other state for the 1997 $PM_{2.5}$ NAAQS, consistently with the requirements of element (1) of CAA section 110(a)(2)(D)(i).

Significant Contribution Element—8-Hour Ozone

As noted above, Section 110(a)(2)(D)(i) provides that EPA cannot approve a state's SIP for a new or revised NAAQS unless it contains adequate measures to prohibit emissions from sources within the state from contributing significantly to nonattainment of the NAAQS in another state. EPA's August 15, 2006, guidance to states concerning section 110(a)(2)(D)(i) recommended various methods by which states might evaluate whether or not its emissions significantly contribute to violations of the 1997 ozone standards in another state. Among other methods, EPA recommended consideration of available EPA modeling conducted in conjunction with CAIR, or in the absence of such EPA modeling, consideration of other information such as the amount of emissions, the geographic location of violating areas, meteorological data, or various other forms of information that would be relevant to assessing the likelihood of significant contribution to violations of the NAAQS in another state. The assessment of significant contribution to nonattainment is not restricted to impacts upon areas that are formally designated nonattainment. Consistent with EPA's approach in CAIR, this impact must be evaluated with respect to monitors showing a violation of the NAAQS (70 FR 25172, May 12, 2005, and 63 FR 57371, October 27, 1998). Furthermore, although relevant information other than modeling may be considered in assessing the likelihood of significant contribution to violations of the 1997 8-hour ozone standard in another state, EPA notes that no single piece of information in the following discussion is by itself dispositive of the issue. Instead, the total weight of all the evidence taken together supports the conclusion that emissions from North Dakota sources are unlikely to contribute significantly to violations in another state of the 1997 8-hour ozone standard.

[6] State of Montana, Department of Environmental Quality, "State Implementation Plan-Libby Annual $PM_{2.5}$ Control Plan," submitted to EPA April 1, 2008.

[7] This threshold was upheld by the U.S. Court of Appeals for the DC Circuit in its adjudication of consolidated challenges to CAIR. *See North Carolina* v. *EPA,* 531 F.3d 896, 930 (DC Cir. 2008).

[8] As EPA only evaluated sources of NO_X and SO_2 in CAIR, the CAIR modeling analysis, like the other evidence considered in this action, is not by itself dispositive of the issue of significant contribution.

[9] Unless otherwise referenced, for AQS monitoring data and related design values referenced in this action see Table 1 and Table 2 in the docket document entitled: "Relevant Guidance and Supporting Documentation for the Proposed Rulemaking **Federal Register** Action Docket ID # EPA–R08–OAR–2009–0282."

Although significant contribution must be measured not just against nonattainment areas, but against areas with monitors showing violations of the NAAQS, nonattainment areas are a convenient starting point for the analysis. For the 1997 8-hour ozone NAAQS, the North Dakota Interstate Transport SIP revision identifies the Denver Metro Area/North Front Range (DMA/NFR) in Colorado, and the Illinois and Wisconsin counties along the southwestern shores of Lake Michigan as the closest designated nonattainment areas.[10] EPA's evaluation of whether emissions from North Dakota contribute significantly to the ozone nonattainment in these areas is based on an examination of how geographical and meteorological factors affect transport from North Dakota to the two areas noted above. Our approach does not rely on a quantitative determination of North Dakota's contribution, as EPA did for other states in its CAIR rulemaking, but on a weight-of-evidence analysis based on qualitative assessments and estimates of the relevant factors. While conclusions reached for each of the factors considered in the following analysis are not in and by themselves determinative, consideration of the likely effect of all factors provides a reliable qualitative conclusion on whether North Dakota's emissions are likely to contribute significantly to nonattainment in the DMA/NFR area and the Illinois/Wisconsin Counties.

The DMA/NFR nonattainment area is approximately 550 miles southwest of Bismarck, North Dakota.[11] Distance per se is not an obstacle to long range transport of ozone and/or its precursors, as discussed in the January 30, 2004 notice proposing CAIR (69 FR 4599); NO_X (the primary ozone precursor that was the object of the CAIR transport study) may be transported for long distances, contributing significantly to high ozone concentrations in other states. However, with increasing distance there are greater opportunities for ozone and/or NO_X dispersion and/or removal from the atmosphere due to the effects of winds and chemical sink processes. In this context, one may conclude that the 550 mile distance between North Dakota and the DMA/NFR reduces but does not exclude the possibility of significant contribution to this area's nonattainment.

Another transport factor is wind direction. Research for North Dakota and states immediately to the south and east shows that in North Dakota both surface and regional transport winds from the northeast, needed to transport ozone to the DMA/NFR area, are generally rare. Thirty years of data collected by the United States Geological Survey (USGS) on surface wind direction for several North Dakota locations show that there was much variability by location and time of the year, with the exception of northeasterly winds, which were very infrequent.[12] For long range transport winds, a modeling analysis of ozone dispersion during the summer months (June to August) of the five year period 1991–1995 shows that on high local ozone days North Dakota and states immediately to the south or east were characterized by southerly regional transport winds. On high regional ozone days, during the same period transport winds did not have a prevailing orientation, and certainly not a northeasterly one.[13] To the extent that these results are representative of general ozone transport patterns not limited to the 1991–95 period, the rarity of northeasterly winds in North Dakota and adjacent areas provides evidence that NO_X emissions from North Dakota are likely to be transported in a direction away from the Colorado DMA/NFR nonattainment area, and therefore supports the conclusion that emissions sources in North Dakota are unlikely to contribute significantly to violations of the 1997 ozone NAAQS in Denver.[14]

The Illinois/Wisconsin counties along the southwestern shores of Lake Michigan (which make up the other nonattainment area within possible transport distance of North Dakota) are approximately 700 miles east-southeast from Bismarck. The CAIR modeling domain for 8-hour ozone transport analysis included only the eastern half of North Dakota, and the CAIR modeling analysis did not determine whether NO_X emissions from North Dakota sources contributed significantly to ozone nonattainment in any downwind states.[15] However, the CAIR modeling analysis results for Minnesota provide us the opportunity to draw inferences about ozone contribution from North Dakota sources to nonattainment in the Illinois/Wisconsin area. It must be noted that Minnesota is nearly half as distant from this nonattainment area as North Dakota (400 miles as compared with 700),[16] and that to reach the Illinois/Wisconsin nonattainment area, ozone transport winds from Minnesota would have to have a northwesterly orientation similar to that necessary for substantial ozone transport from North Dakota. In addition, the CAIR modeling analysis estimated the Minnesota's NO_X emissions for the 2010 base year to be approximately twice as large as the NO_X emissions from North Dakota's sources (381,500 as compared with 182, 800 tons).[17] Finally, the CAIR analysis determined that emissions from Minnesota were below the initial threshold for including states in CAIR.[18] In light of this CAIR determination, and of Minnesota's larger NO_X emissions and shorter distance to the nonattainment area, it is plausible to conclude that NO_X emissions from North Dakota sources are not likely to contribute significantly to nonattainment of the 1997 8-hour ozone standard in the Illinois and Wisconsin counties along the southwestern shores of Lake Michigan.

Additional ozone transport factors specific to North Dakota are distance from the nonattainment area and prevailing orientation of the winds. As noted above, Bismarck is approximately 700 miles from the Illinois/Wisconsin nonattainment area, a distance which does not exclude the realistic possibility that significant ozone transport might occur. Research on surface wind direction in North Dakota, reflected in the USGS data referenced earlier, shows a great variability depending on location and time of the year. Northwesterly winds are more frequent than southwesterly or southeasterly winds considered separately, but less frequent

[10] The Wisconsin nonattainment areas for the 1997 8-hour ozone standard include: Door, Kewaunee, Manitowoc, Sheboygan, Ozaukee, Washington, Milwaukee, Waukesha, Racine and Kenosha counties; the Chicago nonattainment area includes Cook County and several adjacent Illinois and Indiana counties (69 FR 23858, April 30, 2004).

[11] Distances from Bismarck, North Dakota, to areas in other states are intended to approximate the average transport distance of emissions from sources in North Dakota to such areas.

[12] *See* USGS data in EPA's January 14, 2010 docket memorandum: "Relevant Guidance and Supporting Documentation for the Proposed Rulemaking **Federal Register** Action Docket ID # EPA–R08–OAR–2009–0282."

[13] Ozone Transport Assessment Group (OTAG), Air Quality Analysis Workgroup, "3.3 Climatology of Ozone Synoptic scale Transport in the Eastern US," Figures 1(a) and 5(a), pp. 3, 6, January 11, 1998. The high ozone days included the days with ozone concentrations in the 90th percentile.

[14] *Ibid.*

[15] 69 FR 4584 (Jan. 30, 2004) ("We are deferring findings for Texas, Oklahoma, Kansas, Nebraska, South Dakota and North Dakota, which at this time cannot be assessed on the same bases as States to the east because they are only partially included in the modeling domain * * *").

[16] The 400 mile distance to the nonattainment area is calculated from St. Cloud, and is intended to be a rough approximation of the average transport distance of NO_X emission sources from Minnesota.

[17] 69 FR 4590.

[18] Minnesota was not listed among the upwind states that contribute significantly to downwind counties projected nonattainment for 8-hour ozone in the 2010 base year, and is not a CAIR state for the 8-hour ozone standard. 69 FR 4602, Table V–2; 70 FR 25167.

than the two combined. On the other hand, as noted earlier in this review, during the ozone season of the years 1991–1995, on local high ozone days regional transport winds in North Dakota were predominantly southerly, and on high regional ozone days they lacked a prevailing orientation. There was no strong northwesterly component that might allow for significant transport of NO_X to the Illinois/Wisconsin area.[19] To the extent that these results are representative of general ozone transport patterns not limited to the 1991–95 period, one may add the relative infrequency of northwesterly transport winds from North Dakota to the other factors that make it unlikely for emissions from North Dakota sources to contribute significantly to nonattainment in the noted Illinois/Wisconsin area.

This conclusion is supported by the recent attainment demonstration developed for the nonattainment counties along the western shores of Lake Michigan by the Wisconsin Department of Natural Resources (WDNR). The WDNR analysis identifies heavy industrial activity and dense urbanization as the major local contributors to the high ozone concentrations in the Illinois and Wisconsin Counties along the southwestern shores of Lake Michigan. Regional ozone transport is thought to contribute from 40 to 60% of the maximum ozone concentrations in the Lake Michigan airshed, and the contributing transport is estimated to originate from south-southwesterly areas, within a span of 160 to 270 degrees. Any ozone transport from North Dakota would fall outside this span. The WDNR finding, in combination with the results of the analysis for other transport factors presented above, strengthens the conclusion that it is unlikely that emissions from North Dakota sources contribute significantly to the nonattainment of the Illinois/Wisconsin Counties on the southwestern shores of Lake Michigan.[20]

Finally, by 2008, the 8-hour ozone design values for the Illinois and Wisconsin nonattainment counties along the shores of Lake Michigan fell below the level of the NAAQS, a reduction attributed to the implementation of State and Federal control measures since the designation of these counties as nonattainment in 2004. In other words, were there emissions from North Dakota sources reaching the Illinois and Wisconsin counties along the western rim of Lake Michigan, they would no longer be significantly contributing to violations of the NAAQS in that area.[21]

As mentioned above, EPA must consider not only significant contribution to nonattainment areas, but also to areas with monitors showing violations of the NAAQS. A review of the AQS monitoring data for adjacent downwind states shows that it is highly unlikely that emissions from North Dakota contribute significantly to downwind areas that have monitors showing violations of the 1997 8-hour ozone NAAQS. Between 1999 and 2008 there were no violations of the 1997 8-hour ozone NAAQS at any of the monitors in adjacent downwind states, such as Minnesota, South Dakota and Iowa.

The design values for Minnesota, South Dakota and Iowa during the 1999–2008 years remained substantially below the 1997 NAAQS in most counties, as shown by the highest design values. In South Dakota, the highest design values were in Custer and Jackson Counties, where they peaked, respectively, at 71 and at 68 ppb. In Minnesota, the highest design values were in Anoka and Washington Counties, where they peaked at 75 ppb. In Iowa, the highest design values were in Clinton and Scott Counties, where they reached levels between 78 and 80 ppb in the early part of the 1999–2008 period, and decreased to levels, respectively, between 67 and 72, and 65 and 70 ppb during 2006–2008. The decrease of Iowa ozone levels between 1998 and 2008 can be gauged by comparing the peak levels of 79–80 ppb in 2000–2003 with peak levels of 70–75 ppb in 2006–2008.

The data and weight of evidence analysis presented above support the conclusion of the North Dakota Interstate Transport SIP (adopted April 1, 2009 and submitted April 6, 2009) that emissions from North Dakota do not contribute significantly to nonattainment in any other state for the 1997 8-hour ozone NAAQS, consistently with the requirements of element (1) of CAA section 110(a)(2)(D)(i).

Interference With PSD Element—$PM_{2.5}$ and Ozone

The third element of section 110(a)(2)(D)(i) requires a SIP to contain adequate provisions prohibiting emissions that interfere with any other state's required measures to prevent significant deterioration of its air quality. The State of North Dakota interstate transport SIP is consistent with the 2006 guidance. The SIP indicates in Section 7.8.1, subsection C, "Impact on Prevention of Significant Deterioration (PSD)," that the State's SIP provisions include an EPA-approved PSD program applicable to all regulated pollutants. North Dakota's regulations for its PSD program were federally-approved and made part of the SIP on November 2, 1979 (44 FR 63103). On July 19, 2007, EPA approved the North Dakota PSD revisions incorporating EPA's December 31, 2002 NSR Reforms into the State's regulations (72 FR 39564). North Dakota does not have nonattainment areas for any of the criteria pollutants and therefore does not have a Nonattainment New Source Review (NNSR) program.

Consistent with EPA's November 29, 2005 Phase II rule for the 1997 8-hour ozone standard (70 FR 71612), the State updated, effective April 1, 2009, its PSD provisions by incorporating by reference most of the federal provisions at 52.21, including the definition of regulated NSR pollutant at 52.21(b)(50), listing NO_X as an ozone precursor. As discussed elsewhere in this notice, EPA proposes in this action to approve the April 1, 2009 update. Thus, the April 1, 2009 update, taken together with interstate transport SIP section 7.8.1, subsection C, satisfies the requirements of the third element of CAA section 110(a)(2)(D)(i) for the 1997 8-hour ozone standard.

For $PM_{2.5}$, North Dakota's SIP declares that the State will follow EPA's interim guidance on use of PM_{10} as a surrogate for $PM_{2.5}$. In response to EPA's request of March 2, 2010, the North Dakota Air Quality Division, in a March 8, 2010 letter to the EPA Region 8 Air Program, has clarified an ambiguity in its interpretation of the interim guidance. The letter states that, until the guidance is ended or replaced, North Dakota will apply it consistent with EPA's interpretation of the federal case law relevant to the use of the PM_{10} Surrogate Policy (see 75 FR 6827, 6831–32, February 11, 2010). The State will also take into account the limits provided in the policy itself, such as the need to identify the technical difficulties that justify the application of the policy in each specific case (75 FR 6834). With that clarification, the North Dakota Interstate Transport SIP satisfies the requirements of the third element of section 110(a)(2)(D)(i) for the 1997 $PM_{2.5}$ NAAQS.

On the basis of the data and analysis presented above, EPA concludes that the North Dakota Interstate Transport

[19] *Ibid.*

[20] Wisconsin Department of Natural Resources, "Attainment Demonstration—The Wisconsin Counties of Kenosha, Racine, Milwaukee, Waukesha, Ozaukee, Washington, Sheboygan, Manitowoc and Door," pp. 8, 51, September 2009.

[21] *Ibid.* p. 14.

non-regulatory provisions adopted into the State SIP April 1, 2009 satisfactorily address the requirements of elements (1) and (3) of section 110(a)(2)(D)(i) for the 1997 $PM_{2.5}$ and 8-hour ozone standards.

V. Proposed Action

EPA is proposing approval of revisions, submitted by the Governor of North Dakota with a letter dated April 6, 2009, to the prevention of significant deterioration provisions in subsection 33–15–15 of the NDAC, and partial approval of the addition to the State SIP of the "Interstate Transport of Air Pollution" SIP addressing the requirements of Clean Air Act section 110(a)(2)(D)(i) for the 1997 $PM_{2.5}$ and 8-hour ozone National Ambient Air Quality Standards (NAAQS). For the North Dakota Interstate Transport SIP, EPA is proposing approval of: (a) The introductory language in the State SIP Section 7.8; (b) the "Overview" language in subsection A., Section 7.8.1; (c) language in Section 7.8.1, subsection B., "Nonattainment and Maintenance Area Impact," that specifically addresses element (1) of section 110(a)(2)(D)(i), the requirement that the SIP contain adequate provisions prohibiting emissions from North Dakota from contributing significantly to nonattainment in any other state; and (d) Section 7.8.1, subsection C, "Impact on Prevention of Significant Deterioration (PSD)."

VI. Statutory and Executive Order Review

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: March 18, 2010.

Carol L. Campbell,

Acting Assistant Regional Administrator, Region 8.

[FR Doc. 2010–6894 Filed 3–30–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2007–1032; FRL–9131–4]

Approval and Promulgation of State Implementation Plans; State of Colorado; Interstate Transport of Pollution Revisions for the 1997 8-Hour Ozone NAAQS: "Significant Contribution to Nonattainment" Requirement

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing partial approval of the State Implementation Plan (SIP) revisions "State of Colorado Implementation Plan to Meet the Requirements of Clean Air Act Section 110(a)(2)(D)(i)(I)—Interstate Transport Regarding the 1997 8-Hour Ozone Standard" submitted by the State of Colorado on June 18, 2009. The Colorado Interstate Transport SIP revisions submitted June 18, 2009 address the requirements of Clean Air Act section 110(a)(2)(D)(i)(I) for the 1997 8-hour ozone National Ambient Air Quality Standards (NAAQS). In this **Federal Register** action EPA proposes approval of the Colorado SIP sections that address the requirement of section 110(a)(2)(D)(i)(I) prohibiting a state's emissions from contributing significantly to any other state's nonattainment of the NAAQS. EPA will act at a later date on the Colorado Interstate Transport SIP sections that address the requirement prohibiting a state's emissions from interfering with any other state's maintenance of the NAAQS. This action is being taken under section 110 of the Clean Air Act.

DATES: Comments must be received on or before April 30, 2010.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2007–1032, by one of the following methods:

- *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *E-mail: videtich.callie@epa.gov* and *mastrangelo.domenico@epa.gov.*
- *Fax:* (303) 312–6064 (please alert the individual listed under **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail:* Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.

• *Hand Delivery:* Callie Videtich, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8 a.m. to 4:30 p.m., excluding Federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2007–1032. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA, without going through *http://www.regulations.gov*, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to Section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8 a.m. to 4 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Domenico Mastrangelo, Air Program, U.S. Environmental Protection Agency, Region 8, Mailcode 8P–AR, 1595 Wynkoop, Denver, Colorado 80202–1129, (303) 312–6436, *mastrangelo.domenico@epa.gov.*

SUPPLEMENTARY INFORMATION:

Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *Colorado* and *State* mean the State of Colorado.

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I. General Information

What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through *http://www.regulations.gov* or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. Background Information

Section 110(a)(2)(D)(i) of the CAA requires that a state's SIP must contain adequate provisions prohibiting any source or other type of emissions activity within the state from emitting any air pollutant in amounts which will: (1) Contribute significantly to nonattainment of the NAAQS in any other state; (2) interfere with maintenance of the NAAQS by any other state; (3) interfere with any other state's required measures to prevent significant deterioration of air quality; or (4) interfere with any other state's required measures to protect visibility. On June 11, 2008, the State of Colorado submitted to EPA an Interstate Transport SIP addressing the interstate transport requirements of CAA section 110(a)(2)(D)(i) for the 1997 $PM_{2.5}$ and 8-hour ozone NAAQS. In response to EPA's concerns with the June 11, 2008 submittal, on December 30, 2008 the State adopted and on June 18, 2009 submitted a revised SIP addressing the requirements of elements (1) and (2) of section 110(a)(2)(D)(i) for the 1997 8-hour ozone NAAQS. The State of Colorado is planning to submit in June 2010 further revisions addressing the requirements of elements (3) and (4) for the 1997 8-hour ozone NAAQS and the requirements of elements (1) through (4) for the 1997 $PM_{2.5}$ NAAQS.

III. What Action Is EPA Proposing?

EPA is proposing partial approval of the Colorado Interstate Transport of Air Pollution SIP addressing the requirements of CAA section 110(a)(2)(D)(i)(I) for the 1997 8-hour ozone NAAQS. On December 30, 2008, the Colorado Air Quality Control Commission (AQCC) adopted the "State of Colorado Implementation Plan to Meet the Requirements of the Clean Air Act Section 110(a)(2)(d)(i)(I)—Interstate Transport Regarding the 1997 8-Hour Ozone Standard." Colorado submitted the December 30, 2008 SIP revision to EPA on June 18, 2009. In this **Federal Register** action EPA is proposing to approve only the language and demonstration that addresses element (1) of section 110(a)(2)(D)(i): Prohibition of significant contribution to nonattainment of the 1997 8-hour ozone NAAQS in any other state.

IV. What Is the State Process To Submit These Materials to EPA?

Section 110(k) of the CAA addresses EPA's rulemaking action on SIP submissions by states. The CAA requires states to observe certain procedural requirements in developing SIP revisions for submittal to EPA. Section 110(a)(2) of the CAA requires that each SIP revision be adopted after reasonable notice and public hearing. This must occur prior to the revision being submitted by a state to EPA.

The Colorado AQCC held a public hearing in December 2008 for the interstate transport SIP revision: "State of Colorado Implementation Plan to Meet the Requirements of Clean Air Act Section 110(a)(2)(D)(i)(I)—Interstate Transport Regarding the 1997 8-Hour Ozone Standard." The AQCC adopted this revision on December 30, 2008, and the State submitted it to EPA on June 18, 2009.

On November 18, 2009, the AQCC provided EPA with an exact color duplicate of the SIP adopted by the AQCC on December 30, 2008 and included in the June 18, 2009 submittal to EPA. In the original submittal, AQCC provided a black and white copy. The SIP's color duplicate, available for review as part of the Docket, makes it easier to understand modeling results reported in several graphs that are part of the SIP technical demonstration.

EPA has reviewed the submittal from the State of Colorado and has determined that the State met the requirements for reasonable notice and public hearing under section 110(a)(2) of the CAA.

V. EPA's Review and Technical Information

The interstate transport provisions at CAA section 110(a)(2)(D)(i), also referred to as the "good neighbor" provisions, require that each state's SIP contain adequate provisions prohibiting emissions that adversely affect any other state's air quality through interstate transport of air pollutants. As discussed in the Background Information section of this notice, a state's SIP must contain provisions that satisfy the four elements of section 110(a)(2)(D)(i). On August 15, 2006, EPA issued guidance for SIP submissions addressing the requirements of section 110(a)(2)(D)(i) for the 1997 $PM_{2.5}$ and 8-hour ozone NAAQS.[1] The portions of the Colorado Interstate Transport SIP revision that address element (1) of section 110(a)(2)(D)(i) for the 1997 8-hour ozone NAAQS are consistent with EPA's 2006 guidance.

To demonstrate that emissions from Colorado do not contribute significantly to nonattainment of the 1997 8-hour ozone NAAQS in any other state, the Colorado Interstate Transport SIP relies on a combination of: (a) Modeling analysis done by the State as part of the attainment demonstration SIP for the Denver Metropolitan Area/North Front Range (DMA/NFR) nonattainment area for the 1997 8-hour ozone standard; (b) monitoring data gathered by states and reported to EPA in the Air Quality System (AQS) database; and (c) considerations of geographical and meteorological factors. In this action, EPA expands on the analysis of geographical and meteorological factors, and of ozone concentration levels reflecting AQS monitoring data.

Section 110(a)(2)(D)(i) provides that EPA cannot approve a state's SIP for a new or revised NAAQS unless it contains adequate measures to prohibit emissions from sources within the state from contributing significantly to nonattainment of the NAAQS in another state. EPA's August 15, 2006 guidance to states concerning section 110(a)(2)(D)(i) recommended various methods by which states might evaluate whether or not its emissions significantly contribute to violations of the 1997 ozone standards in another state. Among other methods, EPA recommended consideration of available EPA modeling conducted in conjunction with CAIR,[2] or in the absence of such EPA modeling, consideration of other information such as the amount of emissions, the geographic location of violating areas, meteorological data, or various other forms of information that would be relevant to assessing the likelihood of significant contribution to violations of the NAAQS in another state. The assessment of significant contribution to nonattainment is not restricted to impacts upon areas that are formally designated nonattainment. Consistent with EPA's approach in CAIR, this impact must be evaluated with respect to any monitors showing a violation of the NAAQS (70 FR 25172, May 12, 2005, and 63 FR 57371, October 27, 1998). Furthermore, although relevant information other than modeling may be considered in assessing the likelihood of significant contribution to violations of the 1997 8-hour ozone standard in another state, EPA notes that no single piece of information in the following discussion is by itself dispositive of the issue. Instead, the total weight of all the evidence taken together supports the conclusion that emissions from Colorado sources are unlikely to contribute significantly to violations of the 1997 8-hour ozone standard in any other state.

The Colorado Interstate Transport SIP uses results from Colorado's 2009 "8-Hour Ozone Attainment Plan" for the DMA/NFR nonattainment area, and a report from the Western States Air Resource (WESTAR) Council to underscore that: (a) Local anthropogenic ozone contribution to high ozone concentrations in Denver is only about 25%; and (b) on days of highest ozone concentrations (reflecting a design value of 84.9 ppb) in the DMA/NFR area, the projected design values decrease to 63 ppb or less for all downwind Colorado counties east of an imaginary north-south line approximately 70 miles east from Denver.[3] EPA does not accept the State of Colorado Interstate Transport SIP assessment that these results

[1] Memorandum from William T. Harnett entitled Guidance for State Implementation Plan (SIP) Submissions to Meet Current Outstanding Obligations Under Section 110(a)(2)(D)(i) for the 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards (Aug. 15, 2006) ("2006 Guidance"). Available for review in EPA's January 14, 2010 docket document entitled: "Relevant Guidance and Supporting Documentation for the Proposed Rulemaking **Federal Register** Action Docket ID # EPA–R08–OAR–2007–1032.

[2] In this action the expression "CAIR" refers to the final rule published in the May 12, 2005 **Federal Register** and entitled "Rule to Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to NO_X SIP Call; Final Rule" (70 FR 25162).

[3] See Figure 5, page 15 of the Interstate Transport SIP submitted June 18, 2009. It must be noted that the modeling analysis domain for the DMA/NFR attainment plan was limited to the State territory, and that the 70-mile distance represents the approximate distance from Denver to the western border of Morgan County.

demonstrate that "the magnitude of ozone transport from Colorado to other states is too low to significantly contribute to nonattainment in * * * any other state with respect to the 0.08 ppb NAAQS."[4] Similarly, EPA does not accept the claim in Colorado's SIP that the absence of violations of the 8-hour ozone NAAQS in adjacent downwind states such as Kansas, Nebraska and Wyoming suffices to show that emissions from Colorado sources do not significantly affect farther downwind ozone nonattainment areas such as St. Louis.[5] The relatively limited contribution of local emissions to nonattainment in the DMA/NFR, the quick drop in ozone levels in the easternmost Colorado counties, and even the substantial gap between the 1997 NAAQS and design values in adjacent downwind states do not exclude a potential significant contribution from Colorado emissions to downwind nonattainment areas. However, as a reflection of emission levels, the relatively (to the 1997 8-hour ozone NAAQS) moderate ozone concentrations in eastern Colorado and in adjacent downwind states somewhat reduces the probability of significant ozone contribution from Colorado emission sources to considerably farther downwind nonattainment areas such as St. Louis, Missouri, and Chicago, Illinois.

In addition, significant contribution should be measured not just against nonattainment areas, but also against areas with monitors showing violations of the NAAQS. That said, nonattainment areas are a convenient starting point for EPA's analysis. For the 1997 8-hour ozone NAAQS, the St. Louis area and the Illinois and Wisconsin Counties along the southwestern shore of Lake Michigan (Illinois/Wisconsin area) are the designated downwind nonattainment areas closest to Colorado.[6] EPA's evaluation of whether emissions from Colorado contribute significantly to ozone nonattainment in these areas relies on an examination of a variety of data and analysis that provide insight on ozone transport from Colorado to these two areas. Because EPA does not have detailed modeling for Colorado and nearby downwind states, our approach does not rely on a quantitative determination of Colorado's contribution, as EPA did for other states in its CAIR rulemaking, but on a weight-of-evidence analysis based on qualitative assessments and estimates of the relevant factors. While conclusions reached for each of the factors considered in the following analysis are not in and by themselves determinative, consideration of all of these factors provides a reliable qualitative conclusion on whether Colorado's emissions are likely to contribute significantly to nonattainment in the St. Louis and the Illinois/Wisconsin areas.

The Illinois/Wisconsin nonattainment area is approximately 900 miles east/northeast from the Colorado DMA/NFR area. Distance per se is not an obstacle to long range transport of ozone and/or its precursors, as discussed in the January 30, 2004 notice proposing CAIR (69 FR 4599). NOx, the primary ozone precursor that was the object of the CAIR transport study, may be transported for long distances, contributing significantly to high ozone concentrations in other states. However, with increasing distance there are greater opportunities for ozone or NO_X dispersion and/or removal from the atmosphere due to the effect of winds or chemical sink processes. As a result, one may conclude that the 900-mile distance from Colorado sources of NO_X emissions and the Illinois/Wisconsin area reduces, but does not exclude, the possibility of significant contribution to this area's nonattainment.

Another transport factor is wind direction. For long range transport winds, a modeling analysis of ozone dispersion during the summer months (June to August) of the five-year period 1991–1995 shows that on high local ozone days the prevailing long range transport winds in States immediately to the east and north of Colorado (Kansas, Nebraska, South Dakota, Iowa, Minnesota, and North Dakota) had a southerly direction. On high regional ozone days, during the same period, regional transport winds in the same States were southwesterly, but with a westerly component so weak that a greater portion of NO_X emissions from Colorado would likely remain significantly west of the Illinois/Wisconsin nonattainment area.[7] To the extent that these results are representative of general ozone transport patterns not limited to the 1991–1995 period, the weak western component of long range transport winds during high ozone days in the States east and north of Colorado provides evidence that NO_X emissions from Colorado are unlikely to contribute significantly to violations of the 1997 ozone NAAQS in the Illinois/Wisconsin counties along the southwestern shores of Lake Michigan.

Additional circumstantial evidence supporting this conclusion is found in technical documentation developed in recent years by the States of Kansas and Wisconsin. To support its Interstate Transport SIP, the State of Kansas submitted to EPA Region 7 technical documentation that includes back trajectory analyses gauging the pathway of air masses impacting the Illinois/Wisconsin nonattainment area on the four days with highest ozone concentrations during each of the years 2005–2007. The back trajectory analyses in Appendix G of the technical support section show that, for the four days with the highest ozone readings, none of the pathways followed by air masses moving into the Chicago Metropolitan Statistical Area (MSA) or into several of the Wisconsin nonattainment counties came from Colorado. Since these back trajectories refer to the pathways of air masses and not specifically to ozone transport, the results of this analysis cannot be considered determinative as to the significant contribution of ozone or NO_X from Colorado emissions to the nonattainment counties along the southwestern shores of Lake Michigan. However, the lack of any back trajectories from Colorado indicates that it is unlikely that NO_X emissions from the State contribute significantly to the nonattainment of the Illinois/Wisconsin area.

Further support is given by a recent attainment demonstration by the Wisconsin Department of Natural Resources (WDNR) for the nonattainment counties along the southwestern shores of Lake Michigan.[8] The WDNR analysis identifies heavy industrial activity and dense urbanization as the major local contributors to the high ozone concentrations in the Indiana, Illinois and Wisconsin Counties along the southwestern shores of Lake Michigan. Between 40 and 60 percent of the maximum ozone concentrations in the Lake Michigan airshed is attributed to

[4] "State of Colorado Implementation Plan to Meet the Requirements of Clean Air Act Section 110(a)(2)(D)(i)(I)—Interstate Transport Regarding the 1997 8-hour Ozone Standard," p. 17, December 12, 2009.

[5] Ibid., pp. 8–9.

[6] The Wisconsin nonattainment areas for the 1997 8-hour ozone standard include: Door, Kewaunee, Manitowoc, Sheboygan, Ozaukee, Washington, Milwaukee, Waukesha, Racine and Kenosha counties; the Chicago nonattainment area includes Cook County and several adjacent Illinois and Indiana counties (69 FR 23858, April 30, 2004).

[7] Ozone Transport Assessment Group (OTAG), Air Quality Analysis Workgroup: "3.3 Climatology of Ozone Synoptic Scale Transport in the Eastern US," Figures 1(a) and 5(a), pp. 3, 6, January 11, 1998. High ozone days were days with ozone concentrations in the 90th percentile.

[8] Wisconsin Department of Natural Resources, "Attainment Demonstration—The Wisconsin Counties of Kenosha, Racine, Milwaukee, Waukesha, Ozaukee, Washington, Sheboygan, Manitowoc and Door," September 2009.

regional transport, occurring from emission sources located within a south-southwesterly arc spanning from 160 to 270 degrees (compass direction). Colorado's location at the western margins of this arc (Denver is approximately 260 degrees southwest of Chicago) substantially reduces the likelihood for NO_X emissions from the State to contribute significantly to nonattainment in the Illinois/Wisconsin area.[9] Given the southerly orientation of regional transport winds in States east and north of Colorado, it is likely that Colorado ozone or NO_X emissions would be heavily dispersed in a northward direction west of this nonattainment area.

Finally, by 2008, the 8-hour ozone design values for the Illinois and Wisconsin nonattainment counties along the shores of Lake Michigan fell below the level of the NAAQS, a reduction attributed to the implementation of State and Federal control measures since the designation of these counties as nonattainment in 2004. In other words, were there emissions from Colorado sources reaching the Illinois and Wisconsin counties along the western rim of Lake Michigan, they would no longer be significantly contributing to violations of the NAAQS in that area.[10]

The other nonattainment area, St. Louis and adjacent counties, is approximately 800 miles straight east from the Colorado DMA/NFR area. This substantial distance does not, in and by itself, exclude the possibility of significant contribution from Colorado's NO_X emissions to nonattainment in the St. Louis area. However, it is also sufficient to provide many opportunities for ozone dispersion and removal from the atmosphere due to the effect of winds and chemical sink processes, and thus reduce the likelihood of significant contribution from Colorado to nonattainment in this area.

The impact of wind direction on ozone transport from Colorado to the St. Louis area is gauged through the results of several findings. Kansas, immediately east of Colorado and west of Missouri, is characterized by strong southerly surface winds that match prevailing regional transport winds, which have a southerly orientation during days of elevated ozone concentration. Throughout 2005 its winds averaged daily speeds slightly over 9 mph.[11] The OTAG modeling analysis referred to earlier shows that, during the five years from 1991 to 1995, on high ozone days regional transport winds in Kansas and Missouri have a prevailing southerly orientation. To the extent that these results are representative of general ozone transport patterns not limited to the 1991–95 period, they indicate that ozone/NO_X emissions from Colorado reaching Kansas or Missouri were very likely to be redirected northward and away from the St. Louis area, thus lessening the likelihood for a significant ozone contribution to nonattainment from Colorado.

Results from other studies are consistent with these tentative conclusions. In a study published by OTAG in 1997, the St. Louis area showed higher ozone concentrations (70 as compared with 55 ppb) on days with winds from the south or the east than on days with winds from the west (the general direction from Colorado) or southwest.[12] More recent back trajectory analyses gauging the pathway of air masses impacting St. Louis on days of high ozone allow similar conclusions. The State of Kansas' technical documentation supporting its Interstate Transport SIP (approved by EPA in March 2007) include back trajectory analyses independent of their source regions (i.e., Colorado or Kansas.) The results show that for each of the 2005–2007 years, on the four days with the highest ozone readings the frequency of trajectory "contribution" from Colorado to St. Louis was negligible. There is only one instance of a 500 meter trajectory from Colorado, while there were none for transport at 1500 meter of altitude.[13] These findings, in combination with the other circumstantial evidence examined above, strengthen the conclusion that it is unlikely that emissions from Colorado sources contribute significantly to the nonattainment of the St. Louis area.

As mentioned above, EPA must consider not only significant contribution to nonattainment areas, but also to areas with monitors showing violations of the NAAQS. A review of the AQS monitoring data for adjacent downwind states shows that it is highly unlikely that emissions from Colorado contribute significantly to downwind areas that have monitors showing violations of the 1997 8-hour ozone NAAQS. Between 1999 and 2008 there were no violations of the 1997 8-hour ozone NAAQS at any of the monitors in adjacent downwind states, such as Kansas, Nebraska and Wyoming.

Design values for the years 2005–2007[14] show that in adjacent downwind states such as Kansas, Nebraska, and Wyoming, there were no violations of the 1997 8-hour ozone NAAQS, and that in most counties ozone levels remained substantially below the NAAQS. In Kansas, the 2007 design value for Trego County, the county with a monitoring station closest to Colorado, was 71 ppb, or 16 percent below the ozone NAAQS. The counties that had the highest design values are at or near the eastern edge of the state, about 400 miles from Colorado's eastern border, and their design values ranged from 76 ppb for Johnson and Sumner Counties to 77 ppb for Leavenworth and Wyandotte Counties. In Nebraska and Wyoming, the highest ozone design values did not exceed 69 ppb in Douglas County, Nebraska and 72 ppb in Sublette County, Wyoming.

The historical trend over the period 1998–2008 for the 1997 8-hour ozone design values in these states places the 2005–2007 data reviewed above in context. In Nebraska, ozone design values were consistently low throughout the period. In Wyoming, design values were also constant in most of the monitored areas, where ozone monitoring only began between 2003 and 2005. Kansas design values show a clear trend of declining ozone levels from the late 1990s to the most recent years. In Linn, Sedgwick, and Sumner Counties, design values decreased from highs ranging between 77 and 82 ppb during 2000–2003 to levels ranging between 66 and 75 ppb in 2006–2008.

The data and weight of evidence analysis presented above support the conclusion of the Colorado Interstate Transport SIP (adopted into the State SIP on December 30, 2008 and submitted to EPA June 18, 2009) that emissions from Colorado do not contribute significantly to nonattainment in any other state for the 1997 8-hour ozone NAAQS, consistently with the requirements of element (1) of CAA section 110(a)(2)(D)(i).

VI. Proposed Action

EPA is proposing partial approval of the Colorado SIP to meet the requirements of Section 110(a)(2)(D)(i)(I) regarding the 1997 ozone standard. Specifically, in this action EPA is proposing to approve only the language and demonstration that, in this SIP revision, address the requirements of element (1): Prohibition of significant

[9] Ibid., p. 51.

[10] Ibid.

[11] See the January 4, 2007 State of Kansas submittal to EPA of Interstate Transport SIP revisions, Document ID# EPA–R07–OAR–2007–0141–0003, pp. 6–7.

[12] OTAG, "Ozone as Function of Local Wind Speed and Direction: Evidence of Local and Regional Transport," p. 33, July 26, 1997.

[13] Document ID# EPA–R07–OAR–2007–0141–0003, Appendix G.

[14] See Table 4, pages 7 and 8, of the Colorado Interstate Transport SIP.

contribution to nonattainment of the 1997 8-hour ozone NAAQS in any other state. At a later date, EPA will act on the language and demonstration addressing element (2): prohibition of interference with maintenance of the 1997 8-hour ozone NAAQS in any other state.

VII. Statutory and Executive Order Review

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile Organic Compounds.

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

Dated: March 18, 2010.

Carol L. Campbell,

Acting Deputy Regional Administrator, Region 8.

[FR Doc. 2010–6893 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 261

[EPA–R06–RCRA–2009–0549; SW–FRL–9131–6]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Proposed Exclusion

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule and request for comment.

SUMMARY: EPA is proposing to grant a petition submitted by Tokusen USA, Inc. (called just Tokusen hereinafter) to exclude (or delist) a wastewater treatment plant (WWTP) sludge filter cake (called just sludge hereinafter) generated by Tokusen in Conway, AR from the lists of hazardous wastes. EPA used the Delisting Risk Assessment Software (DRAS) in the evaluation of the impact of the petitioned waste on human health and the environment.

EPA bases its proposed decision to grant the petition on an evaluation of waste-specific information provided by the petitioner. This proposed decision, if finalized, would exclude the petitioned waste from the requirements of hazardous waste regulations under the Resource Conservation and Recovery Act (RCRA).

If finalized, EPA would conclude that Tokusen's petitioned waste is non-hazardous with respect to the original listing criteria. EPA would also conclude that Tokusen's process minimizes short-term and long-term threats from the petitioned waste to human health and the environment.

DATES: We will accept comments until April 30, 2010. We will stamp comments postmarked after the close of the comment period as "late." These "late" comments may not be considered in formulating a final decision.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–RCRA–2009–0549 by one of the following methods:

1. *Federal e-Rulemaking Portal: http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *E-mail: kim.youngmoo@epa.gov.*
3. *Mail:* Youngmoo Kim, Environmental Protection Agency, Multimedia Planning and Permitting Division, RCRA Branch, Mail Code: 6PD–C, 1445 Ross Avenue, Dallas, TX 75202.
4. *Hand Delivery or Courier:* Deliver your comments to: Youngmoo Kim, Environmental Protection Agency, Multimedia Planning and Permitting Division, RCRA Branch, Mail Code: 6PD–C, 1445 Ross Avenue, Dallas, TX 75202.

Instructions: Direct your comments to Docket ID No. EPA–R06–RCRA–2009–0549. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be

able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the Environmental Protection Agency, RCRA Branch, 1445 Ross Avenue, Dallas, TX 75202. The hard copy RCRA regulatory docket for this proposed rule, EPA–R06–RCRA–2009–0549, is available for viewing from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. The public may copy material from any regulatory docket at no cost for the first 100 pages, and at fifteen cents per page for additional copies. EPA requests that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: For technical information regarding the Tokusen, contact Youngmoo Kim at 214–665–6788 or by e-mail at *kim.youngmoo@epa.gov*.

Your requests for a hearing must reach EPA by April 15, 2010. The request must contain the information described in § 260.20(d).

SUPPLEMENTARY INFORMATION: The information in this section is organized as follows:

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I. Overview Information

A. What Action Is EPA Proposing?

EPA is proposing:

(1) To grant Tokusen's delisting petition to have its WWTP sludge excluded, or delisted, from the definition of a hazardous waste; and subject to certain verification and monitoring conditions.

(2) To use the Delisting Risk Assessment Software (DRAS) to evaluate the potential impact of the petitioned waste on human health and the environment. The Agency used this model to predict the concentration of hazardous constituents released from the petitioned waste, once it is disposed.

B. Why Is EPA Proposing To Approve This Delisting?

Tokusen's petition requests an exclusion from the F006 waste listing pursuant to 40 CFR 260.20 and 260.22. Tokusen does not believe that the petitioned waste meets the criteria for which EPA listed it. Tokusen also believes no additional constituents or factors could cause the waste to be hazardous. EPA's review of this petition included consideration of the original listing criteria and the additional factors required by the Hazardous and Solid Waste Amendments of 1984 (HSWA). *See* section 3001(f) of RCRA, 42 U.S.C. 6921(f), and 40 CFR 260.22(d)(1)–(4) (hereinafter all sectional references are to 40 CFR unless otherwise indicated). In making the initial delisting determination, EPA evaluated the petitioned waste against the listing criteria and factors cited in § 261.11(a)(2) and (a)(3). Based on this review, EPA agrees with the petitioner that the waste is non-hazardous with respect to the original listing criteria. If EPA had found, based on this review, that the waste remained hazardous based on the factors for which the waste was originally listed, EPA would have proposed to deny the petition. EPA evaluated the waste with respect to other factors or criteria to assess whether there is a reasonable basis to believe that such additional factors could cause the waste to be hazardous. EPA considered whether the waste is acutely toxic, the concentration of the constituents in the waste, their tendency to migrate and to bioaccumulate, their persistence in the environment once released from the waste, plausible and specific types of management of the petitioned waste, the quantities of waste generated, and waste variability. EPA believes that the petitioned waste does not meet the listing criteria and thus should not be a listed waste. EPA's proposed decision to delist waste from Tokusen is based on the information submitted in support of this rule, including descriptions of the wastes and analytical data from the Conway, AR facility.

C. How Will Tokusen Manage the Waste, if It Is Delisted?

If the sludge is delisted, the WWTP sludge from Tokusen will be disposed at a RCRA Subtitle D landfill: The Waste Management Industrial Landfill, North Little Rock, Arkansas.

D. When Would the Proposed Delisting Exclusion Be Finalized?

RCRA section 3001(f) specifically requires EPA to provide a notice and an opportunity for comment before granting or denying a final exclusion. Thus, EPA will not grant the exclusion until it addresses all timely public comments (including those at public hearings, if any) on this proposal.

RCRA section 3010(b)(1) at 42 USCA 6930(b)(1), allows rules to become effective in less than six months when the regulated facility does not need the six-month period to come into compliance. That is the case here, because this rule, if finalized, would reduce the existing requirements for persons generating hazardous wastes.

EPA believes that this exclusion should be effective immediately upon final publication because a six-month deadline is not necessary to achieve the purpose of section 3010(b), and a later effective date would impose unnecessary hardship and expense on this petitioner. These reasons also provide good cause for making this rule effective immediately, upon final publication, under the Administrative Procedure Act, 5 U.S.C. 553(d).

E. How Would This Action Affect States?

Because EPA is issuing this exclusion under the Federal RCRA delisting program, only states subject to Federal RCRA delisting provisions would be affected. This would exclude states which have received authorization from EPA to make their own delisting decisions.

EPA allows states to impose their own non-RCRA regulatory requirements that are more stringent than EPA's, under section 3009 of RCRA, 42 U.S.C. 6929. These more stringent requirements may include a provision that prohibits a Federally issued exclusion from taking effect in the state. Because a dual system (that is, both Federal (RCRA) and state (non-RCRA programs) may regulate a petitioner's waste, EPA urges petitioners to contact the state regulatory authority to establish the status of their wastes under the state law.

EPA has also authorized some states (for example, Louisiana, Oklahoma, Georgia, Illinois) to administer a RCRA delisting program in place of the Federal program, that is, to make state delisting decisions. Therefore, this exclusion does not apply in those authorized states unless that state makes the rule part of its authorized program. If Tokusen transports the petitioned waste to or manages the waste in any state with delisting authorization, Tokusen must obtain delisting authorization from that state before it can manage the waste as non-hazardous in the state.

II. Background

A. What Is the History of the Delisting Program?

EPA published an amended list of hazardous wastes from non-specific and specific sources on January 16, 1981, as part of its final and interim final regulations implementing section 3001 of RCRA. EPA has amended this list several times and published it in 40 CFR 261.31 and 261.32.

EPA lists these wastes as hazardous because: (1) The wastes typically and frequently exhibit one or more of the characteristics of hazardous wastes identified in Subpart C of Part 261 (that is, ignitability, corrosivity, reactivity, and toxicity), (2) the wastes meet the criteria for listing contained in § 261.11(a)(2) or (a)(3), or (3) the wastes are mixed with or derived from the treatment, storage or disposal of such characteristic and listed wastes and which therefore become hazardous under § 261.3(a)(2)(iv) or (c)(2)(i), known as the "mixture" or "derived-from" rules, respectively.

Individual waste streams may vary, however, depending on raw materials, industrial processes, and other factors. Thus, while a waste described in these regulations or resulting from the operation of the mixture or derived-from rules generally is hazardous, a specific waste from an individual facility may not be hazardous.

For this reason, 40 CFR 260.20 and 260.22 provide an exclusion procedure, called delisting, which allows persons to prove that EPA should not regulate a specific waste from a particular generating facility as a hazardous waste.

B. What Is a Delisting Petition, and What Does It Require of a Petitioner?

A delisting petition is a request from a facility to EPA or an authorized state to exclude wastes from the list of hazardous wastes. The facility petitions EPA because it does not consider the wastes hazardous under RCRA regulations.

In a delisting petition, the petitioner must show that wastes generated at a particular facility do not meet any of the criteria for which the waste was listed. The criteria for which EPA lists a waste are in part 261 and further explained in the background documents for the listed waste.

In addition, under 40 CFR 260.22, a petitioner must prove that the waste does not exhibit any of the hazardous waste characteristics (that is, ignitability, reactivity, corrosivity, and toxicity) and present sufficient information for EPA to decide whether factors other than those for which the waste was listed warrant retaining it as a hazardous waste. (*See* Part 261 and the background documents for the listed waste.)

Generators remain obligated under RCRA to confirm whether their waste remains non-hazardous based on the hazardous waste characteristics even if EPA has "delisted" the waste.

C. What Factors Must EPA Consider in Deciding Whether To Grant a Delisting Petition?

Besides considering the criteria in 40 CFR 260.22(a) and section 3001(f) of RCRA, 42 U.S.C. 6921(f), and in the background documents for the listed wastes, EPA must consider any factors (including additional constituents) other than those for which EPA listed the waste, if a reasonable basis exists that these additional factors could cause the waste to be hazardous.

EPA must also consider as hazardous waste mixtures containing listed hazardous wastes and wastes derived from treating, storing, or disposing of listed hazardous waste. *See* § 261.3(a)(2)(iii and iv) and (c)(2)(i), called the "mixture" and "derived-from" rules, respectively. These wastes are also eligible for exclusion and remain hazardous wastes until excluded. *See* 66 FR 27266 (May 16, 2001).

III. EPA's Evaluation of the Waste Information and Data

A. What Waste Did Tokusen Petition EPA To Delist?

On March 25, 2009, Tokusen petitioned EPA to exclude from the lists of hazardous wastes contained in § 261.31, WWTP sludge (F006) generated from its facility located in Conway, Arkansas. The waste falls under the classification of listed waste pursuant to § 261.31. Specifically, in its petition, Tokusen requested that EPA grant a standard exclusion for 2,000 cubic yards per year of the WWTP sludge.

B. Who Is Tokusen and What Process Does It Use To Generate the Petitioned Waste?

The Tokusen USA, Inc. facility produces high-carbon steel tire cord for use in radial tire manufacturing. The steel cord is produced from steel rod which has been reduced in size and electroplated with copper and zinc to produce a brass coating. The facility generates F006 filter cake by the dewatering of wastewater sludge generated at the on-site wastewater treatment plants. This waste is stored on-site less than 90 days and is then transported from the site to the RCRA Subtitle C facility, Chemical Waste Management in Sulphur, LA 70556.

C. How Did Tokusen Sample and Analyze the Data in This Petition?

To support its petition, Tokusen submitted:

(1) Historical information on waste generation and management practices;

(2) Analytical results from four samples for total concentrations of compounds of concern (COCs);

(3) Analytical results from four samples for Toxicity Characteristic Leaching Procedure (TCLP) extract values of COCs; and

(4) Multiple pH testing for the petitioned waste.

D. What Were the Results of Tokusen's Analyses?

EPA believes that the descriptions of the Tokusen analytical characterization provide a reasonable basis to grant Tokusen's petition for an exclusion of the WWTP sludge. EPA believes the data submitted in support of the petition show the WWTP sludge is non-hazardous. Analytical data for the

WWTP sludge samples included in the March 2009 petition were used in the DRAS to develop delisting levels. The data summaries for COCs are presented in Table I. EPA has reviewed the sampling procedures used by Tokusen and has determined that it satisfies EPA criteria for collecting representative samples of the variations in constituent concentrations in the WWTP sludge. In addition, the data submitted in support of the petition show that constituents in Tokusen's waste are presently below health-based levels used in the delisting decision-making. EPA believes that Tokusen has successfully demonstrated that the WWTP sludge is non-hazardous.

ANALYTICAL RESULTS/MAXIMUM ALLOWABLE DELISTING CONCENTRATION

[Wastewater treatment sludge; Tokusen, Conway, Arkansas]

Constituents	Maximum total (mg/kg)	Maximum TCLP (mg/L)	Maximum allowable TCLP delisting level (mg/L)
Antimony	11.9	<0.3	0.4
Arsenic	26.3	J 0.12	1.59
Barium	111	0.313	(100)
Chromium	38.9	<0.02	(5.0)
Cobalt	<9.69	0.059	0.8
Copper	4090	30	91.3
Lead	334	0.06	2.32
Nickel	35.6	0.774	50.5
Selenium	253	0.21	(1.0)
Acetone	0.0293	BJ 0.0429	1950
Zinc	26400	553	748

Notes:

1. These levels represent the highest constituent concentration found in any one sample and do not necessarily represent the specific level found in one sample.
2. The delisting levels are from the DRAS analyses except the chemical concentrations with a parenthesis which are the TCLP regulatory levels.
3. J: Estimated Value.

E. How Did EPA Evaluate the Risk of Delisting This Waste?

For this delisting determination, EPA used such information gathered to identify plausible exposure routes (*i.e.,* groundwater, surface water, air) for hazardous constituents present in the petitioned waste. EPA determined that disposal in a landfill is the most reasonable, worst-case disposal scenario for Tokusen's petitioned waste. EPA applied the Delisting Risk Assessment Software (DRAS) described in 65 FR 58015 (September 27, 2000), 65 FR 75637 (December 4, 2000), and 73 FR 28768 (May 19, 2008) to predict the maximum allowable concentrations of hazardous constituents that may be released from the petitioned waste after disposal and determined the potential impact of the disposal of Tokusen's petitioned waste on human health and the environment. A copy of this software can be found on the world wide web at *http://www.epa.gov/reg5rcra/wptdiv/hazardous/delisting/dras-software.html.* In assessing potential risks to groundwater, EPA used the maximum waste volumes and the maximum reported extract concentrations as inputs to the DRAS program to estimate the constituent concentrations in the groundwater at a hypothetical receptor well down gradient from the disposal site. Using the risk level (carcinogenic risk of 10^{-5} and non-cancer hazard index of 1.0). The DRAS program can back-calculate the acceptable receptor well concentrations (referred to as compliance-point concentrations) using standard risk assessment algorithms and EPA health-based numbers. Using the maximum compliance-point concentrations and EPA's Composite Model for Leachate Migration with Transformation Products (EPACMTP) fate and transport modeling factors, the DRAS further back-calculates the maximum permissible waste constituent concentrations not expected to exceed the compliance-point concentrations in groundwater.

EPA believes that the EPACMTP fate and transport model represents a reasonable worst-case scenario for possible groundwater contamination resulting from disposal of the petitioned waste in a landfill, and that a reasonable worst-case scenario is appropriate when evaluating whether a waste should be relieved of the protective management constraints of RCRA Subtitle C. The use of some reasonable worst-case scenarios resulted in conservative values for the compliance-point concentrations and ensures that the waste, once removed from hazardous waste regulation, will not pose a significant threat to human health or the environment.

The DRAS also uses the maximum estimated waste volumes and the maximum reported total concentrations to predict possible risks associated with releases of waste constituents through surface pathways (*e.g.,* volatilization from the landfill). As in the above groundwater analyses, the DRAS uses the risk level, the health-based data and standard risk assessment and exposure algorithms to predict maximum compliance-point concentrations of waste constituents at a hypothetical point of exposure. Using fate and transport equations, the DRAS uses the maximum compliance-point concentrations and back-calculates the maximum allowable waste constituent concentrations (or "delisting levels").

In most cases, because a delisted waste is no longer subject to hazardous waste control, EPA is generally unable to predict, and does not presently control, how a petitioner will manage a waste after delisting. Therefore, EPA currently believes that it is inappropriate to consider extensive site-specific factors when applying the fate and transport model. EPA does control the type of unit where the waste is disposed. The waste must be disposed in the type of unit the fate and transport model evaluates.

The DRAS results which calculate the maximum allowable concentration of chemical constituents in the waste are presented in Table I. Based on the comparison of the DRAS and TCLP Analyses results found in Table I, the petitioned waste should be delisted

because no constituents of concern tested are likely to be present or formed as reaction products or by-products in Tokusen waste.

F. What Did EPA Conclude About Tokusen's Analysis?

EPA concluded, after reviewing Tokusen's processes that no other hazardous constituents of concern, other than those for which tested, are likely to be present or formed as reaction products or by-products in the waste. In addition, on the basis of explanations and analytical data provided by Tokusen, pursuant to § 260.22, EPA concludes that the petitioned waste do not exhibit any of the characteristics of ignitability, corrosivity, reactivity or toxicity. *See* §§ 261.21, 261.22 and 261.23, respectively.

G. What Other Factors Did EPA Consider in Its Evaluation?

During the evaluation of Tokusen's petition, EPA also considered the potential impact of the petitioned waste via non-groundwater routes (*i.e.,* air emission and surface runoff). With regard to airborne dispersion in particular, EPA believes that exposure to airborne contaminants from Tokusen's petitioned waste is unlikely. Therefore, no appreciable air releases are likely from Tokusen's waste under any likely disposal conditions. EPA evaluated the potential hazards resulting from the unlikely scenario of airborne exposure to hazardous constituents released from Tokusen's waste in an open landfill. The results of this worst-case analysis indicated that there is no substantial present or potential hazard to human health and the environment from airborne exposure to constituents from Tokusen's WWTP waste.

H. What Is EPA's Evaluation of This Delisting Petition?

The descriptions of Tokusen's hazardous waste process and analytical characterization provide a reasonable basis for EPA to grant the exclusion. The data submitted in support of the petition show that constituents in the waste are below the leachable concentrations (*see* Table I). EPA believes that Tokusen's waste, F006 from copper and zinc electroplating process to produce a brass coating will not impose any threat to human health and the environment.

Thus, EPA believes Tokusen should be granted an exclusion for the WWTP sludge. EPA believes the data submitted in support of the petition show Tokusen's WWTP sludge is non-hazardous. The data submitted in support of the petition show that constituents in Tokusen's waste are presently below the compliance point concentrations used in the delisting decision and would not pose a substantial hazard to the environment. EPA believes that Tokusen has successfully demonstrated that the WWTP sludge is non-hazardous.

EPA therefore, proposes to grant an exclusion to Tokusen in Conway, Arkansas, for the WWTP sludge described in its petition. EPA's decision to exclude this waste is based on descriptions of the treatment activities associated with the petitioned waste and characterization of the WWTP sludge.

If EPA finalizes the proposed rule, EPA will no longer regulate the petitioned waste under Parts 262 through 268 and the permitting standards of Part 270. Tokusen must comply with the LDR requirements before disposing of the delisted waste because the LDR attaches at the point of generation of the waste. The delisting, if granted, will absolve the generator from his obligation of handling the waste as hazardous. The appropriate waste code for this waste is F006. The LDR treatment standard for F006 is found in 40 CFR 268.40.

IV. Next Steps

A. With What Conditions Must the Petitioner Comply?

The petitioner, Tokusen, must comply with the requirements in 40 CFR Part 261, Appendix IX, Table 1. The text below gives the rationale and details of those requirements.

(1) *Delisting Levels:*

This paragraph provides the levels of constituents for which Tokusen must test the WWTP sludge, below which these wastes would be considered non-hazardous. EPA selected the set of inorganic and organic constituents specified in paragraph (1) of 40 CFR Part 261, Appendix IX, Table 1, (the exclusion language) based on information in the petition. EPA compiled the inorganic and organic constituents list from the composition of the waste, descriptions of Tokusen's treatment process, previous test data provided for the waste, and the respective health-based levels used in delisting decision-making. These delisting levels correspond to the allowable levels measured in the TCLP concentrations.

(2) *Waste Holding and Handling:*

The purpose of this paragraph is to ensure that Tokusen manages and disposes of any WWTP sludge that contains hazardous levels of inorganic and organic constituents according to Subtitle C of RCRA. Managing the WWTP sludge as a hazardous waste until initial verification testing is performed will protect against improper handling of hazardous material. If EPA determines that the data collected under this paragraph do not support the data provided for in the petition, the exclusion will not cover the petitioned waste. The exclusion is effective upon publication in the **Federal Register** but the disposal as non-hazardous cannot begin until the verification sampling is completed.

(3) *Verification Testing Requirements:*

Tokusen must complete a rigorous verification testing program on the WWTP sludge to assure that the sludge does not exceed the maximum levels specified in paragraph (1) of the exclusion language. This verification program operates on two levels. The first part of the verification testing program consists of testing the WWTP sludge for specified indicator parameters as per paragraph (1) of the exclusion language. If EPA determines that the data collected under this paragraph do not support the data provided for the petition, the exclusion will not cover the generated wastes. If the data from the initial verification testing program demonstrate that the leachate meets the delisting levels, Tokusen may request quarterly testing. EPA will notify Tokusen in writing, if and when it may replace the testing conditions in paragraph (3)(A) with the testing conditions in (3)(B) of the exclusion language.

The second part of the verification testing program is the quarterly testing of representative samples of WWTP sludge for all constituents specified in paragraph (1) of the exclusion language. EPA believes that the concentrations of the constituents of concern in the WWTP sludge may vary over time. Consequently this program will ensure that the sludge is evaluated in terms of variation in constituent concentrations in the waste over time.

The proposed subsequent testing would verify that Tokusen operates a treatment facility where the constituent concentrations of the WWTP sludge do not exhibit unacceptable temporal and spatial levels of toxic constituents. EPA is proposing to require Tokusen to analyze representative samples of the WWTP sludge quarterly during the first year of waste generation. Tokusen would begin quarterly sampling 60 days after the final exclusion as described in paragraph (3)(B) of the exclusion language.

EPA, per paragraph 3(C) of the exclusion language, is proposing to end the subsequent testing conditions after

the first year, if Tokusen has demonstrated that the waste consistently meets the delisting levels. To confirm that the characteristics of the waste do not change significantly over time, Tokusen must continue to analyze a representative sample of the waste on an annual basis. Annual testing requires analyzing the full list of components in paragraph (1) of the exclusion language. If operating conditions change as described in paragraph (4) of the exclusion language; Tokusen must reinstate all testing in paragraph (1) of the exclusion language. Tokusen must prove through a new demonstration that their waste meets the conditions of the exclusion. If the annual testing of the waste does not meet the delisting requirements in paragraph (1), Tokusen must notify EPA according to the requirements in paragraph (6) of the exclusion language. The facility must provide sampling results that support the rationale that the delisting exclusion should not be withdrawn.

(4) *Changes in Operating Conditions:*

Paragraph (4) of the exclusion language would allow Tokusen the flexibility of modifying its processes (for example, changes in equipment or change in operating conditions) to improve its treatment process. However, Tokusen must prove the effectiveness of the modified process and request approval from EPA. Tokusen must manage wastes generated during the new process demonstration as hazardous waste until it has obtained written approval and paragraph (3) of the exclusion language is satisfied.

(5) *Data Submittals:*

To provide appropriate documentation that Tokusen's WWTP sludge is meeting the delisting levels, Tokusen must compile, summarize, and keep delisting records on-site for a minimum of five years. It should keep all analytical data obtained through paragraph (3) of the exclusion language including quality control information for five years. Paragraph (5) of the exclusion language requires that Tokusen furnish these data upon request for inspection by any employee or representative of EPA or the State of Arkansas.

If the proposed exclusion is made final, it will apply only to 2,000 cubic yards per year of wastewater treatment sludge generated at Tokusen after successful verification testing.

EPA would require Tokusen to file a new delisting petition under any of the following circumstances:

(a) If it significantly alters the manufacturing process treatment system except as described in paragraph (4) of the exclusion language;

(b) If it uses any new manufacturing or production process(es), or significantly changes from the current process(es) described in their petition; or

(c) If it makes any changes that could affect the composition or type of waste generated.

Tokusen must manage waste volumes greater than 2,000 cubic yards per year of WWTP waste as hazardous until EPA grants a new exclusion. When this exclusion becomes final, Tokusen's management of the wastes covered by this petition would be relieved from Subtitle C jurisdiction, and the WWTP sludge from Tokusen will be disposed to the RCRA Subtitle D landfill of Waste Management Industrial Subtitle D landfill in North Little Rock, AR.

(6) *Re-opener:*

The purpose of paragraph (6) of the exclusion language is to require Tokusen to disclose new or different information related to a condition at the facility or disposal of the waste, if it is pertinent to the delisting. Tokusen must also use this procedure if the waste sample in the annual testing fails to meet the levels found in paragraph (1). This provision will allow EPA to reevaluate the exclusion, if a source provides new or additional information to EPA. EPA will evaluate the information on which EPA based the decision to see if it is still correct, or if circumstances have changed so that the information is no longer correct or would cause EPA to deny the petition, if presented.

This provision expressly requires Tokusen to report differing site conditions or assumptions used in the petition in addition to failure to meet the annual testing conditions within 10 days of discovery. If EPA discovers such information itself or from a third party, it can act on it as appropriate. The language being proposed is similar to those provisions found in RCRA regulations governing no-migration petitions at § 268.6.

EPA believes that it has the authority under RCRA and the Administrative Procedures Act (APA), 5 U.S.C. 551 (1978) *et seq.,* to reopen a delisting decision. EPA may reopen a delisting decision when it receives new information that calls into question the assumptions underlying the delisting.

EPA believes a clear statement of its authority in delistings is merited in light of EPA's experience. *See* Reynolds Metals Company at 62 FR 37694 and 62 FR 63458 where the delisted waste leached at greater concentrations in the environment than the concentrations predicted when conducting the TCLP, thus leading EPA to repeal the delisting. If an immediate threat to human health and the environment presents itself, EPA will continue to address these situations on a case by case basis. Where necessary, EPA will make a good cause finding to justify emergency rulemaking. *See* APA section 553 (b).

(7) *Notification Requirements*

In order to adequately track wastes that have been delisted, EPA is requiring that Tokusen provide a one-time notification to any state regulatory agency through which or to which the delisted waste is being carried. Tokusen must provide this notification 60 days before commencing this activity.

B. What Happens if Tokusen Violates the Terms and Conditions?

If Tokusen violates the terms and conditions established in the exclusion, EPA will start procedures to withdraw the exclusion. Where there is an immediate threat to human health and the environment, EPA will evaluate the need for enforcement activities on a case-by-case basis. EPA expects Tokusen to conduct the appropriate waste analysis and comply with the criteria explained above in paragraph (1) of the exclusion.

V. Public Comments

A. How May I as an Interested Party Submit Comments?

EPA is requesting public comments on this proposed decision. Please send three copies of your comments. Send two copies to Ben Banipal, Section Chief of the Corrective Action and Waste Minimization Section (6PD–C), Multimedia Planning and Permitting Division, Environmental Protection Agency (EPA), 1445 Ross Avenue, Dallas, Texas 75202. Send a third copy to the Hazardous Waste Division, Arkansas Department of Environmental Quality, P.O. Box 8913, Little Rock, AR 72118. Identify your comments at the top with this regulatory docket number: "EPA–R06–RCRA–2009–0549." You may submit your comments electronically to Youngmoo Kim at *kim.youngmoo@epa.gov.*

You should submit requests for a hearing to Ben Banipal, Section Chief of the Corrective Action and Waste Minimization Section (6PD–C), Multimedia Planning and Permitting Division, U.S. Environmental Protection Agency, 1445 Ross Avenue, Dallas, Texas 75202.

B. How May I Review the Docket or Obtain Copies of the Proposed Exclusion?

You may review the RCRA regulatory docket for this proposed rule at the

Environmental Protection Agency Region 6, 1445 Ross Avenue, Dallas, Texas 75202. It is available for viewing in EPA Freedom of Information Act Review Room from 9 a.m. to 4 p.m., Monday through Friday, excluding Federal holidays. Call (214) 665–6444 for appointments. The public may copy material from any regulatory docket at no cost for the first 100 pages, and at fifteen cents per page for additional copies.

VI. Statutory and Executive Order Reviews

Under Executive Order 12866, "Regulatory Planning and Review" (58 FR 51735, October 4, 1993), this rule is not of general applicability and therefore is not a regulatory action subject to review by the Office of Management and Budget (OMB). This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) because it applies to a particular facility only. Because this rule is of particular applicability relating to a particular facility, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202, 204, and 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Because this rule will affect only a particular facility, it will not significantly or uniquely affect small governments, as specified in section 203 of UMRA. Because this rule will affect only a particular facility, this proposed rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, "Federalism," (64 FR 43255, August 10, 1999). Thus, Executive Order 13132 does not apply to this rule. Similarly, because this rule will affect only a particular facility, this proposed rule does not have tribal implications, as specified in Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000). Thus, Executive Order 13175 does not apply to this rule. This rule also is not subject to Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997), because it is not economically significant as defined in Executive Order 12866, and because the Agency does not have reason to believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The basis for this belief is that the Agency used the DRAS program, which considers health and safety risks to children, to calculate the maximum allowable concentrations for this rule. This rule is not subject to Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355 May 22, 2001), because it is not a significant regulatory action under Executive Order 12866. This rule does not involve technical standards; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988, "Civil Justice Reform," (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report which includes a copy of the rule to each House of the Congress and to the Comptroller General of the United States. Section 804 exempts from section 801 the following types of rules (1) rules of particular applicability; (2) rules relating to agency management or personnel; and (3) rules of agency organization, procedure, or practice that do not substantially affect the rights or obligations of non-agency parties 5 U.S.C. 804(3). EPA is not required to submit a rule report regarding this action under section 801 because this is a rule of particular applicability. Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. The Agency's risk assessment did not identify risks from management of this material in a Subtitle D landfill. Therefore, EPA does not believe that any populations in proximity of the landfills used by this facility should not be adversely affected by common waste management practices for this delisted waste.

Lists of Subjects in 40 CFR Part 261

Environmental protection, Hazardous Waste, Recycling, Reporting and recordkeeping requirements.

Authority: Sec. 3001(f) RCRA, 42 U.S.C. 6921(f).

Dated: March 17, 2010.

Susan Spalding,

Acting Director, Multimedia Planning and Permitting Division, Region 6.

For the reasons set out in the preamble, 40 CFR part 261 is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, and 6938.

2. In Table 1 of Appendix IX of part 261 add the following waste stream in alphabetical order by facility to read as follows:

Appendix IX to Part 261—Waste Excluded Under § 260.20 and 260.22

TABLE 1—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES

Facility	Address	Waste description
*	*	* * * * *
Tokusen, USA Inc	Conway AR	Wastewater Treatment Sludge (EPA Hazardous Waste No. F006) generated at a maximum annual rate of 2,000 cubic yards per calendar year after [insert publication date of the final rule] will be disposed in Subtitle D landfill. For the exclusion to be valid, Tokusen must implement a verification testing program that meets the following paragraphs: (1) *Delisting Levels:* All leachable concentrations for those constituents must not exceed the following levels (mg/l for TCLP). (A) Inorganic Constituents: Antimony—0.4; Arsenic—1.59; Barium—100; Chromium—5.0; Cobalt—0.8; Copper—91.3; Lead—2.32; Nickel—50.5; Selenium—1.0; Zinc—748. (B) Organic Constituents: Acetone—1950. (2) *Waste Management:* (A) Tokusen must manage as hazardous all WWTP sludge generated, until it has completed initial verification testing described in paragraph (3)(A) and (B), as appropriate, and valid analyses show that paragraph (1) is satisfied and approval is received by EPA. (B) Levels of constituents measured in the samples of the WWTP sludge that do not exceed the levels set forth in paragraph (1) are non-hazardous. Tokusen can manage and dispose of the non-hazardous WWTP sludge according to all applicable solid waste regulations. (C) If constituent levels in a sample exceed any of the Delisting Levels set in paragraph (1) Tokusen can collect one additional sample and perform expedited analyses to verify if the constituent exceeds the delisting level. If this sample confirms the exceedance, Tokusen must, from that point forward, treat all the waste covered by this exclusion as hazardous until it is demonstrated that the waste again meets the levels in paragraph (1). Tokusen must manage and dispose of the waste generated under Subtitle C of RCRA from the time that it becomes aware of any exceedance. (D) Upon completion of the verification testing described in paragraph 3(A) and (B) as appropriate and the transmittal of the results to EPA, and if the testing results meet the requirements of paragraph (1), Tokusen may proceed to manage its WWTP sludge as non-hazardous waste. If subsequent Verification Testing indicates an exceedance of the Delisting Levels in paragraph (1), Tokusen must manage the WWTP sludge as a hazardous waste after it has received approval from EPA as described in paragraph (2)(C). (3) *Verification Testing Requirements:* Tokusen must perform sample collection and analyses, including quality control procedures, using appropriate methods. As applicable to the method-defined parameters of concern, analyses requiring the use of SW–846 methods incorporated by reference in 40 CFR 260.11 must be used without substitution. As applicable, the SW–846 methods might include Methods 8260B, 1311/8260B, 8270C, 6010B, 7470, 9034A, ASTMD–4982B, ASTMD–5049, E413.2. Methods must meet Performance Based Measurement System Criteria in Which The Data Quality Objectives are to demonstrate that representative samples of sludge meet the delisting levels in paragraph (1). If EPA judges the process to be effective under the operating conditions used during the initial verification testing, Tokusen may replace the testing required in paragraph (3)(A) with the testing required in paragraph (3)(B). Tokusen must continue to test as specified in paragraph (3)(A) until and unless notified by EPA in writing that testing in paragraph (3)(A) may be replaced by paragraph (3)(B). (A) *Initial Verification Testing:* After EPA grants the final exclusion, Tokusen must do the following: (i) Within 60 days of this exclusion becoming final, collect eight samples, before disposal, of the WWTP sludge. (ii) The samples are to be analyzed and compared against the Delisting Levels in paragraph (1). (iii) Within sixty (60) days after this exclusion becomes final, Tokusen will report initial verification analytical test data for the WWTP sludge, including analytical quality control information for the first thirty (30) days of operation after this exclusion becomes final. Tokusen must request in writing that EPA allow Tokusen to substitute the testing conditions in (3)(B) for (3)(A). (B) *Subsequent Verification Testing:* Following written notification by EPA, Tokusen may substitute the testing conditions in (3)(B) for (3)(A). Tokusen must continue to monitor operating conditions, and analyze two representative samples of the wastewater treatment sludge for each quarter of operation during the first year of waste generation. The samples must represent the waste generated during the quarter. If levels of constituents measured in the samples of the WWTP sludge that do not exceed the levels set forth in paragraph (1) in two consecutive quarters after this exclusion become effective, Tokusen can manage and dispose of the WWTP sludge according to all applicable solid waste regulations. After the first year of analytical sampling verification sampling can be performed on a single annual sample of the wastewater treatment sludge. The results are to be compared to the Delisting Levels in paragraph (1). (C) *Termination of Testing:* (i) After the first year of quarterly testing, if the Delisting Levels in paragraph (1) are met, Tokusen may then request in writing that EPA not require quarterly testing. (ii) Following cancellation of the quarterly testing, Tokusen must continue to test a representative sample for all constituents listed in paragraph (1) annually.

TABLE 1—WASTE EXCLUDED FROM NON-SPECIFIC SOURCES—Continued

Facility	Address	Waste description
		(4) *Changes in Operating Conditions:* If Tokusen significantly changes the process described in its petition or starts any processes that generate(s) the waste that may or could significantly affect the composition or type of waste generated as established under paragraph (1) (by illustration, but not limitation, changes in equipment or operating conditions of the treatment process), it must notify EPA in writing; it may no longer handle the wastes generated from the new process as non-hazardous until the wastes meet the delisting Levels set in paragraph (1) and it has received written approval to do so from EPA. (5) *Data Submittals:* Tokusen must submit the information described below. If Tokusen fails to submit the required data within the specified time or maintain the required records on-site for the specified time, EPA, at its discretion, will consider this sufficient basis to reopen the exclusion as described in paragraph 6. Tokusen must: (A) Submit the data obtained through paragraph(3) to the Section Chief, Corrective Action and Waste Minimization Section, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202–2733, Mail Code, (6PD–C) within the time specified. (B) Compile records of operating conditions and analytical data from paragraph (3), summarized, and maintained on-site for a minimum of five years. (C) Furnish these records and data when EPA or the state of Arkansas requests them for inspection. (D) Send along with all data a signed copy of the following certification statement, to attest to the truth and accuracy of the data submitted: Under civil and criminal penalty of law for the making or submission of false or fraudulent statements or representations (pursuant to the applicable provisions of the Federal Code, which include, but may not be limited to, 18 U.S.C. 1001 and 42 U.S.C. 6928), I certify that the information contained in or accompanying this document is true, accurate and complete. As to the (those) identified section(s) of this document for which I can not personally verify its (their) truth and accuracy I certify as the company official having supervisory responsibility for the persons who, acting under my direct instructions, made the verification that this information is true, accurate and complete. If any of this information is determined by EPA in its sole discretion to be false, inaccurate or incomplete, and upon conveyance of this fact to the company, I recognize and agree that this exclusion of waste will be void as if it never had effect or to the extent directed by EPA and that the company will be liable for any actions taken in contravention of the company's RCRA and CERCLA obligations premised upon the company's reliance on the void exclusion. (6) *Re-Opener:* (A) If, any time after disposal of the delisted waste, Tokusen possesses or is otherwise made aware of any environmental data (including but not limited to leachate data or groundwater monitoring data) or any other data relevant to the delisted waste indicating that any constituent identified for the delisting verification testing is at level higher than the delisting level allowed by the Division Director in granting the petition, then the facility must report the data, in writing, to the Division Director within 10 days of first possessing or being made aware of that data. (B) If the annual testing of the waste does not meet the delisting requirements in paragraph (1), Tokusen must report the data in writing to the Division Director within 10 days of first possessing or being made aware of that data. (C) If Tokusen fails to submit the information described in paragraphs (5), (6)(A) or (6)(B) or if any other information is received from any source, the Division Director will make a preliminary determination as to whether the reported information requires EPA action to protect human health and/or the environment. Further action may include suspending, or revoking the exclusion, or other appropriate response necessary to protect human health and the environment. (D) If the Division Director determines that the reported information does require action, EPA's Division Director will notify the facility in writing of the actions the Division Director believes are necessary to protect human health and the environment. The notice shall include a statement of the proposed action and a statement providing the facility with an opportunity to present information as to why the proposed action by EPA is not necessary. The facility shall have 10 days from the date of the Division Director's notice to present such information. (E) Following the receipt of information from the facility described in paragraph (6)(D) or (if) no information is presented under paragraph(6)(D)) the initial receipt of information described in paragraphs (5), (6)(A) or (6)(B), the Division Director will issue a final written determination describing EPA's actions that are necessary to protect human health and/or the environment. Any required action described in the Division Director's determination shall become effective immediately, unless the Division Director provides otherwise. (7) *Notification Requirements:* Tokusen must do the following before transporting the delisted waste. Failure to provide this notification will result in a violation of the delisting petition and a possible revocation of the decision. (A) Provide a one-time written notification to any state Regulatory Agency to which or through which it will transport the delisted waste described above for disposal, 60 days before beginning such activities. (B) Update one-time written notification, if it ships the delisted waste into a different disposal facility. (C) Failure to provide this notification will result in a violation of the delisting variance and a possible revocation of the decision.

* * * * * * *

[FR Doc. 2010–7037 Filed 3–30–10; 8:45 am]
BILLING CODE 6560–50–P?≤

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R8-ES-2009-0019]
[MO 92210-0-0008 B2]

RIN 1018-AV91

Endangered and Threatened Wildlife and Plants; Listing Casey's June Beetle as Endangered and Designation of Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period, notice of availability of draft economic analysis, and amended required determinations.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the comment period on our July 9, 2009, proposed listing and critical habitat designation for Casey's June beetle (*Dinacoma caseyi*) under the Endangered Species Act of 1973, as amended (Act). We also announce the availability of the draft economic analysis (DEA), and an amended required determinations section of the proposal. We are reopening the comment period for an additional 30 days to allow all interested parties an opportunity to comment simultaneously on the proposed listing and critical habitat designation, the DEA, and the amended required determinations section. If you submitted comments previously, you do not need to resubmit them because we have already incorporated them into the public record and will fully consider them in preparation of the final rule.

DATES: We will consider comments that we receive on or before April 30, 2010.

ADDRESSES: You may submit comments by one of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments to Docket No. FWS–R8–ES–2009–0019.
- U.S. mail or hand-delivery: Public Comments Processing, Attn: FWS–R8–ES–2009–0019; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, Suite 222; Arlington, VA 22203.

We will post all comments on *http://www.regulations.gov*. This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

FOR FURTHER INFORMATION CONTACT: Jim Bartel, Field Supervisor, U.S. Fish and Wildlife Service, Carlsbad Fish and Wildlife Office, 6010 Hidden Valley Road, Suite 101, Carlsbad, CA 92011; telephone (760) 431–9440; facsimile (760) 431–5901. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at (800) 877–8339.

SUPPLEMENTARY INFORMATION:

Public Comments

We intend that any final action resulting from the proposed rule will be based on the best scientific data available and will be as accurate and as effective as possible. Therefore, we request comments or information from the public, other concerned government agencies, the scientific community, industry, or other interested party during this reopened comment period on the proposed rule to list the Casey's June beetle (*Dinacoma caseyi*) with critical habitat that was published in the **Federal Register** on July 9, 2009 (74 FR 32857), including the DEA of the proposed critical habitat designation and the amended required determinations section provided in this document. We are particularly interested in comments concerning:

(1) Any available information on known or suspected threats and proposed or ongoing projects with the potential to threaten Casey's June beetle, specifically:

(a) The present or threatened destruction, modification or curtailment of its habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; and

(e) Other natural or manmade factors affecting its continued existence.

(2) Additional information concerning the range, distribution, and population size of this species, including the locations of any additional populations of this species.

(3) The reasons why we should or should not designate habitat as "critical habitat" under section 4 of the Endangered Species Act of 1973, as amended (Act; 16 U.S.C. 1531 *et seq.*), including whether there are threats to Casey's June beetle from human activity, the degree of which can be expected to increase due to the designation, and whether that increase in threat outweighs the benefit of designation, such that the designation of critical habitat is not prudent.

(4) Specific information on areas that provide habitat for Casey's June beetle that we did not discuss in the proposed rule, whether such areas contain the physical and biological features essential to the conservation of Casey's June beetle, and what special management considerations or protections may be required to maintain or enhance the essential features.

(5) Land-use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(6) Any foreseeable economic, national security, or other relevant impact that may result from designating particular areas as critical habitat, and, in particular, any impacts to small entities (such as small businesses or small governments), and the benefits of including or excluding areas from the proposed designation that exhibit these impacts.

(7) Whether any particular area being proposed as critical habitat should be excluded under section 4(b)(2) of the Act, and whether the benefits of potentially excluding any particular area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(8) Whether inclusion of tribal lands of the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California (preferred name "Agua Caliente Band of Cahuilla Indians"), in Riverside County is appropriate and why.

(9) The likelihood of adverse social reactions to the designation of critical habitat, and how the consequences of such reactions, if they occur, would relate to the conservation of the species and regulatory benefits of the proposed critical habitat designation.

(10) Information on the extent to which the description of potential economic impacts in the DEA is complete and accurate.

(11) The potential effects of climate change on this species and its habitat and whether the critical habitat may adequately account for these potential effects.

(12) Whether our approach to designating critical habitat could be improved or modified in any way to provide an opportunity for greater public participation and understanding, or to assist us in accommodating public concerns and comments.

If you submitted comments or information on the proposed rule (74 FR 32857) during the initial comment period from July 9, 2009, to September 8, 2009, please do not resubmit them. These comments are included in the public record for this rulemaking, and

we will fully consider them in the preparation of our final determination. Our final determination concerning listing the Casey's June beetle as an endangered species and designating critical habitat will take into consideration all written comments and any additional information we receive during both comment periods. On the basis of public comments, we may, during the development of our final determination, find that areas within the proposed critical habitat designation do not meet the definition of critical habitat, that some modifications to the described boundaries are appropriate, or that areas may or may not be appropriate for exclusion under section 4(b)(2) of the Act.

You may submit your comments and materials concerning the proposed rule and the DEA associated with the proposed critical habitat designation by one of the methods listed in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov*, your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via hard copy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov*. Please include sufficient information with your comments to allow us to verify any scientific or commercial information you include.

Comments and materials we receive, as well as supporting documentation used to prepare this notice, will be available for public inspection on *http://www.regulations.gov*, or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service, Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**). You may obtain copies of the proposed listing and proposed critical habitat (74 FR 32857) and the DEA on the Internet at *http://www.regulations.gov* at Docket No. FWS-R8-ES-2009-0019, or by mail from the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Background

It is our intent to discuss only those topics directly relevant to the proposed designation of critical habitat for Casey's June beetle in this document. For more detailed information on the taxonomy, biology, and ecology of Casey's June beetle, please refer to the 90–day finding on the petition to list the species under the Act, published in the **Federal Register** on August 8, 2006 (71 FR 44960); the 12–month finding, published in the **Federal Register** on July 5, 2007 (72 FR 36635); or the proposed listing and designation of critical habitat rule, published in the **Federal Register** on July 9, 2009 (74 FR 32857). Alternatively, you may contact the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Section 3 of the Act defines critical habitat as "(i) the specific areas within the geographical area occupied by the species, at the time it is listed in accordance with... [the Act], on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed . . . upon a determination by the Secretary that such areas are essential for the conservation of the species" (16 USC 1532(5)(A)). If the proposed rule is made final, section 7 of the Act will prohibit destruction or adverse modification of critical habitat by any activity funded, authorized, or carried out by any Federal agency. Federal agencies proposing actions that may affect critical habitat must consult with us on the effects of their proposed actions, under section 7(a)(2) of the Act.

Draft Economic Analysis

Section 4(b)(2) of the Act requires that we designate critical habitat based upon the best scientific and commercial data available, after taking into consideration the economic impact, impact on national security, or any other relevant impact of specifying any particular area as critical habitat.

We prepared a DEA (Industrial Economics Inc. 2010) that identifies and analyzes the potential impacts associated with the proposed designation of critical habitat for Casey's June beetle that we published in the **Federal Register** on July 9, 2009 (74 FR 32857). The DEA quantifies the economic impacts of all potential conservation efforts for Casey's June beetle; some of these costs will likely be incurred regardless of whether or not we finalize the critical habitat. The economic impact of the proposed critical habitat designation is analyzed by comparing scenarios both "with critical habitat" and "without critical habitat." The "without critical habitat" scenario represents the baseline for the analysis, considering protections that are already in place for the species or that will be in place for the species upon listing (such as protections under the Act and other Federal, State, and local regulations). The baseline, therefore, represents the costs incurred regardless of whether critical habitat is designated. The "with critical habitat" scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts are those not expected to occur absent the critical habitat designation for Casey's June beetle. In other words, the incremental costs are those attributable solely to the designation of critical habitat above and beyond the baseline costs. The DEA also discusses the potential benefits associated with the designation of critical habitat, but does not monetize these benefits. The incremental impacts are the impacts we may consider in the final designation of critical habitat when evaluating the benefit of excluding particular areas under section 4(b)(2) of the Act. The analysis forecasts both baseline and incremental impacts likely to occur if we finalize the proposed designation of critical habitat.

The primary intended benefit of critical habitat is to support the conservation of endangered and threatened species, such as the Casey's June beetle. Thus, attempts to develop monetary estimates of the benefits of this proposed critical habitat designation would focus on the public's willingness to pay to achieve the conservation benefits to the beetle resulting from this designation. Quantification and monetization of species conservation benefits requires information on the incremental change in the probability of Casey's June beetle conservation that is expected to result from the designation. No studies exist that provide such information for this species. Even if this information existed, the published valuation literature does not support monetization of incremental changes in conservation probability for this species. Because it is not possible to determine the probability that benefits will occur in this instance, the Service has decided not to include such estimates in the DEA. Rather than rely on economic measures, the Service believes that the direct benefits of the proposed rule are best expressed in biological terms that can be weighed against the expected cost impacts of the rulemaking.

The DEA (made available with the publication of this notice and referred to throughout this document unless otherwise noted) estimates the foreseeable economic impacts of the proposed critical habitat designation for Casey's June beetle. The economic analysis identifies potential incremental

costs as a result of the proposed critical habitat designation, which are those costs attributed to critical habitat over and above those baseline costs associated solely with the listing. It also discusses the potential economic benefits of the proposed designation. The DEA describes economic impacts of Casey's June beetle conservation efforts associated with the following categories of activity: (1) residential and commercial development, (2) tribal activities, (3) flood control activities, and (4) recreational activities.

Baseline economic impacts are those impacts that result from listing and other conservation efforts for Casey's June beetle. Conservation efforts related to development activities constitute the majority of total baseline costs (approximately 80 percent) in areas of proposed critical habitat. Impacts to flood control activities comprise the remaining approximately 20 percent of impacts. Total future baseline impacts are estimated to be $12,703,600 ($1,182,600 annualized) in present value terms using a 7 percent discount rate over the next 20 years (2010 to 2029) in areas proposed as critical habitat (Industrial Economics Inc. 2010, pp. ES-7).

Almost all incremental impacts attributed to the proposed critical habitat designation are expected to be related to development activities (approximately 100 percent). The DEA estimates total potential incremental economic impacts in areas proposed as critical habitat over the next 20 years (2010 to 2029) to be $9,792,270 ($924,131 annualized) in present value terms using a 7 percent discount rate (Industrial Economics Inc. 2010, p. ES-8). This value is based on an assumption of total avoidance of designated areas and thus represents the upper-bound potential cost for each project. As such, it likely overstates the expected absolute cost of future actions to protect critical habitat.

The DEA considers both economic efficiency and distributional effects. In the case of habitat conservation, efficiency effects generally reflect the "opportunity costs" associated with the commitment of resources to comply with habitat protection measures (such as lost economic opportunities associated with restrictions on land use). The DEA also addresses how potential economic impacts are likely to be distributed, including an assessment of any local or regional impacts of habitat conservation and the potential effects of conservation activities on government agencies, private businesses, and individuals. The DEA measures lost economic efficiency associated with residential and commercial development and public projects and activities, such as economic impacts on water management and transportation projects, Federal lands, small entities, and the energy industry. Decision-makers can use this information to assess whether the effects of the critical habitat designation might unduly burden a particular group or economic sector.

Required Determinations—Amended

In our proposed rule that published in the **Federal Register** on July 9, 2009 (74 FR 32857), we indicated we would defer our determination of compliance with several statutes and Executive Orders until the information concerning potential economic impacts of the designation and potential effects on landowners and stakeholders became available in the DEA. We have now made use of the DEA to make these determinations. In this document, we affirm the information in our proposed rule concerning Executive Order (E.O.) 12866 (*Regulatory Planning and Review*), E.O. 13132 (Federalism), E.O. 12988 (Civil Justice Reform), the Paperwork Reduction Act, the National Environmental Policy Act, the President's memorandum of April 29, 1994, "Government-to-Government Relations with Native American Tribal Governments" (59 FR 22951), and E.O. 12630 (Takings). However, based on the DEA data, we revised our required determinations concerning the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), and E.O. 13211 (Energy Supply, Distribution, or Use).

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 802(2)), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (i.e., small businesses, small organizations, and small government jurisdictions), as described below. However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. Based on our DEA of the proposed critical habitat designation, we provide our analysis for determining whether the proposed designation would result in a significant economic impact on a substantial number of small entities. Based on comments we receive, we may revise this determination as part of a final rulemaking.

According to the Small Business Administration, small entities include small organizations, such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under the proposed designation as well as types of project modifications that may result. In general, the term significant economic impact is meant to apply to a typical small business firm's business operations.

To determine if the proposed designation of critical habitat for Casey's June beetle would affect a substantial number of small entities, we consider the number of small entities affected within particular types of economic activities, such as residential and commercial development. In order to determine whether it is appropriate for our agency to certify that this rule would not have a significant economic impact on a substantial number of small entities, we considered each industry or category individually. If we finalize this proposed listing and proposed critical habitat designation, Federal agencies must consult with us under section 7 of the Act if their activities may affect the species or the designated critical habitat. Incremental impacts to small entities may occur as a direct result of a required consultation under section 7 of the Act. Additionally, even in the absence of a Federal nexus, indirect incremental impacts may still result because, for example, a city may request project modifications due to the designation of critical habitat via its review under the California Environmental Quality Act (CEQA).

In the DEA of the proposed critical habitat designation, we evaluate the

potential economic effects on small business entities resulting from implementation of conservation actions related to the proposed critical habitat for Casey's June beetle. The DEA identifies the estimated incremental impacts associated with the proposed rulemaking as described in Appendix A of the DEA, and evaluates the potential for economic impacts related to activity categories including residential and commercial development, tribal activities, flood control activities, and recreational activities (Industrial Economics, Inc. 2010). The DEA concludes that the incremental impacts resulting from this rulemaking that may be borne by small businesses will be associated only with development. Incremental impacts are either not expected for the other types of activities considered or, if expected, will not be borne by small entities.

As discussed in Appendix A of the DEA, the only impacts of the proposed rule on small businesses would potentially result from lost land values associated with the identified development projects. In the 20–year timeframe for the analysis, three developers may experience impacts. The potential incremental costs are expected to vary by project, depending on the size and the value of the land. The total annualized incremental impacts are forecast at approximately $965,000 (discounted at 7 percent). The SBREFA analysis estimates that three small businesses may be affected by the designation of critical habitat (Industrial Economics, Inc. 2010, pp. A-3–A-6). Because only three small businesses may be affected, we do not find that the number of small entities that would be significantly affected is substantial.

In summary, we considered whether the proposed rule would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if adopted, the proposed critical habitat would not have a significant economic impact on a substantial number of small entities. Therefore, an initial regulatory flexibility analysis is not required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501), we make the following findings:

(a) This rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both "Federal intergovernmental mandates" and "Federal private sector mandates." These terms are defined in 2 U.S.C. 658(5)-(7). "Federal intergovernmental mandate" includes a regulation that "would impose an enforceable duty upon State, local, or Tribal governments," with two exceptions. It excludes "a condition of federal assistance." It also excludes "a duty arising from participation in a voluntary Federal program," unless the regulation "relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority," if the provision would "increase the stringency of conditions of assistance" or "place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding" and the State, local, or Tribal governments "lack authority" to adjust accordingly. "Federal private sector mandate" includes a regulation that "would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance; or (ii) a duty arising from participation in a voluntary Federal program."

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. Designation of critical habitat may indirectly impact non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat. However, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above on to State governments.

(b) As discussed in the DEA of the proposed designation of critical habitat for Casey's June beetle, we do not believe that the rule would significantly or uniquely affect small governments because it would not produce a Federal mandate of $100 million or greater in any year; that is, it is not a "significant regulatory action" under the Unfunded Mandates Reform Act. The DEA concludes incremental impacts may occur due to project modifications that may need to be made for development and flood control activities; however, these are not expected to affect small governments. Incremental impacts stemming from various species conservation and development controls are expected to be borne by the Riverside County Flood Control and Water Conservation District (FCWCD), which is not considered a small government based on the county's population. Consequently, we do not believe that the critical habitat designation would significantly or uniquely affect small government entities. As such, a Small Government Agency Plan is not required.

Executive Order 13211—Energy Supply, Distribution, and Use

On May 18, 2001, the President issued E.O. 13211 on regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. The OMB's guidance for implementing this Executive Order outlines nine outcomes that may constitute "a significant adverse effect" when compared to no regulatory action. As discussed in Appendix A, the DEA finds that none of these criteria are relevant to this analysis. The DEA identified no potentially affected entities involved in the production of energy, and a Statement of Energy Effects is therefore not required.

References Cited

A complete list of all references we cited in the proposed rule and in this document is available on the Internet at *http://www.regulations.gov* or by contacting the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT** section).

Author

The primary authors of this notice are the staff members of the Carlsbad Fish and Wildlife Office (see **FOR FURTHER INFORMATION CONTACT**).

Authority

The authority for this action is the Endangered Species Act of 1973 as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 23, 2010

Will Shafroth,

Acting Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2010–7131 Filed 3–30–10; 8:45 am]

BILLING CODE 4310–55–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS-R2-ES-2009-0070]
[MO 92210-0-0008-B2]

Endangered and Threatened Wildlife and Plants; 12-Month Finding on a Petition to List the Tucson Shovel-Nosed Snake (*Chionactis occipitalis klauberi*) as Threatened or Endangered with Critical Habitat

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of 12–month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce a 12–month finding on a petition to list the Tucson shovel-nosed snake (*Chionactis occipitalis klauberi*) as threatened or endangered with critical habitat under the Endangered Species Act of 1973, as amended (Act). After review of the best scientific and commercial information available, we find that listing the Tucson shovel-nosed snake as threatened or endangered throughout its range is warranted. Currently, however, listing the Tucson shovel-nosed snake is precluded by higher priority actions to amend the Lists of Endangered and Threatened Wildlife and Plants. Upon publication of this 12–month petition finding, we will add the Tucson shovel-nosed snake to our candidate species list. We will develop a proposed rule to list the Tucson shovel-nosed snake as our priorities allow. We will make any determination on critical habitat during development of the proposed rule.

DATES: The finding announced in this document was made on March 31, 2010.

ADDRESSES: This finding is available on the Internet at *http://www.regulations.gov* at Docket Number FWS-R2-ES-2009-0070. Supporting documentation we used in preparing this finding is available for public inspection, by appointment, during normal business hours by contacting the U.S. Fish and Wildlife Service, Arizona Ecological Services Office, 2321 West Royal Palm Road, Suite 103, Phoenix, AZ 85021-4951. Please submit any new information, comments, or questions concerning this finding to the above address.

FOR FURTHER INFORMATION CONTACT: Steve Spangle, Field Supervisor, Arizona Ecological Services Office (see **ADDRESSES**) (telephone 602-242-0210; facsimile 602-242-2513). If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service (FIRS) at 800-877-8339.

SUPPLEMENTARY INFORMATION:

Background

Section 4(b)(3)(B) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), requires that, for any petition containing substantial scientific or commercial information indicating that listing the species may be warranted, we make a finding within 12 months of the date of receipt of the petition. In this finding we determine that the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted, but immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are threatened or endangered, and expeditious progress is being made to add or remove qualified species from the Lists of Endangered and Threatened Wildlife and Plants. Section 4(b)(3)(C) of the Act requires that we treat a petition for which the requested action is found to be warranted but precluded as though resubmitted on the date of such finding, that is, requiring a subsequent finding to be made within 12 months. We must publish these 12–month findings in the **Federal Register**.

Previous Federal Actions

We received a petition, dated December 15, 2004, from the Center for Biological Diversity requesting that we list the Tucson shovel-nosed snake as threatened or endangered throughout its range and designate critical habitat within its range in the United States. The petition, which was clearly identified as such, contained detailed information on the natural history, biology, current status, and distribution of the Tucson shovel-nosed snake. It also contained information on what the petitioner reported as potential threats to the subspecies from urban development, agricultural practices, collecting, inadequacy of existing regulations, drought, and climate change. In response to the petitioner's requests, we sent a letter to the petitioner, dated September 7, 2005, explaining that, due to funding constraints in fiscal year 2005, we would not be able to address the petition in a timely manner. On February 28, 2006, the petitioner filed a 60–day notice of intent to sue (NOI) the Department of the Interior for failure to issue 90–day and 12–month findings, and a proposed listing rule, as appropriate, in response to the petition as required by 16 U.S.C. 1533(b)(3)(A) and (B). In response to the NOI, we agreed to submit a 90–day finding to the **Federal Register** as expeditiously as possible.

On July 29, 2008, we made our 90–day finding that the petition presented substantial scientific information indicating that listing the Tucson shovel-nosed snake (*Chionactis occipitalis klauberi*) may be warranted. The finding and our initiation of a status review was published in the **Federal Register** on July 29, 2008 (73 FR 43905).

This notice constitutes the 12–month finding on the December 15, 2004, petition to list the Tucson shovel-nosed snake as threatened or endangered.

Species Information

Species Description

The Tucson shovel-nosed snake is a small snake (250–425 millimeters (mm) (9.84–16.73 inches (in) total length) in the family Colubridae, with a shovel-shaped snout, an inset lower jaw, and coloring that mimics coral snakes (Mahrdt *et al.* 2001, p. 731.1). The most notable features of the Tucson shovel-nosed snake distinguishing it from the other subspecies are (a) the red crossbands suffused with dark pigment, making them appear brown or partly black, and (b) both black and red crossbands not encircling the body (Center for Biological Diversity 2004, p. 2).

Taxonomy

In considering taxonomic data, the Service relies "on standard taxonomic distinctions and the biological expertise of the Department and the scientific community concerning the relevant taxonomic group" (50 CFR §424.11(a)) and "on the basis of the best scientific and commercial information" (50 CFR §424.11(b)). The Service, not any professional organization or expert, bears the responsibility for deciding what taxonomic entities are to be protected under the Act. We address any conflicting information or expert opinion by carefully evaluating the underlying scientific information and weighing its reliability and adequacy according to the considerations of the Act and our associated policies and procedures and using the best scientific information available.

Taxonomic nomenclature for the Tucson shovel-nosed snake has changed over time. The snake was first described as a subspecies, *Sonora occipitalis klauberi*, by Stickel in 1941 (p. 138). The genus was changed to *Chionactis* two years later (Stickel 1943, pp. 122–123). Since being described, the Tucson shovel-nosed snake has been widely

accepted as a subspecies (Klauber 1951, p. 187; Stebbins 2003, p. 394; Crother 2008a, p. 48; Collins and Taggart 2009, p. 28), and is one of four currently recognized subspecies of the Western shovel-nosed snake, *Chionactis occipitalis* (Crother 2008a, p. 48; Collins and Taggart 2009, p. 28).

In our 90–day finding for this petition (73 FR 43905), we determined that a recent study of genetic variation of mitochondrial DNA (Wood *et al.* 2006, hereafter Wood *et al.* 2008) found significant geographical structuring suggesting two distinct subspecies of Western shovel-nosed snake rather than four, combining western populations of *Chionactis occipitalis occipitalis*, the Mojave shovel-nosed snake, with *Chionactis occipitalis talpina*, the Nevada shovel-nosed snake; and southeastern populations of *C. o. occipitalis* with *Chionactis occipitalis annulata*, the Colorado Desert shovel-nosed snake, and *C. o. klauberi*. However, this study's inference was based on a single genetic marker of mitochondrial DNA and did not include examination of nuclear markers, which would more fully elucidate our understanding of the taxonomic standing of this subspecies. Therefore, in our 90–day finding, we continued to accept the currently recognized arrangement of subspecies, which includes *C. o. klauberi* (Mardt *et al.* 2001).

Additionally, the petition requested that the Service consider an "intergrade zone" between the Tucson shovel-nosed snake and the Colorado Desert shovel-nosed snake as part of the Tucson shovel-nosed snake's range. An intergrade zone is an area of overlap between the ranges of two subspecies where individuals may possess intermediate characters (attributes or features that distinguish a subspecies, such as coloration) or traits of both subspecies. It is generally recognized and accepted by practitioners of subspecies taxonomy that intergrade zones may exist between the ranges of two subspecies where the diagnostic characters of both subspecies may be found (Mayr 1942, p. 107; Huxley 1943, p. 210–211; Mayr 1963, p. 368; Mayr 1969, pp. 193–196; Mayr 1970, pp. 219–226; Wake 1997, pp. 7761–7762; Rodríguez-Robles and De Jesus-Escobar 2000, p. 42; Isaac *et al.* 2004, p. 465; Krysko and Judd 2006, p. 18; Wake 2006, p. 12). Current practice in the scientific literature is to objectively describe the ranges of different subspecies and any intergrade zones between them with narrative descriptions, maps, or both (e.g., Wake 1997, pp. 7761–7767; Rodríguez-Robles and De Jesus-Escobar 2000, Fig. 1; Mahrdt *et al.* 2001, p. 731.2; Leache and Reeder 2002, p. 202; Krysko and Judd 2006, p. 18; Wake 2006, p. 11). Following this practice, intergrade zones are identified, but not assigned to either of the subspecies. As such, we find that including all shovel-nosed snakes within the intergrade zone into the subspecies taxon of the Tucson shovel-nosed snake would not be consistent with current scientific practice in describing the ranges of subspecies and the intergrade zone between them, and, therefore, we do not consider shovel-nosed snakes within the intergrade zone to be members of the Tucson shovel-nosed snake subspecies.

In order to be compliant with 50 CFR 424.11(a) and to understand the taxonomic entity to consider for listing, the Service requested review and input on the issue of taxonomic classification and distribution of the Tucson shovel-nosed snake from nine individuals with biological and taxonomic expertise and background in this issue. Of the nine, six provided comments and input on specific questions we asked regarding the issue of determining species and subspecies, taxonomic classification, and geographical ranges (including the location of the boundary between the Tucson shovel-nosed snake and the intergrade zone) based on recent and historical studies and publications related to Tucson shovel-nosed snake taxonomic classification.

We considered publications by Collins and Taggart (2009), Crother (2008a), Wood *et al.* (2008), Rosen (2003), Mahrdt *et al.* (2001), Klauber (1951), and the input from our solicited review by current experts in the field (four herpetological taxonomists and two *C. occipitalis* experts). The four herpetological taxonomists believed that, based on the most recent genetic work by Wood *et al.* (2008) using mitochondrial DNA, the subspecies *C. o. klauberi* does not warrant taxonomic recognition (Boundy 2008, p. 2; Burbrink 2008, p. 2; Crother 2008b, p. 2; Frost 2008, p. 2). They suggested, based on Wood *et al.* (2008), that two lineages of *C. occipitalis* exist in the northwestern and southeastern portions of the species' range, which are not consistent with the current subspecies designations and their current ranges. Three of the taxonomists, plus one of the species experts, suggested additional studies using nuclear DNA markers or microsatellites (numerous short segments of DNA that are distributed throughout the genetic material of an organism) were needed to determine if *C. o. klauberi* is distinct, and if so, where the boundaries of its range are actually located (Boundy 2008, p. 3; Burbrink 2008, p. 2; Crother 2008b, p. 3; Holm 2008, p. 2).

The two species experts believed that there is some agreement between morphological and mitochondrial DNA data, and supported acknowledging *C. o. klauberi* as a unique taxonomic entity (Holm 2008, p. 1; Rosen 2008a, pp. 6–12). One of the experts suggested a range similar to the one that is currently recognized for *klauberi* (Holm 2008, p. 5) and the other, although recommending retaining the current subspecies boundaries, acknowledged that the genetic data, as represented by nesting clades in Wood *et al.* (2008), argue for a much larger range that includes eastern populations of *C. o. annulata* (Rosen 2008a, p. 11).

According to most phylogenetic species concepts, the taxonomists (Boundy 2008, Burbrink 2008, Crother 2008b, Frost 2008) are using a criterion for species, not subspecies, and all four of these reviewers acknowledge that, following this reasoning, they do not believe subspecies are real biological units and that the concept of subspecies is antiquated. However, the Act recognizes conservation concern below the level of species by defining "species" to include subspecies and vertebrate Distinct Population Segments. Published lists of reptile and amphibian taxa, including those authored by our taxonomic peer reviewers (for example, Crother 2008a, Collins and Taggart 2009 (F. Burbrink is an author on the snake section)), still include subspecies, and the International Code of Zoological Nomenclature (ICZN), a universally accepted system of nomenclature (Frost *et al.* 2009, pp. 136–137), includes articles pertaining to the naming of subspecies (ICZN 1999). Therefore, we continue to recognize subspecies as unique taxonomic entities, including the Tucson shovel-nosed snake.

Additionally, mitochondrial DNA, as analyzed by Wood *et al.* (2008), represents a single genetic locus that accumulates mutations relatively slowly, and therefore differences between groups based on mitochondrial DNA typically reflect historical separation of groups rather than more recent population-level differences (Fallon 2007a, p. 1191). As a result, differentiation at mitochondrial genes reflects deep historical separation rather than more recent divergence, and does not reflect evolutionary difference shaped by the organism's ecology and environment (Fallon 2007a, p. 1191). Genetic differences among groups that have experienced more recent separation (such as those below the species level) may require combinations

of markers and/or additional genetic data to reveal variation, if it exists (Fallon 2007a, p. 1192). Microsatellites provide a highly variable marker widely accepted as appropriate for detecting changes at this level (Fallon 2007a, p. 1191), and would be applicable in determining the subspecies status of the Tucson shovel-nosed snake.

For the available information we considered, we find that uncertainty exists in both the taxonomic entity and subspecies range of *C. o. klauberi*. Information submitted by four of the six experts who provided input on these issues indicated that, while there are certain aspects of existing information that support rejecting the petitioned entity, there is uncertainty, and additional work is needed to clarify the validity and distribution of the subspecies (Boundy 2008, p. 3; Burbrink 2008, p. 2; Crother 2008b, p. 3; Holm 2008, p. 2). Specifically, they suggest that nuclear DNA markers or microsatellites be used to determine if *C. o. klauberi* is distinct, and if so, where the boundary between it and the intergrade zone is actually located. Public comment received related to this 12–month finding both supported the need for nuclear DNA markers or microsatellites (Arizona Game and Fish Department 2008, p. 3; Fallon 2007b, pp. 1–2; Jones 2008, p. 2), as well as questioned the validity of the subspecies based on Wood *et al.* (2008) (Carothers *et al.* 2008, pp. 9–14; James 2008, pp. 4–5; Taczanowsky 2008, pp. 1–2; Warren 2008, pp. 1 and 6). Therefore, because we received inconclusive expert opinion regarding the subspecies status of the Tucson shovel-nosed snake, as well as recommendations that further genetic study (nuclear DNA or microsatellites) is needed before this determination can be made, we regard the currently recognized taxonomic status and distribution of *C. o. klauberi* (Mardt *et al.* 2001) as the best available science, with the understanding that, as we acquire more information, the definition of this taxonomic entity (including its range) may change, and our finding may need to be revisited.

Biology

The diet of shovel-nosed snakes consists of a variety of invertebrates, including scorpions, beetle larvae, spiders, crickets, centipedes, native roaches, and ants, (Mattison 1989, p. 25; Rosen *et al.* 1996, pp. 22–23; Brennan and Holycross 2006, p. 98). Glass (1972, p. 447) and Rosen *et al.* (1996, p. 22) suggest that shovel-nosed snakes eat relatively frequently. The authors (pp. 22–23) further support this observation by noting that individual shovel-nosed snakes in captivity each consumed five to eight crickets per week and showed significant weight loss after a 2- to 3–week lapse in feeding.

Like the other three subspecies of the western shovel-nosed snake, the Tucson shovel-nosed snake uses "sand swimming" as its primary locomotion. The snake moves using a sideways swaying motion while it is either on or under the sand or loose soil (Stebbins 2003, p. 393). Klauber (1951, p. 192) suggests that shovel-nosed snakes rarely move more than 30.5 m (100 ft) in one night, as they do not normally move great distances below the sand surface; however, Rorabaugh (2002, p. 42) documented one shovel-nosed snake (*C. o. annulata*) that moved 37 m (121 ft) in about 2 hours. Shovel-nosed snakes were thought to be primarily nocturnal in activity, but specimens have been documented as active during crepuscular (dawn and dusk) and daylight hours (*C. occipitalis*: Rosen *et al.* 1996, pp. 21–22; *C. o. annulata*: Rorabaugh 2002, pp. 42–43; Brennan and Holycross 2006, p. 98). Shovel-nosed snakes are predominantly active at air temperatures between 70 and 90 degrees Fahrenheit (21 and 32 degrees Celsius) and when surface temperatures in the sun are between 75 and 115 degrees Fahrenheit (24 and 46 degrees Celsius) (Klauber 1951, p. 187; Rorabaugh 2002, pp. 42–43). Rosen *et al.* (1996, p. 21) and Rorabaugh (2002, p. 42) have also observed that shovel-nosed snakes have been documented to be active in the morning and just before sunset. Rosen *et al.* (1996, p. 21) further note that activity seems to be highest when summer and spring temperatures are moderate and when the relative humidity is high.

Reproductive studies have not been conducted specific to *C. o. klauberi*; however, some information is available for shovel-nosed snakes in general, which appear similar to that of other fossorial (burrowing) North American desert snakes in which sperm formation coincides with the period of maximum aboveground activity (Goldberg and Rosen 1999, pp. 155 and 157). Reproductive activity for shovel-nosed snakes occurs in April through July, and the clutch size ranges from two to four eggs (Klauber 1951, p. 194; Goldberg and Rosen 1999, p. 156), although Brennan and Holycross (2006, p. 98) state that clutch size is from two to nine eggs.

Limited information suggests the existence of four age classes in the Western shovel-nosed snake, based on snout-to-vent length (SVL): 0.5, 1.5, 2.5, and 3.5 years and older (Rosen *et al.* 1996, p. 12). Sex ratios for shovel-nosed snakes appear to be skewed towards males, but this is likely due to sampling bias, as most shovel-nosed snake sightings are on roads, and males likely cross roads more frequently in search of females (Rosen *et al.* 1996, p. 21). Rosen *et al.* (1996, p. 21) observed 1 female to 1.21 male shovel-nosed snakes while on foot in the Mohawk Dunes, suggesting that the extreme skewing seen in road collection represents observational bias.

Klauber (1951, p. 185) indicates that scattered sand hummocks, crowned with mesquite or other desert shrubs, are favorite refuges for shovel-nosed snakes. Rosen (2003, p. 8) suggests that the Tucson shovel-nosed snake is found in more productive creosote-mesquite floodplain environments, differing from the habitats preferred by other subspecies of the Western shovel-nosed snake. Rosen (2003, p. 8) describes the associated soils of the Tucson shovel-nosed snake as soft, sandy loams, with sparse gravel.

Distribution

The subspecies was historically known from Pima County in the Avra and Santa Cruz valleys (Rosen 2003, p. 4) and from western Pinal and a portion of eastern Maricopa counties (Klauber 1951, p. 196).

As of 2001, over one-third of the range of the Tucson shovel-nosed snake (Mardt *et al.* 2001, p. 731.2) had been converted to either urban development or agriculture (U.S. Geological Survey National Gap Analysis Program 2004). The area between the Tucson and Phoenix metropolitan areas is believed to encompass the majority of the current range of this subspecies, particularly west of Tucson northward along Avra Valley in Pima County to western Pinal County, and then north into eastern Maricopa County, although no systematic surveys have been conducted to assess the status of Tucson shovel-nosed snakes throughout their range (Arizona Game and Fish Department 2008, p. 2). The last verifiable record of the Tucson shovel-nosed snake in Pima County was in 1979, near the intersection of Avra Valley Road and Sanders Road in the Avra Valley (Rosen 2003, p. 10). Although habitat still exists in Pima County, the current distribution and abundance in Pima County is unknown. Most of the currently occupied range of the Tucson shovel-nosed snake is believed to lie in southwestern Pinal County and eastern Maricopa County, where the most recent records occur (Rosen 2008b, p. 8; Mixan and Lowery, p. 1).

Survey efforts on the Florence Military Reservation (Mixan and Lowery

2008) and in the northern Avra Valley (Rosen 2003, 2004, and 2008b) provide the only recent intensive survey data available. Dr. Rosen conducted road surveys in 2003, 2004, and 2007, as well as trap arrays in 2007. From the road surveys he detected four Tucson shovel-nosed snakes, plus one photo-vouchered specimen from 2006, all near Eloy and Picacho in Pinal County, Arizona (Rosen 2004, p. 18; 2008b, p. 2). The trap arrays, which were set in previously occupied habitat in Pima County, did not result in any Tucson shovel-nosed snake captures. In the spring and summer of 2008, the Arizona Game and Fish Department conducted Tucson shovel-nosed snake surveys on the Florence Military Reservation in Pinal County, Arizona. A total of 29 Tucson shovel-nosed snakes were found during these surveys: 6 within trap arrays west of State Route 79 and 23 as road kill mortalities on State Route 79 (Mixan and Lowery 2008, p. 5).

In 2006, the Arizona Game and Fish Department coordinated attempts to collect shovel-nosed snake tissues for genetic analyses. Based on these efforts, populations are persisting in areas dominated by creosote flats along State Route 79, north of Florence and south of Florence Junction; along Maricopa Road (including State Route 238) between Maricopa and Gila Bend (likely including much of the Rainbow Valley and lower Vekol Wash); east of the San Tan Mountains; along State Route 349 between Maricopa and Casa Grande; south of Interstate 8 near the northern boundary of the Tohono O'odham Reservation; and in the vicinity of the Santa Cruz Flats near Eloy and Picacho (Arizona Game and Fish Department 2008, p. 2).

Factors Affecting the Tucson Shovel-Nosed Snake

Section 4 of the Act (16 U.S.C. 1533), and implementing regulations at 50 CFR 424, set forth procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species, subspecies, or distinct population segment of vertebrate taxa may be determined to be endangered or threatened due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Below we provide a summary of our analysis of the threats to the Tucson shovel-nosed snake.

A. The present or threatened destruction, modification, or curtailment of its habitat or range.

Urban and Rural Development

As of 2001, more than 20 percent of the area within the range of the Tucson shovel-nosed snake had been converted to urban development (U.S. Geological Survey National Gap Analysis Program 2004). The effects of urban and rural development are expected to increase as human populations increase. The human population in Arizona increased by 394 percent from 1960 to 2000 (Social Science Data Analysis Network 2000, p. 1) and another 26.7 percent from 2000 to 2008 (U.S. Census Bureau 2008, p. 1). Since 2000, population growth rates in Arizona counties where the Tucson shovel-nosed snake historically occurred or may still occur have varied by county but are no less remarkable: Maricopa (28.7 percent); Pima (19.9 percent); and Pinal (82.1 percent) (U.S. Census Bureau 2008, p. 1). Increasing human populations threaten the Tucson shovel-nosed snake as further modification and loss of habitat is required to accommodate this growth.

Human population growth trends in Arizona are expected to continue into the future. By 2030, projections estimate the population in Arizona will have more than doubled when compared to the 2000 population estimate (U.S. Census Bureau 2005, p. 1). In particular, a wide swath (called the Sun Corridor "Megapolitan") from the international border in Nogales, through Tucson, Phoenix, and north past the Prescott area is predicted to house eight million people by 2030 (Gammage *et al.* 2008, pp. 15 and 22–23). This Megapolitan encompasses the entire historical range of the Tucson shovel-nosed snake and would contain approximately 82.5 percent more residents in 2030 than in 2000 (Gammage *et al.* 2008, pp. 22–23).

In response to our 90–day finding on the Tucson shovel-nosed snake, we received information stating that the prospect of continuing development is no longer a threat to the snake because of current economic conditions, and that these conditions have not only halted most real estate projects in central Arizona, but have also eliminated the demand for State Trust land in central Arizona to be sold for development (James 2008, p. 10). We acknowledge that development pressure across Arizona has slowed due to the recent economic downturn and housing market collapse. However, this does not negate the fact that development likely still will continue in the future, although perhaps at a slower pace than in the earlier part of this century. For instance, the most recent draft Pinal County Comprehensive Plan (February 2009) acknowledges that the county is in the middle of the Sun Corridor Megapolitan (Tucson, Phoenix, and the corridor between them), and proposes four shorter-term Growth Areas to define areas where development will occur or be encouraged to develop over the next decade, although it does not mean to discourage growth outside of these areas (Pinal County Comprehensive Plan 2009, p. 109). These four Growth Areas (Gateway/Superstition Vistas, West Pinal, Red Rock, and Tri-Communities) fall either completely or partially within the range of the Tucson shovel-nosed snake. The Gateway/Superstition Vistas Growth Area alone encompasses 71,225 hectares (176,000 acres, or 275 square miles) of State Trust land, at least two-thirds of which falls within the range of the snake, and it is anticipated that more than 800,000 to more than 1,000,000, people will one day live in this development (Pinal County Comprehensive Plan 2009, p. 115). The Comprehensive Plan (2009, p. 117) identifies many kilometers (miles) of new freeways and principal arterials in this Growth Area at buildout, which the plan acknowledges may take over a half century to realize (p. 115). Roads can have a negative effect on reptiles in general, and snakes specifically, and pose a threat to the Tucson shovel-nosed snake, as well. This is discussed in more detail in the Road Construction, Use, and Maintenance section below.

Additionally, the Maricopa County Comprehensive Plan calls for Growth Areas to the south and east of the Chandler and Mesa areas, which are within the range of the Tucson shovel-nosed snake (Maricopa County Comprehensive Plan 2002 (revised), p. 92). City comprehensive plans within the range of the snake also call for future Growth Areas; for example, the City of Eloy has designated six Growth Areas encompassing 15,520 acres mostly along the Interstate 10 corridor (City of Eloy General Plan 2004, pp. 7-6 through 7-10), of which more than half fall within the range of the snake. These Growth Areas include the locations of some of the most recent sightings of the snake (Rosen 2008b, p. 8). While much of this area has already been impacted by development or irrigated agriculture, any remaining habitat for the Tucson shovel-nosed snake will likely be negatively affected as development and

its associated infrastructure progress into these areas.

James (2008, p. 9) also stated that, as a consequence of restrictions imposed on both agricultural and municipal uses of groundwater by Arizona law, development within the range of the Tucson shovel-nosed snake, particularly in Pinal County, has primarily involved the conversion of agricultural land to municipal uses. Although James (2008, p. 9) considers the actual impact of development on suitable habitat for the Tucson shovel-nosed snake to be exaggerated, we did not find evidence to support this claim. As of 2001, more than one third of the area within the range of the snake was in agricultural use or under development (U.S. Geological Survey National Gap Analysis Program 2004). We acknowledge that the conversion of agricultural land to municipal uses has occurred and continues to occur within the range of the Tucson shovel-nosed snake (as noted above). Much of the land in the western half of Pinal County is primarily used for irrigated agriculture because of low desert valleys (Arizona Department of Agriculture 2009, p. 1), which includes a large portion of the range of the Tucson shovel-nosed snake. However, the above-mentioned Gateway/Superstition Vistas Growth Area occurs on 71,225 hectares (176,000 acres, or 275 square miles) of Arizona State Trust land that, while portions of it are moderately grazed, are not currently in irrigated agriculture. Additionally, conversion from agriculture to residential development involves building additional roadways and transportation corridors, which may negatively affect the snake, even in pockets of remaining habitat (see Road Construction, Use, and Maintenance section below). Therefore, while development may be occurring on lands that were already compromised by a previous use, it still poses a threat, as areas of remaining habitat (especially within the Sun Corridor Megapolitan) are expected to be developed for residential and commercial use over the next decade and beyond.

Road Construction, Use, and Maintenance

As noted in the previous section, roadways and transportation corridors are expected to increase over the next decade and beyond as counties within the range of the Tucson shovel-nosed snake, and particularly in Pinal County, continue to develop residential and commercial infrastructure. Roads pose unique threats to herpetofauna and specifically to the Tucson shovel-nosed snake, its prey base, and the habitat where it occurs through: (1) fragmentation, modification, and destruction of habitat; (2) increased genetic isolation; (3) alteration of movement patterns and behaviors; (4) facilitation of the spread of non-native species via human vectors; (5) increased recreational access and the likelihood of subsequent, decentralized urbanization; (6) interference with or inhibition of reproduction; and (7) population sinks through direct mortality (resulting in unnaturally high death rates that exceed birth rates within a population) (Rosen and Lowe 1994, pp. 146–148; Carr and Fahrig 2001, pp. 1074–1076; Hels and Buchwald 2001, p. 331; Smith and Dodd 2003, pp. 134–138; Angermeier *et al.* 2004, pp. 19–24; Shine *et al.* 2004, pp. 9–11; Andrews and Gibbons 2005, pp. 777–781; Roe *et al.* 2006, p. 161).

Roe *et al.* (2006, p. 161) conclude that mortality rates due to roads are higher in mobile species, such as shovel-nosed snakes (active hunters), than those of more sedentary species, which more commonly employ sit-and-wait foraging strategies. Mixan and Lowery (2008, p. 5) found 23 Tucson shovel-nosed snakes dead on the road near the Florence Military Reservation over 45 days of survey efforts, indicating this subspecies is vulnerable to road mortality. The effect of road mortality of snakes becomes most significant in the case of small, highly fragmented populations where removal of mature females from the population may appreciably degrade the viability of a population. Additionally, if snakes traverse only 37 m (121 ft) each night (Rorabaugh 2002, p. 42), roads that are wider than this may serve as barriers, further fragmenting the population.

Off-highway vehicle (OHV) use has grown considerably in Arizona. As of 2007, 385,000 OHVs were registered in Arizona (a 350 percent increase since 1998) and 1.7 million people (29 percent of the Arizona's public) engaged in off-road activity from 2005 to 2007 (Sacco 2007, pers. comm.). Over half of OHV users reported that merely driving off-road was their primary activity, versus using the OHV for the purpose of hunting, fishing, or hiking (Sacco 2007, pers. comm.). Given the pervasive use of OHVs on the landscape, OHV-related mortalities are likely a threat to Tucson shovel-nosed snakes. Ouren *et al.* (2007, pp. 16–22) provided additional data on the effects of OHV use on wildlife. Specifically, OHV use may cause mortality or injury to species that attempt to cross trails created through occupied habitat, and may even lead to depressed populations of snakes depending on the rate of use and number of trails within a given area (Ouren *et al.* 2007, pp. 20–21). This threat may be even more extensive from OHVs than from conventional vehicles because OHV trails often travel through undeveloped habitat. In particular, the Gateway/Superstition Vistas Growth Area has been and continues to be impacted by OHV use, although the Arizona State Land Department is in the process of fencing off a part of this area for dust-abatement reasons (Windes 2009, pers. comm.).

Solar Power Facilities and Transmission Corridors

Solar radiation levels in the Southwest, including Arizona, are some of the highest in the world, and interest in tapping into this source of potential energy is growing. Of the solar technologies available to harness this energy, Concentrating Solar Power (CSP) technologies are the most likely to be used, although photovoltaic cells could be used in some cases. CSP technologies use mirrors to reflect and concentrate sunlight onto receivers that collect solar energy and convert it to heat. This thermal energy can then be used to produce electricity via a steam turbine or heat engine driving a generator.

Within Arizona, the Bureau of Land Management (BLM) has received 35 solar right-of-way applications, including one that is pending on 850 hectares (2,100 acres) approximately 19 kilometers (12 miles) south of Eloy, which is within the range of the Tucson shovel-nosed snake (BLM 2009b, p. 1 and map). Additionally, within Arizona, the Arizona State Land Department is considering solar projects on some of the lands under its jurisdiction. These potential sites are mostly west of Phoenix and Gila Bend, but one project could be located along Interstate 10 in the vicinity of Red Rock, which is within the range of the Tucson shovel-nosed snake. Little information is available about these projects, so we do not know the exact location or extent of each project (Scott 2009, p. 29).

Solar energy development and transmission corridors pose similar threats to the Tucson shovel-nosed snake as development and roadway projects (see Rural and Urban Development and Road Construction, Use, and Maintenance sections above). An average utility-scale solar facility to generate 250 megawatts of electricity would occupy about 506 hectares (1,250 acres) of land (BLM 2009a, p. 1), and would involve removal of all vegetation within this area. Additionally, CSP facilities employ liquids such as oils or molten salts to create steam to power conventional turbines and generators, as

well as various industrial fluids, such as hydraulic fluids, coolants, and lubricants, all of which may present a contaminants-related risk should these fluids leak onto the ground (Scott 2009, p. 12). New transmission lines would need to be built to these facilities, as well as additional roads to maintain the facilities, likely increasing traffic in these areas. These activities pose a threat to the Tucson shovel-nosed snake through removal and contamination of remaining habitat and increased potential for road kill mortality.

Agricultural Uses

While the number of farms in Arizona has almost doubled since 1997, the total amount of farmed area has decreased (U.S. Department of Agriculture 2009, p. 7). Within Maricopa, Pima, and Pinal counties, the amount of irrigated farmland decreased from 2002 to 2007 by 13.5 percent (58,724 hectares (145,109 acres)), 4.1 percent (3,327 hectares (8,222 acres), and 0.7 percent (2,366 hectares (5,846 acres)), respectively (U.S. Department of Agriculture 2009, p. 273). This decrease in irrigated farmland is likely due to the conversion of agricultural areas to urban development. As of 2001, more than 10 percent of the area within the range of the Tucson shovel-nosed snake had been converted to agriculture (U.S. Geological Survey National Gap Analysis Program 2004).

Pinal County is the county with the most agricultural production within the range of the Tucson shovel-nosed snake. In 2007, the amount of farmland still in production in Pinal County was 125,420 hectares (309,920 acres), or approximately nine percent of the entire county (U.S. Department of Agriculture 2009, p. 273). Much of this land, however, is in the western half of the county (Arizona Department of Agriculture 2009, p. 1), which is within the range of the Tucson shovel-nosed snake. Conversion of low desert valleys to farmland renders habitats unsuitable for the Tucson shovel-nosed snake. Agricultural practices can impact this subspecies in a number of ways. Farmers typically use pesticides and herbicides to maintain high agricultural yields, but because arthropods are the primary food for the snake (Mattison 1989, p. 25; Rosen *et al.* 1996, pp. 22–23), the loss or contamination of this prey base may cause mortality, impaired health, or abandonment of an area. Additionally, traffic associated with agricultural roads can result in mortality of individuals (see Road Construction, Use, and Maintenance section above).

Wildfires

Fire has become an increasingly significant threat in the Sonoran Desert. Esque and Schwalbe (2002, pp. 180–190) discuss the effect of wildfires in the Arizona Upland and Lower Colorado River subdivisions of Sonoran desertscrub, both of which are found in the range of the Tucson shovel-nosed snake. The widespread invasion of non-native annual grasses appears to be largely responsible for altered fire regimes that have been observed in these communities, which are not adapted to fire (Esque and Schwalbe 2002, p. 165). In areas comprised entirely of native species, ground vegetation density is mediated by barren spaces that do not allow fire to carry across the landscape. However, in areas where non-native grasses have become established, the fine fuel load is continuous, and fire is capable of spreading quickly and efficiently (Esque and Schwalbe 2002, p. 175). Non-native annual grasses prevalent within the range of the Tucson shovel-nosed snake include brome grasses (*Bromus rubens* and *B. tectorum*) and Mediterranean grasses (*Schismus* spp.) (Esque and Schwalbe 2002, p. 165). The perennial African buffelgrass (*Pennisetum ciliare*), which also poses a fire risk to Sonoran desertscrub, is prevalent within the range of the snake in the Avra and Santa Cruz valleys (Van Devender and Dimmit 2006, p. 5), as well as along Interstate 10 to the City of Phoenix (Kidnocker 2009, p. 1).

After disturbances such as fire, non-native grasses may exhibit dramatic population explosions, which hasten their effect on native vegetation communities. Additionally, with increased fire frequency, these population explosions may lead to a type-conversion of the vegetation community from desert scrub to grassland (Esque and Schwalbe 2002, pp. 175–176; Overpeck and Weiss 2005, p. 2075). Fires carried by the fine fuel loads created by non-native grasses often burn at unnaturally high temperatures, which may result in soils becoming hydrophobic (water repelling), exacerbating sheet erosion, and contributing large amounts of sediment to receiving drainages and water bodies (Esque and Schwalbe 2002, pp. 177–178). Buffelgrass, in particular, is acknowledged as one of the most serious invasive weeds in the Sonoran Desert due to its ability to spread exponentially (Buffelgrass Working Group 2007, p. 2). It has the potential to invade much of southern and central Arizona, which can lead to recurring grassland fires and the destruction of native desert vegetation (Buffelgrass Working Group 2007, p. 2). These changes can negatively affect the habitat and prey base of the Tucson shovel-nosed snake, although precisely how snake populations would respond is unknown.

Summary of Factor A

Much of the habitat within the range of the Tucson shovel-nosed snake already has been converted to development or agriculture, and remaining habitat continues to be threatened by both these land uses, as well as the construction of large-scale solar power facilities and transmission lines. By the year 2030, the human population in Arizona is expected to be more than double the 2000 population, particularly in the Sun Corridor Megapolitan, which is an area completely encompassing the range of the Tucson shovel-nosed snake. Road construction, maintenance, and use have been documented to affect this subspecies directly through mortality and indirectly through habitat loss and fragmentation, the impacts of which will likely increase with new development and an increasing human population. The need for alternative energy sources is continuing to rise, which will lead to construction of solar energy facilities and transmission corridors in the State of Arizona, some of which will likely be sited within the range of the Tucson shovel-nosed snake. Agricultural use within the range of the snake has been decreasing, a trend that will probably continue as land use converts from agriculture to residential and commercial development. Agriculture that persists will continue to impact the snake by reducing the available prey base and fragmenting habitat. The threat of wildfire due to non-native plants is expected to rise, given the prevalence of Mediterranean grasses, brome grasses, and especially buffelgrass within the range of the Tucson shovel-nosed snake and the invasive nature of these grasses. How snakes would respond to vegetation community change brought about by increasing fire frequency is unknown. The best available information indicates shovel-nosed snakes travel only short distances (37 m (121 ft)), which likely makes the subspecies particularly susceptible to habitat fragmentation as barriers formed by the above-mentioned threats isolate small populations from one another. Therefore, we find that the present or threatened destruction, modification, or curtailment of its habitat or range is a threat to the Tucson shovel-nosed snake within the foreseeable future.

B. Overutilization for commercial, recreational, scientific, or educational purposes.

Based on the information available, overutilization of the Tucson shovel-nosed snake does not appear to pose a threat to this subspecies. Shovel-nosed snakes in general, and Tucson shovel-nosed snakes in particular, are not regularly seen in the pet trade (Arizona Game and Fish Department 2008). There have been few scientific or educational studies of Tucson shovel-nosed snakes over the years, and most recently they have been limited largely to surveys (Arizona Game and Fish Department 2008). Few animals have been collected for these studies other than animals found on highways, where their survival was already likely compromised. Additionally, Arizona State University and the University of Arizona recently began to accept photographic vouchers, versus physical specimens, in their respective museum collections, which may reduce the amount of collection. We believe these measures reduce the necessity for field biologists to collect physical specimens (unless discovered postmortem) for locality voucher purposes and, therefore, further reduce impacts to vulnerable populations of the Tucson shovel-nosed snake. Based on this information, we find that overutilization for commercial, recreational, scientific, or educational purposes is not a threat to the Tucson shovel-nosed snake.

C. Disease or Predation

Disease in Tucson shovel-nosed snakes has not yet been documented as a specific threat. However, little is known about disease in wild snakes. Predation on *Chionactis occipitalis* by a variety of carnivores has been documented, including by various snakes, foxes, coyotes, shrikes, and owls (Brennan and Holycross 2006, p. 98). However, we are not aware of data suggesting that predation poses a threat beyond that expected in a normally functioning ecosystem. Therefore, we do not consider disease or predation a threat to Tucson shovel-nosed snakes.

D. Inadequacy of existing regulatory mechanisms.

The Tucson shovel-nosed snake is considered a "Tier 1b Species of Greatest Conservation Need" in the Arizona Game and Fish Department draft document, Arizona's Comprehensive Wildlife Conservation Strategy (CWCS) (Arizona Game and Fish Department 2006, pp. 32 and 723). The purpose of the CWCS is to provide a foundation for the future of wildlife conservation and a stimulus to conservation partners to strategically think about their roles in prioritizing conservation efforts (Arizona Game and Fish Department 2006, p. 2). A Tier 1b species is one that requires immediate conservation actions aimed at improving conditions through intervention at the population or habitat level (Arizona Game and Fish Department 2006, p. 32). The CWCS, however, does not provide regulatory protection for the snake. It serves only to prioritize funds and guide implementation of conservation activities for Arizona's vulnerable wildlife (Arizona Game and Fish Department 2006, p. 9). The Arizona Game and Fish Department does not have specified or mandated recovery goals for the Tucson shovel-nosed snake, but it continues as a strong partner in research and survey efforts that further our understanding of current populations within Arizona.

With a valid hunting license, the Arizona Game and Fish Department allows for take of up to four Tucson shovel-nosed snakes per person per year as specified in Commission Order Number 43. The Arizona Game and Fish Department defines "take" as "pursuing, shooting, hunting, fishing, trapping, killing, capturing, snaring, or netting wildlife or the placing or using any net or other device or trap in a manner that may result in the capturing or killing of wildlife." If more than four are to be collected (e.g., for research purposes), a scientific collecting permit must be obtained. It is illegal to commercially sell, barter, or trade any native Arizona wildlife.

While we are aware that the Arizona Game and Fish Department enforces these laws to the extent that it can, encounters between humans and Tucson shovel-nosed snakes can result in the capture, injury, or death of the snake due to the lay person's fear or dislike of snakes, and the snake's resemblance to venomous coral snakes (Rosen and Schwalbe 1988, p. 43; Ernst and Zug 1996, p. 75; Green 1997, pp. 285–286; Nowak and Santana-Bendix 2002, p. 39). We believe that unregulated take may occur, but it is likely infrequent because Tucson shovel-nosed snakes generally are difficult to locate in the wild.

The majority of currently known populations of Tucson shovel-nosed snakes occur on lands managed by the Arizona State Land Department, which at present has no regulations or programs to protect the subspecies. State Trust Land is distinguished from public land (such as Federal land administered by the BLM or U.S. Forest Service) in that all uses of the land must benefit the 13 Trust beneficiaries, the largest of which are the Common Schools (Arizona State Land Department 2009a, p. 1). Arizona State Trust Lands are managed to enhance value and optimize economic return for the Trust beneficiaries (Arizona State Land Department 2009b, p. 1), which can include the sale or long-term lease of lands for commercial or residential development. Although State lands currently provide open space within the range of the Tucson shovel-nosed snake, there are no known plans to require protection of habitat on State lands, and no other protections are afforded the snake on State lands.

BLM manages some lands within the range of the Tucson shovel-nosed snake. BLM currently has no regulations to protect the Tucson shovel-nosed snake, and does not survey for the snake or its habitat. BLM lands usually are secure from agricultural and urban development; however, BLM may dispose of lands identified under its land use planning through the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 *et seq.*), and may also issue permits for uses such as solar facilities and rights-of-way. Additionally, the open space provided by BLM lands can be and often is heavily impacted by OHV use, which may pose a threat to the Tucson shovel-nosed snake (see Road Construction, Use, and Maintenance under Factor A above).

Some lands within the range of the Tucson shovel-nosed snake are owned by county, city, or private entities. These lands may provide habitat for the Tucson shovel-nosed snake if they are maintained as natural open space; however, there are no regulatory mechanisms in place to protect the snake should the land use change.

We are aware of three habitat conservation plans currently being developed that include the Tucson shovel-nosed snake as a covered species: the Pima County Multi-species Conservation Plan, the Town of Marana Habitat Conservation Plan, and the City of Tucson's Avra Valley Habitat Conservation Plan. As none of these plans have been finalized, we will not explore the adequacies of these plans as possible regulatory mechanisms for the snake.

The Gila River Indian Community owns lands within the range of the Tucson shovel-nosed snake. We are not aware of any mechanisms in place to protect the snake on their lands.

Summary of Factor D

Currently, there are no regulatory mechanisms in place that specifically target the conservation of the Tucson shovel-nosed snake or its habitat. Regulations protecting the quantity and quality of open space are inadequate to protect the habitat of the Tucson shovel-nosed snake, particularly in the face of the significant population growth expected within the historical range of the snake discussed under Factor A. Therefore, we consider the inadequacy of existing regulatory mechanisms a threat to the Tucson shovel-nosed snake.

E. Other natural or manmade factors affecting its continued existence.

Seager *et al.* (2007, pp. 1181-1184) analyzed 19 different computer models of differing variables to estimate the future climatology of the southwestern United States and northern Mexico in response to predictions of changing climatic patterns. All but one of the 19 models predicted a drying trend within the Southwest; one predicted a trend toward a wetter climate (Seager *et al.* 2007, p. 1181). A total of 49 projections were created using the 19 models; all but 3 of the projections predicted a shift to increasing dryness in the Southwest as early as 2021–2040 (Seager *et al.* 2007, p. 1181). The current prognosis for climate change impacts on the Sonoran Desert of the American Southwest includes fewer frost days; warmer temperatures; greater water demand by plants, animals, and people; and an increased frequency of extreme weather events (heat waves, droughts, and floods) (Overpeck and Weiss 2005, p. 2074; Archer and Predick 2008, p. 24). How climate change will affect summer precipitation is less certain, because precipitation predictions are based on continental-scale general circulation models that do not yet account for land use and land cover change effects on climate or regional phenomena, such as those that control monsoonal rainfall in the Southwest (Overpeck and Weiss 2005, p. 2075; Archer and Predick 2008, pp. 23–24). Some models predict dramatic changes in Southwestern vegetation communities as a result of climate change (Overpeck and Weiss 2005, p. 2074; Archer and Predick 2008, p. 24), especially as wildfires carried by non-native plants (e.g., buffelgrass) potentially become more frequent, promoting the presence of exotic species over native ones (Overpeck and Weiss 2005, p. 2075). The shovel-nosed snake currently persists, often in abundance, within portions of its range (e.g., southwestern Arizona and southeastern California) that experience less precipitation and higher temperatures and are characterized by simpler vegetation communities (Turner and Brown 1982, pp. 190–202) than that found within the range of the Tucson shovel-nosed snake. Hence, if climates dry and become warmer, with concomitant changes in vegetation communities, the Tucson shovel-nosed snake may be able to persist under those conditions. However, the precise habitat components and ecological relationships necessary for persistence are unknown, so predicting the response of the snake to environmental change induced by climate change is speculative. If changes include increased fire frequency due to increasing non-native plants, this tends to increase uncertainty in predicting population response, because how the snake responds to these fire-altered communities is unknown. At this time, it is not possible to determine how these changes will affect the Tucson shovel-nosed snake, as potential trajectories of vegetation change within the range of the subspecies are difficult to predict due to uncertain changes in warm season precipitation variability and fire (Overpeck and Weiss 2005, p. 2075), and the response of the snake to changing vegetation communities is speculative.

Summary of Factor E

Temperatures in the desert Southwest are expected to rise in the next two decades and likely throughout the 21st century (Intergovernmental Panel on Climate Change 2007, pp. 45–46), with an increased frequency of extreme weather events, such as heat waves, droughts, and floods. We do not know the extent to which changing climate patterns will affect the Tucson shovel-nosed snake; however, this environmental change injects additional uncertainty into the future status of the subspecies.

Finding

In our review of the status of the Tucson shovel-nosed snake, we carefully examined the best scientific and commercial information available. We identified a number of potential threats to this species, including: urban and rural development; road construction, use, and maintenance; concentrating solar power facilities and transmission corridors; agriculture; wildfires; and lack of adequate management and regulation.

Limited surveys have been conducted only in small parts of its range, so information on rangewide population size and trends for the Tucson shovel-nosed snake is not available. As of 2001, over one-third of the area within the range of the snake had been converted to either urban development or agriculture. There are indications that in the Avra Valley, where the snake was once present, it has now disappeared or persists in such low numbers that it is difficult to locate. In other areas (e.g., Florence Military Reservation), the snake appears to be persisting. Therefore, based on the best available information, we find that the only information we have indicates that populations in the Avra Valley have declined, which is near development and agriculture; while in areas with little or no development or agriculture, the population is persisting.

We evaluated existing and potential threats to the Tucson shovel-nosed snake to determine what effects on the subspecies are currently occurring, whether these threats are likely to increase or decrease in the future, and which of the impacts may be expected to rise to the level of a threat to the subspecies, either rangewide or at the population level. We examined threats posed by urban and rural development; road construction, use, and maintenance; solar power facilities and transmission corridors; agricultural uses; wildfires; overutilization; disease and predation; the inadequacy of existing regulatory mechanisms; and climate change. We did not find that overutilization, disease, or predation are currently threatening the Tucson shovel-nosed snake. We also found it likely that the threat of agricultural uses will decrease in the future, as farmland is and will continue to be converted to residential and commercial uses.

Next we considered whether any of the potential threats are likely to increase within the foreseeable future. Data suggest that urban and rural development in most of the snake's range is likely to increase in the future. Comprehensive Plans encompassing the entire range of the snake encourage large Growth Areas in the next 20 years and beyond, portions of which occur in Tucson shovel-nosed snake habitat not already impacted by development or agriculture. These Plans also call for an increase in roads and transportation corridors, which have been documented to impact the snake through direct mortality. Additionally, development of solar energy facilities and transmission corridors throughout the State is being pursued, and demand for these facilities will likely increase. Some of these facilities are being considered within the range of the Tucson shovel-nosed snake and have the potential to degrade

or destroy approximately 506 hectares (1,250 acres), on average, of habitat per facility. We also believe that wildfires due to infestations of non-native grasses (especially buffelgrass) in the snake's habitat, which has native plants not adapted to survive wildfires, are likely to increase in frequency and magnitude in the future as these invasive grasses continue to spread rapidly. It appears that the snake only travels short distances, which makes the subspecies particularly susceptible to habitat fragmentation, as barriers created by development, roads, solar facilities, and wildfires isolate populations from one another. We found that regulations are not in place to minimize or mitigate these threats to the Tucson shovel-nosed snake and its habitat, and, therefore, they are likely to put the snake at risk of local extirpation or extinction.

Climate change is likely to continue for the next century, but there is uncertainty as to how climate change, described under Factor E, will affect the Tucson shovel-nosed snake and its habitat. Predictions are that temperatures in the Southwestern United States will continue to increase, with extreme weather events (such as heat waves, drought, and flooding) occurring with more frequency. How summer precipitation may be affected is less certain. Current models suggest that a 10- to 20–year (or longer) drought is anticipated, and some models predict dramatic changes in Southwestern vegetation communities as a result of climate change, although trajectories of vegetation change are difficult to predict because of variability in warm season precipitation and fire frequency. These changes could affect the habitat of the Tucson shovel-nosed snake, but because of the lack of specific modeling data within the range of the snake, we cannot predict how climate change will impact the Tucson shovel-nosed snake now or in the foreseeable future.

We next considered whether the existing level of threats causes us to conclude that the species is in danger of extinction now or in the foreseeable future. The threats discussed above, particularly those that lead to a loss of habitat, are likely to reduce the population of Tucson shovel-nosed snakes across its entire range. Given the limited geographic distribution of this snake and the fact that its entire range lies within the path of future development, we believe the subspecies is likely to become in danger of extinction within the foreseeable future. Therefore, we find that listing the Tucson shovel-nosed snake throughout its range is warranted.

We have reviewed the available information to determine if the existing and foreseeable threats pose an emergency. We have determined that an emergency listing is not warranted for this subspecies at this time because, within the current distribution of the subspecies throughout its range, there are at least some populations of the Tucson shovel-nosed snake that exist in relatively natural conditions that are unlikely to change in the short-term. However, if at any time we determine that emergency listing of the Tucson shovel-nosed snake is warranted, we will initiate an emergency listing.

The Service adopted guidelines on September 21, 1983 (48 FR 43098) to establish a rational system for allocating available appropriations to the highest priority species when adding species to the Lists of Endangered or Threatened Wildlife and Plants or reclassifying threatened species to endangered status. The system places greatest importance on the immediacy and magnitude of threats, but also factors in the level of taxonomic distinctiveness by assigning priority in descending order to monotypic genera, full species, and subspecies (or equivalently, distinct population segments of vertebrates). We assigned the Tucson shovel-nosed snake an LPN of 3, based on our finding that the subspecies faces imminent and high-magnitude threats from the present or threatened destruction, modification, or curtailment of its habitat and the inadequacy of existing regulatory mechanisms. One or more of the threats discussed above is occurring or is expected to occur throughout the entire range of this subspecies. These threats are on-going and, in some cases (e.g., loss of habitat through urban development), considered irreversible. While we conclude that listing the Tucson shovel-nosed snake is warranted, an immediate proposal to list this subspecies is precluded by other higher priority listing, which we address below.

Significant Portion of the Range

The Act defines an endangered species as one ''in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as one ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The term ''significant portion of its range'' is not defined by the statute. For the purposes of this finding, a significant portion of a species' range is an area that is important to the conservation of the species because it contributes meaningfully to the representation, resiliency, or redundancy of the species. The contribution must be at a level such that its loss would result in a decrease in the ability to conserve the species.

If an analysis of whether a species is threatened or endangered in a significant portion of its range is appropriate, we engage in a systematic process that begins with identifying any portions of the range of the species that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose in analyzing portions of the range that are not reasonably likely to be significant and threatened or endangered. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that (i) the portions may be significant and (ii) the species may be in danger of extinction there or likely to become so within the foreseeable future. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are essentially uniform throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats applies only to portions of the range that are unimportant to the conservation of the species, such portions will not warrant further consideration.

On the basis of an analysis of factors that may threaten the Tucson shovel-nosed snake, we have determined that listing is warranted throughout its range. Therefore, it is not necessary to conduct further analysis with respect to the significance of any portion of its range at this time. We will further analyze whether threats may be disproportionate and warrant further consideration as a significant portion of its range at such time that we develop a proposed listing determination.

Preclusion and Expeditious Progress

Preclusion is a function of the listing priority of a species in relation to the resources that are available and competing demands for those resources. Thus, in any given fiscal year (FY), multiple factors dictate whether it will be possible to undertake work on a proposed listing regulation or whether promulgation of such a proposal is warranted but precluded by higher-priority listing actions.

The resources available for listing actions are determined through the annual Congressional appropriations process. The appropriation for the Listing Program is available to support work involving the following listing actions: proposed and final listing rules;

90–day and 12–month findings on petitions to add species to the Lists of Endangered and Threatened Wildlife and Plants (Lists) or to change the status of a species from threatened to endangered; annual determinations on prior "warranted but precluded" petition findings as required under section 4(b)(3)(C)(i) of the Act; critical habitat petition findings; proposed and final rules designating critical habitat; and litigation-related, administrative, and program-management functions (including preparing and allocating budgets, responding to Congressional and public inquiries, and conducting public outreach regarding listing and critical habitat). The work involved in preparing various listing documents can be extensive and may include, but is not limited to: gathering and assessing the best scientific and commercial data available and conducting analyses used as the basis for our decisions; writing and publishing documents; and obtaining, reviewing, and evaluating public comments and peer review comments on proposed rules and incorporating relevant information into final rules. The number of listing actions that we can undertake in a given year also is influenced by the complexity of those listing actions; that is, more complex actions generally are more costly. For example, during the past several years, the cost (excluding publication costs) for preparing a 12–month finding, without a proposed rule, has ranged from approximately $11,000 for one species with a restricted range and involving a relatively uncomplicated analysis to $305,000 for another species that is wide-ranging and involving a complex analysis.

We cannot spend more than is appropriated for the Listing Program without violating the Anti-Deficiency Act (see 31 U.S.C. § 1341(a)(1)(A)). In addition, in FY 1998 and for each fiscal year since then, Congress has placed a statutory cap on funds which may be expended for the Listing Program, equal to the amount expressly appropriated for that purpose in that fiscal year. This cap was designed to prevent funds appropriated for other functions under the Act (for example, recovery funds for removing species from the Lists), or for other Service programs, from being used for Listing Program actions (see House Report 105-163, 105th Congress, 1st Session, July 1, 1997).

Recognizing that designation of critical habitat for species already listed would consume most of the overall Listing Program appropriation, Congress also put a critical habitat subcap in place in FY 2002 and has retained it each subsequent year to ensure that some funds are available for other work in the Listing Program: "The critical habitat designation subcap will ensure that some funding is available to address other listing activities" (House Report No. 107 - 103, 107th Congress, 1st Session, June 19, 2001). In FY 2002 and each year until FY 2006, the Service has had to use virtually the entire critical habitat subcap to address court-mandated designations of critical habitat, and consequently none of the critical habitat subcap funds have been available for other listing activities. In FY 2007, we were able to use some of the critical habitat subcap funds to fund proposed listing determinations for high-priority candidate species. In FY 2009, while we were unable to use any of the critical habitat subcap funds to fund proposed listing determinations, we did use some of this money to fund the critical habitat portion of some proposed listing determinations, so that the proposed listing determination and proposed critical habitat designation could be combined into one rule, thereby increasing efficiency in our work. In FY 2010, we are using some of the critical habitat subcap funds to fund actions with statutory deadlines.

Thus, through the listing cap, the critical habitat subcap, and the amount of funds needed to address court-mandated critical habitat designations, Congress and the courts have in effect determined the amount of money available for other listing activities. Therefore, the funds in the listing cap, other than those needed to address court-mandated critical habitat for already listed species, set the limits on our determinations of preclusion and expeditious progress.

Congress also recognized that the availability of resources was the key element in deciding, when making a 12–month petition finding, whether we would prepare and issue a listing proposal or instead make a "warranted but precluded" finding for a given species. The Conference Report accompanying Public Law 97-304, which established the current statutory deadlines and the warranted-but-precluded finding, states (in a discussion on 90–day petition findings that by its own terms also covers 12–month findings) that the deadlines were "not intended to allow the Secretary to delay commencing the rulemaking process for any reason other than that the existence of pending or imminent proposals to list species subject to a greater degree of threat would make allocation of resources to such a petition [that is, for a lower-ranking species] unwise."

In FY 2010, expeditious progress is that amount of work that can be achieved with $10,471,000, which is the amount of money that Congress appropriated for the Listing Program (that is, the portion of the Listing Program funding not related to critical habitat designations for species that are already listed). However these funds are not enough to fully fund all our court-ordered and statutory listing actions in FY 2010, so we are using $1,114,417 of our critical habitat subcap funds in order to work on all of our required petition findings and listing determinations. This brings the total amount of funds we have for listing action in FY 2010 to $11,585,417. Starting in FY 2010, we are also using our funds to work on listing actions for foreign species since that work was transferred from the Division of Scientific Authority, International Affairs Program to the Endangered Species Program. Our process is to make our determinations of preclusion on a nationwide basis to ensure that the species most in need of listing will be addressed first and also because we allocate our listing budget on a nationwide basis. The $11,585,417 is being used to fund work in the following categories: compliance with court orders and court-approved settlement agreements requiring that petition findings or listing determinations be completed by a specific date; section 4 (of the Act) listing actions with absolute statutory deadlines; essential litigation-related, administrative, and listing program-management functions; and high-priority listing actions for some of our candidate species. The allocations for each specific listing action are identified in the Service's FY 2010 Allocation Table (part of our administrative record).

In FY 2007, we had more than 120 species with an LPN of 2, based on our September 21, 1983, guidance for assigning an LPN for each candidate species (48 FR 43098). Using this guidance, we assign each candidate an LPN of 1 to 12, depending on the magnitude of threats (high vs. moderate to low), immediacy of threats (imminent or nonimminent), and taxonomic status of the species (in order of priority: monotypic genus (a species that is the sole member of a genus); species; or part of a species (subspecies, distinct population segment, or significant portion of the range)). The lower the listing priority number, the higher the listing priority (that is, a species with an LPN of 1 would have the highest listing priority). Because of the large number of

high-priority species, we further ranked the candidate species with an LPN of 2 by using the following extinction-risk type criteria: International Union for the Conservation of Nature and Natural Resources (IUCN) Red list status/rank, Heritage rank (provided by NatureServe), Heritage threat rank (provided by NatureServe), and species currently with fewer than 50 individuals, or 4 or fewer populations. Those species with the highest IUCN rank (critically endangered), the highest Heritage rank (G1), the highest Heritage threat rank (substantial, imminent threats), and currently with fewer than 50 individuals, or fewer than 4 populations, comprised a group of approximately 40 candidate species ("Top 40"). These 40 candidate species have had the highest priority to receive funding to work on a proposed listing determination. As we work on proposed and final listing rules for these 40 candidates, we are applying the ranking criteria to the next group of candidates with LPN of 2 and 3 to determine the next set of highest priority candidate species.

To be more efficient in our listing process, as we work on proposed rules for these species in the next several years, we are preparing multi-species proposals when appropriate, and these may include species with lower priority if they overlap geographically or have the same threats as a species with an LPN of 2. In addition, available staff resources are also a factor in determining high-priority species provided with funding. Finally, proposed rules for reclassification of threatened species to endangered are lower priority, since as listed species, they are already afforded the protection of the Act and implementing regulations.

We assigned the Tucson shovel-nosed snake an LPN of 3, based on our finding that the subspecies faces immediate and high-magnitude threats from the present or threatened destruction, modification, or curtailment of its habitat; predation; and the inadequacy of existing regulatory mechanisms. One or more of the threats discussed above are occurring in each known population in the United States and throughout historically occupied habitats in Mexico. These threats are on-going and, in some cases (e.g., nonnative species), considered irreversible. Pursuant to the 1983 Guidelines, a "species" facing imminent high-magnitude threats is assigned an LPN of 1, 2, or 3 depending on its taxonomic status. Because the Tucson shovel-nosed snake is a subspecies, we assigned it an LPN of 3 (the highest category available for a subspecies). Therefore, work on a proposed listing determination for the Tucson shovel-nosed snake is precluded by work on higher priority candidate species (i.e., species with LPN of 2); listing actions with absolute statutory, court-ordered, or court-approved deadlines; and final listing determinations for those species that were proposed for listing with funds from previous fiscal years. This work includes all the actions listed in the tables below under expeditious progress.

As explained above, a determination that listing is warranted but precluded must also demonstrate that expeditious progress is being made to add or remove qualified species to and from the Lists of Endangered and Threatened Wildlife and Plants. (Although we do not discuss it in detail here, we are also making expeditious progress in removing species from the list under the Recovery program, which is funded by a separate line item in the budget of the Endangered Species Program. As explained above in our description of the statutory cap on Listing Program funds, the Recovery Program funds and actions supported by them cannot be considered in determining expeditious progress made in the Listing Program.) As with our "precluded" finding, expeditious progress in adding qualified species to the Lists is a function of the resources available and the competing demands for those funds. Given that limitation, we find that we are making progress in FY 2010 in the Listing Program. This progress included preparing and publishing the following determinations:

TABLE 1. ACTIONS TAKEN BY THE LISTING PROGRAM OF THE U.S. FISH AND WILDLIFE SERVICE FROM THE BEGINNING OF FY2010 TO DATE.

Publication Date	Title	Actions	FR Pages
10/08/2009	Listing *Lepidium papilliferum* (Slickspot Peppergrass) as a Threatened Species Throughout Its Range	Final Listing Threatened	74 FR 52013-52064
10/27/2009	90-day Finding on a Petition To List the American Dipper in the Black Hills of South Dakota as Threatened or Endangered	Notice of 90–day Petition Finding, Not substantial	74 FR 55177-55180
10/28/2009	Status Review of Arctic Grayling *(Thymallus arcticus*) in the Upper Missouri River System	Notice of Intent to Conduct Status Review	74 FR 55524-55525
11/03/2009	Listing the British Columbia Distinct Population Segment of the Queen Charlotte Goshawk Under the Endangered Species Act: Proposed rule.	Proposed Listing Threatened	74 FR 56757-56770
11/03/2009	Listing the Salmon-Crested Cockatoo as Threatened Throughout Its Range with Special Rule	Proposed Listing Threatened	74 FR 56770-56791
11/23/2009	Status Review of Gunnison sage-grouse *(Centrocercus minimus*)	Notice of Intent to Conduct Status Review	74 FR 61100-61102
12/03/2009	12-Month Finding on a Petition to List the Black-tailed Prairie Dog as Threatened or Endangered	Notice of 12–month petition finding, Not warranted	74 FR 63343-63366
12/03/2009	90-Day Finding on a Petition to List Sprague's Pipit as Threatened or Endangered	Notice of 90–day Petition Finding, Substantial	74 FR 63337-63343

TABLE 1. ACTIONS TAKEN BY THE LISTING PROGRAM OF THE U.S. FISH AND WILDLIFE SERVICE FROM THE BEGINNING OF FY2010 TO DATE.—Continued

Publication Date	Title	Actions	FR Pages
12/15/2009	90-Day Finding on Petitions To List Nine Species of Mussels From Texas as Threatened or Endangered With Critical Habitat	Notice of 90–day Petition Finding, Substantial	74 FR 66260-66271
12/16/2009	Partial 90-Day Finding on a Petition to List 475 Species in the Southwestern United States as Threatened or Endangered With Critical Habitat; Proposed Rule	Notice of 90–day Petition Finding, Not substantial and Subtantial	74 FR 66865-66905
12/17/2009	12–month Finding on a Petition To Change the Final Listing of the Distinct Population Segment of the Canada Lynx To Include New Mexico	Notice of 12–month petition finding, Warranted but precluded	74 FR 66937-66950
1/05/2010	Listing Foreign Bird Species in Peru and Bolivia as Endangered Throughout Their Range	Proposed ListingEndangered	75 FR 605-649
1/05/2010	Listing Six Foreign Birds as Endangered Throughout Their Range	Proposed ListingEndangered	75 FR 286-310
1/05/2010	Withdrawal of Proposed Rule to List Cook's Petrel	Proposed rule, withdrawal	75 FR 310-316
1/05/2010	Final Rule to List the Galapagos Petrel and Heinroth's Shearwater as Threatened Throughout Their Ranges	Final Listing Threatened	75 FR 235-250
1/20/2010	Initiation of Status Review for *Agave eggersiana* and *Solanum conocarpum*	Notice of Intent to Conduct Status Review	75 FR 3190-3191
2/09/2010	12–month Finding on a Petition to List the American Pika as Threatened or Endangered; Proposed Rule	Notice of 12–month petition finding, Not warranted	75 FR 6437-6471
2/25/2010	12-Month Finding on a Petition To List the Sonoran Desert Population of the Bald Eagle as a Threatened or Endangered Distinct Population Segment	Notice of 12–month petition finding, Not warranted	75 FR 8601-8621
2/25/2010	Withdrawal of Proposed Rule To List the Southwestern Washington/Columbia River Distinct Population Segment of Coastal Cutthroat Trout *(Oncorhynchus clarki clarki*) as Threatened	Withdrawal of Proposed Rule to List	75 FR 13068-13071
3/18/2010	90-Day Finding on a Petition to List the Berry Cave salamander as Endangered	Notice of 90-day Petition Finding, Substantial	75 FR 13068-13071
3/23/2010	90 Day Finding on a Petition to List the Southern Hickorynut Mussel (*Obovaria jacksoniana*) as Endangered or Threatened	Notice of 90-day Petition Finding, Not substantial	75 FR 13717-13720
3/23/2010	90-Day Finding on a Petition to List the Striped Newt as Threatened	Notice of 90-day Petition Finding, Substantial	75 FR 13720-13726
3/23/2010	12-Month Findings for Petitions to List the Greater Sage-Grouse (*Centrocercus urophasianus*) as Threatened or Endangered	Notice of 12-month petition finding, Warranted but precluded	75 FR 13910-14014

Our expeditious progress also includes work on listing actions that we funded in FY 2010 but have not yet been completed to date. These actions are listed below. Actions in the top section of the table are being conducted under a deadline set by a court. Actions in the middle section of the table are being conducted to meet statutory timelines, that is, timelines required under the Act. Actions in the bottom section of the table are high-priority listing actions. These actions include work primarily on species with an LPN of 2, and selection of these species is partially based on available staff resources, and when appropriate, include species with a lower priority if they overlap geographically or have the same threats as the species with the high priority. Including these species together in the same proposed rule results in considerable savings in time and funding, as compared to preparing separate proposed rules for each of them in the future.

TABLE 2. LISTING ACTIONS FUNDED IN FY 2010 BUT NOT YET COMPLETED.

Species	Action
Actions Subject to Court Order/Settlement Agreement	
6 Birds from Eurasia	Final listing determination
Flat-tailed horned lizard	Final listing determination
6 Birds from Peru	Proposed listing determination
Sacramento splittail	Proposed listing determination
Mono basin sage-grouse	12–month petition finding
Greater sage-grouse	12–month petition finding
Big Lost River whitefish	12–month petition finding
White-tailed prairie dog	12–month petition finding
Gunnison sage-grouse	12–month petition finding
Wolverine	12–month petition finding
Arctic grayling	12–month petition finding
Agave eggergsiana	12–month petition finding
Solanum conocarpum	12–month petition finding
Mountain plover	12–month petition finding
Hermes copper butterfly	90–day petition finding
Thorne's hairstreak butterfly	90–day petition finding
Actions with Statutory Deadlines	
48 Kauai species	Final listing determination
Casey's june beetle	Final listing determination
Georgia pigtoe, interrupted rocksnail, and rough hornsnail	Final listing determination
2 Hawaiian damselflies	Final listing determination
African penguin	Final listing determination
3 Foreign bird species (Andean flamingo, Chilean woodstar, St. Lucia forest thrush)	Final listing determination
5 Penguin species	Final listing determination
Southern rockhopper penguin – Campbell Plateau population	Final listing determination
5 Bird species from Colombia and Ecuador	Final listing determination
7 Bird species from Brazil	Final listing determination
Queen Charlotte goshawk	Final listing determination
Salmon crested cockatoo	Proposed listing determination
Black-footed albatross	12–month petition finding
Mount Charleston blue butterfly	12–month petition finding
Least chub[1]	12–month petition finding
Mojave fringe-toed lizard[1]	12–month petition finding
Pygmy rabbit (rangewide)[1]	12–month petition finding
Kokanee – Lake Sammamish population[1]	12–month petition finding
Delta smelt (uplisting)	12–month petition finding

TABLE 2. LISTING ACTIONS FUNDED IN FY 2010 BUT NOT YET COMPLETED.—Continued

Species	Action
Cactus ferruginous pygmy-owl[1]	12–month petition finding
Northern leopard frog	12–month petition finding
Tehachapi slender salamander	12–month petition finding
Coqui Llanero	12–month petition finding
Susan's purse-making caddisfly	12–month petition finding
White-sided jackrabbit	12–month petition finding
Jemez Mountains salamander	12–month petition finding
Dusky tree vole	12–month petition finding
Eagle Lake trout[1]	12–month petition finding
29 of 206 species	12–month petition finding
Desert tortoise – Sonoran population	12–month petition finding
Gopher tortoise – eastern population	12–month petition finding
Amargosa toad	12–month petition finding
Wyoming pocket gopher	12–month petition finding
Pacific walrus	12–month petition finding
Wrights marsh thistle	12–month petition finding
67 of 475 southwest species	12–month petition finding
9 Southwest mussel species	12–month petition finding
14 parrots (foreign species)	12–month petition finding
Southeastern pop snowy plover & wintering pop. of piping plover[1]	90–day petition finding
Eagle Lake trout[1]	90–day petition finding
Ozark chinquapin[1]	90–day petition finding
Smooth-billed ani[1]	90–day petition finding
Bay Springs salamander[1]	90–day petition finding
Mojave ground squirrel[1]	90–day petition finding
32 species of snails and slugs[1]	90–day petition finding
Calopogon oklahomensis[1]	90–day petition finding
42 snail species	90–day petition finding
White-bark pine	90–day petition finding
Puerto Rico harlequin	90–day petition finding
Fisher – Northern Rocky Mtns. population	90–day petition finding
Puerto Rico harlequin butterfly[1]	90–day petition finding
42 snail species (Nevada & Utah)	90–day petition finding
HI yellow-faced bees	90–day petition finding
Red knot *roselaari* subspecies	90–day petition finding
Honduran emerald	90–day petition finding
Peary caribou	90–day petition finding

TABLE 2. LISTING ACTIONS FUNDED IN FY 2010 BUT NOT YET COMPLETED.—Continued

Species	Action
Western gull-billed tern	90–day petition finding
Plain bison	90–day petition finding
Giant Palouse earthworm	90–day petition finding
Mexican gray wolf	90–day petition finding
Spring Mountains checkerspot butterfly	90–day petition finding
Spring pygmy sunfish	90–day petition finding
San Francisco manzanita	90–day petition finding
Bay skipper	90–day petition finding
Unsilvered fritillary	90–day petition finding
Texas kangaroo rat	90–day petition finding
Spot-tailed earless lizard	90–day petition finding
Eastern small-footed bat	90–day petition finding
Northern long-eared bat	90–day petition finding
Prairie chub	90–day petition finding
10 species of Great Basin butterfly	90–day petition finding
High Priority Listing Actions[3]	
19 Oahu candidate species[3] (16 plants, 3 damselflies) (15 with LPN = 2, 3 with LPN = 3, 1 with LPN =9)	Proposed listing
17 Maui-Nui candidate species[3] (14 plants, 3 tree snails) (12 with LPN = 2, 2 with LPN = 3, 3 with LPN = 8)	Proposed listing
Sand dune lizard[3] (LPN = 2)	Proposed listing
2 Arizona springsnails[3] *(Pyrgulopsis bernadina* (LPN = 2), *Pyrgulopsis trivialis* (LPN = 2))	Proposed listing
2 New Mexico springsnails[3] *(Pyrgulopsis chupaderae* (LPN = 2), *Pyrgulopsis thermalis* (LPN = 11))	Proposed listing
2 mussels[3] (rayed bean (LPN = 2), snuffbox No LPN)	Proposed listing
2 mussels[3] (sheepnose (LPN = 2), spectaclecase (LPN = 4),)	Proposed listing
Ozark hellbender[2] (LPN = 3)	Proposed listing
Altamaha spinymussel[3] (LPN = 2)	Proposed listing
5 southeast fish[3] (rush darter (LPN = 2), chucky madtom (LPN = 2), yellowcheek darter (LPN = 2), Cumberland darter (LPN = 5), laurel dace (LPN = 5))	Proposed listing
8 southeast mussels (southern kidneyshell (LPN = 2), round ebonyshell (LPN = 2), Alabama pearlshell (LPN = 2), southern sandshell (LPN = 5), fuzzy pigtoe (LPN = 5), Choctaw bean (LPN = 5), narrow pigtoe (LPN = 5), and tapered pigtoe (LPN = 11))	Proposed listing
3 Colorado plants[3] (Pagosa skyrocket *(Ipomopsis polyantha*) (LPN = 2), Parchute beardtongue *(Penstemon debilis*) (LPN = 2), Debeque phacelia *(Phacelia submutica*) (LPN = 8))	Proposed listing

[1] Funds for listing actions for these species were provided in previous FYs.
[2] We funded a proposed rule for this subspecies with an LPN of 3 ahead of other species with LPN of 2, because the threats to the species were so imminent and of a high magnitude that we considered emergency listing if we were unable to fund work on a proposed listing rule in FY 2008.
[3] Funds for these high-priority listing actions were provided in FY 2008 or 2009

We have endeavored to make our listing actions as efficient and timely as possible, given the requirements of the relevant law and regulations, and constraints relating to workload and personnel. We are continually considering ways to streamline processes or achieve economies of scale, such as by batching related actions

together. Given our limited budget for implementing section 4 of the Act, these actions described above collectively constitute expeditious progress.

The Tucson shovel-nosed snake will be added to the list of candidate species upon publication of this 12–month finding. We will continue to monitor the status of this species as new information becomes available. This review will determine if a change in status is warranted, including the need to make prompt use of emergency listing procedures.

We intend that any proposed listing action for the Tucson shovel-nosed snake will be as accurate as possible. Therefore, we will continue to accept additional information and comments from all concerned governmental agencies, the scientific community, industry, or any other interested party concerning this finding.

References Cited

A complete list of all references cited in this document is available on the Internet at http://www.regulations.gov and upon request from the Field Supervisor at the Arizona Ecological Services Office (see **ADDRESSES** section).

Author

The primary author of this notice is the Arizona Ecological Services Office (see **FOR FURTHER INFORMATION CONTACT** section).

Authority

The authority for this action is section 4 of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: March 18, 2010

Rowan W. Gould,

Acting Director, Fish and Wildlife Service.

[FR Doc. 2010–7133 Filed 3–30–10; 8:45 am]

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Notices

Federal Register

Vol. 75, No. 61

Wednesday, March 31, 2010

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

March 26, 2010.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology should be addressed to: Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), *OIRA_Submission@OMB.EOP.GOV* or fax (202) 395–5806 and to Departmental Clearance Office, USDA, OCIO, Mail Stop 7602, Washington, DC 20250–7602. Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling (202) 720–8681.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Rural Utilities Service

Title: Preloan Procedures and Requirements for Telecommunications Program.

OMB Control Number: 0572–0079.

Summary of Collection: The Rural Utilities Service (RUS) is a credit agency of the U.S. Department of Agriculture. It makes mortgage loans and loan guarantees to finance telecommunications, electric, and water and waste facilities in rural areas with a loan portfolio that totals nearly $42 billion. RUS manages loan programs in accordance with the Rural Electrification Act of 1936, 7 U.S.C. 901 *et seq.* as amended, (RE Act). Section 201 of the RE Act authorizes the Administrator to make loans to qualified telephone companies for the purpose of providing telephone service to the widest practicable number of rural subscribers.

Need and Use of the Information: RUS will collect information using several forms to determine an applicant's eligibility to borrow from RUS under the terms of the RE Act. The information is also used to determine that the Government's security for loans made by RUS are reasonably adequate and that the loans will be repaid within the time agreed. Without the information, RUS could not effectively monitor each borrower's compliance with the loan terms and conditions to properly ensure continued loan security.

Description of Respondents: Business or other for-profit; not-for-profit institutions.

Number of Respondents: 50.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 3,539.

Rural Utilities Service

Title: 7 CFR Part 1778, Emergency and Imminent Community Water Assistance Grants.

OMB Control Number: 0572–0110.

Summary of Collection: The Rural Utilities Service (RUS) is authorized under Section 306A of the Consolidated Farm and rural Development Act, (7 U.S.C. 1926(a) to provide grants to rural areas and small communities to secure adequate quantities of safe water. Grants made under this program shall be made for 100 percent of the project cost, can serve rural areas with population not in excess of 5,000, and household income should not exceed 100 percent of a State's non-metropolitan median household income. Grants under this program may be made to public bodies and private nonprofit corporations serving rural areas.

Need and Use of the Information: RUS will collect the information from applicants applying for grants under 7 CFR part 1778. The information is unique to each borrower and emergency situation. Applicants must demonstrate that there is an imminent emergency or that a decline occurred within 2 years of the date the application was filed with Rural Development.

Description of Respondents: State, Local or Tribal Government; not-for-profit institutions.

Number of Respondents: 100.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 400.

Rural Utility Service

Title: Water and Waste Disposal Programs Guaranteed Loans.

OMB Control Number: 0572–0122.

Summary of Collection: The Rural Utilities Service (RUS) is authorized by Section 306 of the Consolidated Farm and Rural Development Act (7 U.S.C. 1926) to make loans to public agencies, nonprofit corporations, and Indian Tribes for the development of water and waste disposal facilities primarily servicing rural residents. The Waste and Water Disposal Programs (WW) of RUS provide insured loan and grant funds through the WW program to finance many types of projects varying in size and complexity. The Waste and Water Disposal Guaranteed Program is implemented through 7 CFR part 1779. The guaranteed loan program encourages lender participation and provides specific guidance in the processing and servicing of guaranteed WW loans.

Need and Use of the Information: Rural Development's field offices will collect information from applicants/borrowers, lenders, and consultants to determine eligibility, project feasibility and to ensure borrowers operate on a sound basis and use loan funds for authorized purposes. There are agency forms required as well as other requirements that involve certifications from the borrower, lenders, and other

parties. Failure to collect proper information could result in improper determinations of eligibility, improper use of funds and or unsound loans.

Description of Respondents: Business or other for-profit; not-for-profit institutions; State, Local or Tribal Government.

Number of Respondents: 15.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 858.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2010–7195 Filed 3–30–10; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

Information Collection Activity; Comment Request

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Rural Utilities Service (RUS), in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, as amended), invites comments on the following information collections for which the Agency intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by June 1, 2010.

FOR FURTHER INFORMATION CONTACT: Michele Brooks, Director, Program Development and Regulatory Analysis, U.S. Department of Agriculture, Rural Utilities Service, 1400 Independence Ave., SW., STOP 1522, Room 5162, South Building, Washington, DC 20250–1522. Telephone: (202) 690–1078. Fax: (202) 720- 8435.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires 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 information collections that RUS is submitting to OMB for extension.

Comments are invited on: (a) Whether this collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information including the validity of the methodology and assumptions used; (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 appropriate automated, electronic, mechanical or other technological collection techniques or other forms of information technology. Comments may be sent to Michele Brooks, Director, Program Development and Regulatory Analysis, U.S. Department of Agriculture, Rural Utilities Service, STOP 1522, 1400 Independence Ave., SW., Washington, DC 20250–1522. Fax: (202) 720–8435.

Title: 7 CFR Part 1794, Environmental policies and Procedures.

OMB Control Number: 0572–0117.

Type of Request: Extension of a currently approved collection.

Abstract: The information collection contained in this rule are requirements prescribed by the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321–4346), the Council on Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1508), and Executive Orders.

USDA Rural Development administers rural utilities programs through the Rural Utilities Service (Agency). Agency applicants provide environmental documentation, as prescribed by the rule, to assure that policy contained in NEPA is followed. The burden varies depending on the type, size, and location of each project, which then prescribes the type of information collection involved. The collection of information is only that information that is essential for the Agency to provide environmental safeguards and to comply with NEPA as implemented by the CEQ regulations.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 146 hours per response.

Respondents: Business or other for-profit and non-for-profit institutions.

Estimated Number of Respondents: 1,339.

Estimated Number of Responses per Respondent: 2

Estimated Total Annual Burden on Respondents: 486,440 hours.

Copies of this information collection can be obtained from MaryPat Daskal, Program Development and Regulatory Analysis, United States Department of Agriculture, Rural Utilities Service, at (202) 720–7853. FAX: (202) 720–8435.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Dated: March 25, 2010.

Jessica Zufolo,

Deputy Administrator, Rural Utilities Service.

[FR Doc. 2010–7125 Filed 3–30–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Designation for the Champaign, IL; Emmett, MI; Davenport, IA; Enid, OK; Keokuk, IA; Marshall, MI; and Omaha, NE Areas

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice.

SUMMARY: GIPSA is announcing the designation of the following organizations to provide official services under the United States Grain Standards Act, as amended (USGSA): Champaign-Danville Grain Inspection Departments, Inc. (Champaign); Detroit Grain Inspection Service, Inc. (Detroit); Eastern Iowa Grain Inspection and Weighing Service, Inc. (Eastern Iowa); Enid Grain Inspection Company, Inc. (Enid); Keokuk Grain Inspection Service (Keokuk); Michigan Grain Inspection Services, Inc. (Michigan); and Omaha Grain Inspection Service, Inc. (Omaha).

DATES: *Effective Date:* April 1, 2010.

ADDRESSES: William A. Ashley, Acting Branch Chief, Review Branch, Compliance Division, GIPSA, USDA, STOP 3604, Room 1647–S, 1400 Independence Avenue, SW., Washington, DC 20250–3604.

FOR FURTHER INFORMATION CONTACT: William A. Ashley, 202–720–8262 or *William.A.Ashley@usda.gov.*

Read Applications: All applications and comments will be available for public inspection at the office above during regular business hours (7 CFR 1.27(c)).

SUPPLEMENTARY INFORMATION: In the September 4, 2009, **Federal Register** (74 FR 45803), GIPSA requested applications for designation to provide official services in the geographic areas presently serviced by the agencies named above. Applications were due by October 1, 2009.

Champaign, Detroit, Eastern Iowa, Enid, Keokuk, Michigan, and Omaha were the sole applicants for

designations to provide official services in these areas. As a result, GIPSA did not ask for additional comments.

GIPSA evaluated all available information regarding the designation criteria in section 7(f)(1) of the USGSA (7 U.S.C. 79(f)) and determined that Champaign, Detroit, Eastern Iowa, Enid, Keokuk, Michigan, and Omaha are able to provide official services in the geographic areas specified in the September 4, 2009 **Federal Register** for which they applied. These designation actions to provide official services in the specified areas are effective April 1, 2010 and terminate on March 31, 2013.

Interested persons may obtain official services by calling the telephone numbers listed below:

Official agency	Headquarters location and telephone	Designation start	Designation end
Champaign	Champaign, IL (217–398–0723). Additional Locations: Hoopeston, IL; Lake Village, IN; and Terre Haute, IN.	4/1/2010	3/31/2013
Detroit	Emmett, MI (810–395–2105)	4/1/2010	3/31/2013
Eastern Iowa	Davenport, IA (563–322–7149). Additional Locations: Dubuque, IA; Muscatine, IA; Gladstone, IL; and Rochelle, IL.	4/1/2010	3/31/2013
Enid	Enid, OK (916–374–9700). Additional Location: Catoosa, OK	4/1/2010	3/31/2013
Keokuk	Keokuk, IA (319–524–6482). Additional Location: Havana, IL	4/1/2010	3/31/2013
Michigan	Marshall, MI (269–781–2711). Additional Locations: Cairo, OH and Carrollton, MI.	4/1/2010	3/31/2013
Omaha	Omaha, NE (402–341–6739)	4/1/2010	3/31/2013

Section 7(f)(1) of the USGSA authorizes GIPSA's Administrator to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)(1)).

Under section 7(g)(1) of the USGSA, designations of official agencies are effective for 3 years unless terminated by the Secretary; however, designations may be renewed according to the criteria and procedures prescribed in section 7(f) of the Act.

Authority: 7 U.S.C. 71–87k.

J. Dudley Butler,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2010–7120 Filed 3–30–10; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Grain Inspection, Packers and Stockyards Administration

Opportunity for Designation in the Amarillo, TX; Cairo, IL; State of Louisiana; State of North Carolina; Belmond, IA; State of New Jersey; and State of New York Areas; Request for Comments on the Official Agencies Servicing These Areas

AGENCY: Grain Inspection, Packers and Stockyards Administration, USDA.

ACTION: Notice.

SUMMARY: The designations of the official agencies listed below will end on September 30, 2010. We are asking persons or governmental agencies interested in providing official services in the areas presently served by these agencies to submit an application for designation. In addition, we are asking for comments on the quality of services provided by the following designated agencies: Amarillo Grain Exchange, Inc. (Amarillo); Cairo Grain Inspection Agency, Inc. (Cairo); Louisiana Department of Agriculture and Forestry (Louisiana); North Carolina Department of Agriculture (North Carolina); and D. R. Schaal Agency, Inc. (Schaal).

DATES: Applications and comments must be received by April 30, 2010.

ADDRESSES: Submit applications and comments concerning this notice using any of the following methods:

- *Internet:* Apply using FGISonline (*https://fgis.gipsa.usda.gov/default_home_FGIS.aspx*) by clicking on the Delegations/Designations and Export Registrations (DDR) link. You will need to obtain an FGISonline customer number and USDA eAuthentication username and password prior to applying. Submit comments at *http://www.regulations.gov.* Instructions for submitting and reading comments are detailed on the site.
- *Hand Delivery/Courier Address:* William A. Ashley, Acting Review Branch Chief, Compliance Division, GIPSA, USDA, Room 1647–S, 1400 Independence Avenue, SW., Washington, DC 20250.
- *Mail:* William A. Ashley, Acting Review Branch Chief, Compliance Division, GIPSA, USDA, STOP 3604, 1400 Independence Avenue, SW., Washington, DC 20250–3604.
- *Fax:* William A. Ashley, 202–690–2755.
- *E-mail:* *William.A.Ashley@usda.gov.*

Read Applications and Comments: All applications and comments will be available for public inspection at the office above during regular business hours (7 CFR 1.27(c)).

FOR FURTHER INFORMATION CONTACT: William A. Ashley, 202–720–8262 or *William.A.Ashley@usda.gov.*

SUPPLEMENTARY INFORMATION: Section 7(f)(1) of the United States Grain Standards Act (USGSA) (7 U.S.C. 71–87k) authorizes GIPSA's Administrator to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services. Under section 7(g)(1) of the USGSA, designations of official agencies are effective for 3 years unless terminated by the Secretary, but may be renewed according to the criteria and procedures prescribed in section 7(f) of the Act.

Areas Open for Designation

Amarillo

Pursuant to Section 7(f)(2) of the Act, the following geographic areas, in the States of Oklahoma and Texas are assigned to this official agency:

- Armstrong (north of Prairie Dog Town Fork of the Red River), Carson, Childress, Collingsworth, Dallam, Deaf Smith (east of U.S. Route 385), Donley, Gray, Hansford, Hall (east of U.S. Route 287), Harley, Hemphill, Hutchinson, Lipscomb, Moore, Ochiltree, Oldham, Potter, Randall (north of Prairie Dog Town Fork of the Red River, State Route 217 and FM 1062), Roberts, Sherman, and Wheeler Counties in Texas.
- Beaver, Cimarron, and Texas Counties in Oklahoma.

Cairo

Pursuant to Section 7(f)(2) of the Act, the following geographic areas, in the States of Illinois, Kentucky, and Tennessee are assigned to this official agency:

• Alexander, Jackson County (south of State Route 3, State Route 149, and State Route 13; west of U.S. Route 51), Johnson, Hardin, Massac, Pope, Pulaski, Randolph County (south of State Route 150 and south of State Route 3), and Union Counties in Illinois.

• Ballard, Calloway, Carlisle, Fulton, Graves, Hickman, Livingston, Lyon, Marshall, McCracken, and Trigg Counties in Kentucky.

• Benton, Dickson, Henry, Houston, Humphreys, Lake, Montgomery, Obion, Stewart, and Weakley Counties in Tennessee.

The Cargill, Inc., grain elevator in Tiptonville, Lake County, Tennessee, which is located within Cairo's assigned areas, is currently serviced, and will continue to be serviced by Midsouth Grain Inspection Service.

Louisiana

Pursuant to Section 7(f)(2) of the Act, the entire State of Louisiana, except those export port locations within the State which are serviced by GIPSA, is assigned to this official agency.

North Carolina

Pursuant to Section 7(f)(2) of the Act, the entire State of North Carolina, except those export port locations within the State which are serviced by GIPSA, is assigned to this official agency.

Schaal

Pursuant to Section 7(f)(2) of the Act, the following geographic areas, in the States of Iowa, Minnesota, New Jersey, and New York are assigned to this official agency:

• Butler (north of County Road C23 and County Road C33, east of County Road T47, and west of State Highway 188/County Road T64), Cerro Gordo, Floyd (west of County Road T64 and north of County Road B60), Franklin (north of County Road C55, County Road C25, and County Road C23 and west of U.S. Route 65, County Road S41, and County Road S56), Hancock, Kossuth (east of U.S. Route 169), Mitchell, Winnebago, Worth, Wright (north of State Route 3 and Interstate 35 and east of State Route 17 and U.S. Route 65) Counties in Iowa.

The following grain elevators, located within Schaal's assigned geographic areas in the State of Iowa, are not serviced by Schaal: (1) Agvantage F.S., Chapin, Franklin County; (2) Five Star Coop, Rockwell, Cerro Gordo County (both serviced by Central Iowa Grain Inspection Service, Inc.); and (3) West Bend Elevator Co., Algona, Kossuth County; Stateline Coop, Burt, Kossuth County; Gold-Eagle, Goldfield, Wright County; and North Central Coop, Holmes, Wright County (serviced by Sioux City Inspection and Weighing Service Company).

• Faribault, Freeborn, and Mower Counties in Minnesota.

• The entire States of New Jersey and New York, except those export port locations within the States which are serviced by GIPSA.

Opportunity for Designation

Interested persons or governmental agencies may apply for designation to provide official services in the geographic areas specified above under the provisions of section 7(f) of the USGSA and 7 CFR 800.196(d). Designation in the specified geographic areas is for the period beginning October 1, 2010, and ending September 30, 2013. To apply for designation or for more information, contact William A. Ashley at the address listed above or visit GIPSA's Web site at *http://www.gipsa.usda.gov.*

Request for Comments

We are publishing this notice to provide interested persons the opportunity to comment on the quality of services provided by the Amarillo, Cairo, Louisiana, North Carolina, and Schaal official agencies. In the designation process, we are particularly interested in receiving comments citing reasons and pertinent data supporting or objecting to the designation of the applicants. Submit all comments to William A. Ashley at the above address or at *http://www.regulations.gov.*

We consider applications, comments, and other available information when determining which applicant will be designated.

Authority: 7 U.S.C. 71–87k.

J. Dudley Butler,

Administrator, Grain Inspection, Packers and Stockyards Administration.

[FR Doc. 2010–7122 Filed 3–30–10; 8:45 am]

BILLING CODE 3410–KD–P

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Southeast Washington Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000, as amended, (Pub. L. 110–343), the Umatilla National Forest, Southeast Washington Resource Advisory Committee will conduct a business meeting. The meeting is open to the public.

DATES: Wednesday, April 7, 2010, beginning at 6:30 p.m.

ADDRESSES: Pomeroy Ranger District Office, 71 West Main Street, Pomeroy, Washington.

SUPPLEMENTARY INFORMATION: Agenda topics will include review and approval of project proposals, and is an open public forum.

FOR FURTHER INFORMATION CONTACT: Monte Fujishin, Designated Federal Official, at (509) 843–1891 or e-mail *mfujishin@fs.fed.us.*

Dated: March 24, 2010.

Monte Fujishin,

District Ranger, Pomeroy Ranger District, Umatilla National Forest.

[FR Doc. 2010–7116 Filed 3–30–10; 8:45 am]

BILLING CODE 3410–BH–P

DEPARTMENT OF AGRICULTURE

Forest Service

Alpine County Resource Advisory Committee (RAC)

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Alpine County Resource Advisory Committee (RAC) will hold a meeting.

DATES: The meeting will be held on April 20, 2010, and will begin at 6 p.m.

The meeting will be held in Alpine County at the Alpine Early Learning Center, 100 Foothill Road, Markleeville, CA 96120.

FOR FURTHER INFORMATION CONTACT: Marnie Bonesteel, RAC Coordinator, USDA, Humboldt-Toiyabe National Forest, Carson Ranger District, 1536 S. Carson Street, Carson City, NV 89701 (775) 352–1240; E–MAIL *mbonesteel@fs.fed.us.*

SUPPLEMENTARY INFORMATION: Agenda items to be covered include: (1) Congratulate new members (2) Discuss and vote on committee bylaws and elect a chairperson (3) Review Title II projects and recommend projects for funding (4) Public Comment. The meeting is open to the public. Public input opportunity will be provided and individuals will have the opportunity to address the Committee at that time.

Dated: March 23, 2010.

Genny E. Wilson,

Designated Federal Officer.

[FR Doc. 2010–6998 Filed 3–30–10; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Notice of Southwest Idaho Resource Advisory Committee Meeting

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: Pursuant to the authorities in the Federal Advisory Committee Act (Pub. L. 92–463) and under the Secure Rural Schools and Community Self-Determination Act of 2000, as amended, (Pub. L. 110–343), the Boise, Payette, and Sawtooth National Forests' Southwest Idaho Resource Advisory Committee will conduct a business meeting. The meeting is open to the public.

DATES: Thursday, April 15, 2010, beginning at 10:30 a.m.

ADDRESSES: Idaho Counties Risk Management Program Building, 3100 South Vista Avenue, Boise, Idaho.

SUPPLEMENTARY INFORMATION: Agenda topics will include review and approval of project proposals, and is an open public forum.

FOR FURTHER INFORMATION CONTACT: Dale Olson, Designated Federal Official, at (208) 347–0322 or e-mail *dolson07@fs.fed.us.*

Dated: March 22, 2010.

Suzanne C. Rainville,

Forest Supervisor, Payette National Forest.

[FR Doc. 2010–7006 Filed 3–30–10; 8:45 am]

BILLING CODE 3410–11–M

COMMISSION ON CIVIL RIGHTS

Sunshine Act Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of meeting cancellation.

SUMMARY: On March 18, 2010 (75 FR 13076) the U.S. Commission on Civil Rights announced a business meeting to be held on Friday, March 26, 2010 at the Commission's headquarters. On Thursday, March 25, 2010, the meeting was cancelled. The decision to cancel the meeting was too close in time to the day of the meeting for the publication of a cancellation notice to appear in advance of the scheduled meeting date. The details of the cancelled meeting are:

DATE AND TIME: Friday, March 26, 2010; 11:30 a.m. EDT.

PLACE: Via Teleconference. Public Dial in: 1–800–597–7623. Conference ID # 63007474.

Meeting open to public.

Meeting Agenda

This meeting is open to the public, except where noted otherwise.

I. Approval of Agenda

II. Program Planning

- Approval of Letter to Youngstown, Ohio City Council Members re Racially Bifurcated Test Results in the Police and Fire Departments
- Update on Status of 2010 Enforcement Report—Some of the discussion of this agenda item may be held in closed session.
- Update on Status of Title IX Project—Some of the discussion of this agenda item may be held in closed session.

III. Adjourn

The Commission's next scheduled meeting is Friday, April 16, 2010, the details of which will be published in the **Federal Register** eight days prior to that meeting.

CONTACT PERSON FOR FURTHER INFORMATION: Lenore Ostrowsky, Acting Chief, Public Affairs Unit (202) 376–8591. TDD: (202) 376–8116.

Persons with a disability requiring special services, such as an interpreter for the hearing impaired, should contact Pamela Dunston at least seven days prior to the meeting at 202–376–8105. TDD: (202) 376–8116.

Dated: March 29, 2010.

David Blackwood,

General Counsel.

[FR Doc. 2010–7313 Filed 3–29–10; 4:15 pm]

BILLING CODE 6335–01–P

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: U.S. Census Bureau.

Title: 2010 Census Quality Survey.

Form Number(s): D–1R1.

OMB Control Number: None.

Type of Request: New collection.

Burden Hours: 43,810.

Number of Respondents: 262,857.

Average Hours per Response: 10 minutes.

Needs and Uses: As the 2010 Census nears, planning for the 2020 Census is already underway. One particular area of interest for the 2020 Census is to make the Census cost-effective and accurate. The Census Bureau will explore the use of the Internet for the 2020 Census as an alternative means for the public to respond to the Census. Therefore, we have established the 2010 Census Quality Survey (CQS), formerly known as the Internet Reinterview Evaluation, as a research component under the 2010 Census Program for Evaluations and Experiments (CPEX).

Projects under the 2010 CPEX will guide future census design as well as benefit other ongoing programs conducted by the Census Bureau, such as the American Community Survey.

As with previous decennial censuses dating back to 1950, the Census Bureau conducts a formal program to assess the census and experimental tests that examine methodologies, techniques, and strategies that will potentially improve the way the Census Bureau conducts the next decennial census. For experimental studies, the actual decennial census environment is required because it provides the necessary conditions to learn the true effects of new ideas within the context of the actual effects of national advertising, outreach partnerships, and other events that occur only during a census.

The 2010 CQS seeks to build on previous Internet data collection research in order to set the stage for the Internet testing cycle for the 2020 Census. The main objective is to estimate measurement errors, such as simple response variance and bias of responses from a census mail questionnaire compared to those from a census Internet questionnaire. The reinterviews will be conducted with a sample of 2010 Census mail respondents in order to provide estimates of measurement errors associated with the design and content of a self-administered census Internet questionnaire. Since the measurement error structure may differ depending on whether a respondent has only one response mode option (*i.e.* mail or Internet) versus having a choice between the two modes, we are testing both 'push' and 'choice' strategies. A sample of the 2010 Census mail questionnaire respondents will be invited to complete an Internet reinterview ('push' Internet), which has the same content as the 2010 mail questionnaire. A separate sample of the 2010 Census mail questionnaire respondents will be invited to complete a mail reinterview ('push' mail) with the same 2010 content. A third sample of the 2010 Census mail questionnaire respondents will be invited to complete a reinterview with the choice of mail or Internet modes ('choice' Internet/mail).

The data from the Internet reinterview will be compared with the data from the mail reinterview to provide additional information for estimating measurement errors associated with responses from each of the data collection modes as well as response option strategies. Internet reinterview data will also be compared to 2010 Census mail questionnaire data for the same households to estimate gross difference rates. A similar comparison will be made for the mail reinterview to estimate gross difference rates for the mail mode. These gross difference rates will be compared to estimate the measurement error that arises from Internet versus census mail questionnaires. In addition to estimating measurement errors, a key objective of the evaluation is to collect data related to respondent interaction with a census Internet questionnaire such as break-off rates and completion times. Laboratory usability testing will also provide data (*e.g.,* eye-tracking and mouse-tracing results) on navigational issues. Note that we are currently considering tracing mouse movement for a sample of survey respondents, which would include presentation of an informed consent statement.

The Internet and mail reinterviews will be conducted in late summer of 2010, after the census enumeration activities have been completed, to minimize the risk to the 2010 Census data collection. However, the reinterviews will be conducted as close to the census enumeration as feasible to effectively compare reinterview results to the 2010 Census self-administered mail questionnaire. Presumably, the results collected within the census environment will reflect a more generalizable measurement error structure than results from a mid-decade census test instrument. In addition, we hope to capitalize on respondents' awareness of the 2010 Census to obtain a higher response to the reinterviews than would be possible in the absence of the 2010 Census environment. However, for the Internet reinterview, compliance may suffer from public messaging informing potential respondents that there is no Internet response option in the 2010 Census.

As with all CPEX experiments and evaluations, the 2010 CQS is primarily designed for use by the Census Bureau to inform early 2020 Census testing and planning. The intent is to use the 2010 CQS quantitative results, in combination with the usability laboratory results, to focus the Census Bureau's Internet development/design resources for early decade testing. This questionnaire design work will be integrated with response option and contact strategy research within the 2020 testing cycle to establish the optimal Internet data collection strategy for the 2020 Census.

The 2010 CQS is intended to provide estimates of measurement error associated with the design and content of a self-administered census Internet questionnaire. The overall goal is to design the most effective census Internet questionnaire, given the time and resource constraints, and then evaluate its associated measurement error and usability issues. The Internet instrument is not intended to simply replicate the 2010 Census mail questionnaire in an electronic mode. Rather, the goal is to evaluate measurement error associated with an Internet questionnaire that exploits the advantages of the electronic technology, while still retaining the meaning and intent of the questions and response options from the mail form. Likewise, this evaluation is not intended to evaluate public compliance (as measured by unit-level response rates). An Internet response strategy study within the 2010 Census production cycle (or shortly after) would be limited by the 2010 Integrated Communication Program (ICP) messages stating that there is no Internet data collection for the 2010 Census.

Affected Public: Individuals or households.

Frequency: One-time only.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, United States Code, Sections 141 and 193.

OMB Desk Officer: Brian Harris-Kojetin, (202) 395–7314.

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 Brian Harris-Kojetin, OMB Desk Officer either by fax (202–395–7245) or e-mail (*bharrisk@omb.eop.gov*).

Dated: March 26, 2010.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2010–7177 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–936]

Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Notice of Amended Final Determination Pursuant to Final Court Decision

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

SUMMARY: On December 11, 2009, the United States Court of International Trade (CIT) sustained the Department of Commerce's (the Department) remand determination in *Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Final Affirmative Countervailing Duty Determination*, 73 FR 70961 (Nov. 24, 2008) (*Line Pipe from the PRC*), amended by *Circular Welded Carbon Quality Steel Line Pipe from the People's Republic of China: Notice of Amended Final Affirmative Countervailing Duty Determination and Notice of Countervailing Duty Order*, 74 FR 4136 (Jan. 23, 2009) (*Amended Line Pipe from the PRC*). Because all litigation in this matter has concluded, the Department is issuing the amended final determination in *Line Pipe from the PRC* in accordance with the CIT's decision.

EFFECTIVE DATE: March 31, 2010.

FOR FURTHER INFORMATION CONTACT: John Conniff, AD/CVD Operations, Office 3, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230; telephone: 202/482–1009.

SUPPLEMENTARY INFORMATION:

Background

On November 24, 2008, the Department published its affirmative countervailing duty determination in *Line Pipe from the PRC*. On January 23, 2009, the Department published an amended affirmative countervailing duty determination in conjunction with the countervailing duty order. *See Amended Line Pipe from the PRC*. After correcting for ministerial errors, the Department calculated an amended subsidy rate for Huludao Seven–Star Steel Pipe Group Co., Ltd. (Huludao Seven Star Group), Huludao Steel Pipe Industrial Co. Ltd. (Huludao Steel Pipe), and Huludao Bohai Oil Pipe Industrial Co. Ltd. (Huludao Bohai) (collectively, the Huludao Companies) of 31.29 percent. *Id.*

In *Line Pipe from the PRC*, the Department found that suppliers of hot–rolled steel were government–owned with a single exception for the Huludao Companies. Accordingly, the Department determined that supplier to be a private company and thus did not include the hot–rolled steel from that supplier in the Huludao Companies' subsidy calculation. Petitioners, United States Steel Corporation and Maverick Tube Corporation, challenged *Line Pipe from the PRC* before the CIT, arguing in relevant part that the Department erred in finding that supplier of hot–rolled steel to the Huludao Companies to be a private company and not a state–owned enterprise. On September 10, 2009, the CIT granted the Department's request for a voluntary remand for the limited purpose of "reconsidering and, as necessary, correcting a potential error related to the factual finding concerning the ownership of a supplier of hot–rolled steel" to the Huludao Companies. *United States Steel Corp. et al. v. United States*, Consol. Court No. 09–00086 (Ct. Int'l Trade Sept. 10, 2009) (order granting motion for voluntary remand).

The Department issued its remand redetermination on October 20, 2009. *See United States Steel Corp. et al. v. United States*, Consol. Court No. 09–00086, Final Redetermination Pursuant to Remand (Oct. 20, 2009) (Final Redetermination). On remand, the Department determined its previous finding concerning the private ownership of the supplier of hot–rolled steel to the Huludao Companies to be in error. The Department corrected for that error by finding the supplier in question to be government–owned through the application of adverse facts available. See Final Redetermination at 3. As a result of that correction, the Department calculated a revised subsidy rate for the Huludao Companies of 33.43 percent and a revised all–others rate pursuant to section 705(c)(5)(A) of the Tariff Act of 1930, as amended (the Act), of 36.74 percent.[1] *Id.* at 4.

Amended Final Determination

On December 11, 2009, the CIT sustained the Department's remand redetermination in its entirety. *See United States Steel Corp. et al. v. United States*, Slip Op. 09–137 (Ct. Int'l Trade Dec. 11, 2009).

Because there is now a final and conclusive decision in the court proceeding, we are further amending *Line Pipe from the PRC* to reflect the results of the Department's remand redetermination, *i.e.*, the inclusion of the previously excluded supplier to the subsidy calculations. Accordingly, we will instruct CBP to collect cash deposits of estimated countervailing duties at the rate of 33.00 percent of the free on board (f.o.b.) invoice price on all shipments of subject merchandise from the Huludao Companies entered or withdrawn from warehouse, for consumption, on or after publication date of this notice in the **Federal Register**. Additionally, we will instruct CBP to collect cash deposits of estimated countervailing duties at the rate of 36.53 percent of the f.o.b. invoice price on all shipments of subject merchandise from companies subject to the all–others rate pursuant to section 705(c)(5)(A) of the Act, entered or withdrawn from warehouse, for consumption, on or after publication date of this notice in the **Federal Register**.

This determination is published pursuant to sections 705(d) and 777(i) of the Act.

Dated: March 25, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–7216 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–DS–S

[1] The all-others rate was recalculated using a simple average of the two responding firms' subsidy rates. *See Line Pipe from the PRC*, 73 FR at 70962-63.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV46

Fisheries Finance Program; Final Program Notice and Announcement of Availability of Federal Financial Assistance

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic andAtmospheric Administration, Department of Commerce.

ACTION: Announcement of availability of Federal financial assistance.

SUMMARY: NMFS announces the availability of long-term direct loans made underthe Fisheries Finance Program (FFP). The FFP provides financing for the purchase of used vessels or the reconstruction of vessels (limited to reconstructions that do not add to fishing capacity); refinancing for existing debt obligations; financing or refinancing fisheries shoreside facilities or aquacultural facilities; and the purchase or refinancing of Individual Fishing Quota (IFQ) in the North Pacific. FFP loans are not issued for purposes which could contribute to over capitalization of the fishing industry.

DATES: All loan funds available for FY 2010 must be obligated before September 30, 2010.

ADDRESSES: Applicants may obtain information and send loan applications to the nearest Financial Services Branch (FSB). FSB locations and contact information are:

1. Northwest Financial Services Branch, F/MB53, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, 7600 Sand Point Way NW, (BIN C15700), Seattle, WA 98115, Branch Chief: Scott Houghtaling, Phone: (206) 526–6122.

2. Northeast Financial Services Branch, F/MB51, National Marine Fisheries Service, National Oceanic and Atmospheric Administration, 55 Great Republic Drive, Suite 02–700, Gloucester, MA 01930–2209, Branch Chief: Ron Linsky, Phone: (978) 281–9154.

3.Southeast Financial Services Branch, National Marine Fisheries Service, F/MB52, National Oceanic and Atmospheric Administration, 263 13th Avenue South, St. Petersburg, FL 33702–2432, Branch Chief: Shawn Berry, Phone: (727) 824–5342.

In addition, information is available at *www.nmfs.noaa.gov/mb/financial_services/ffp.htm*

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

The FFP's primary statutory authority is found in Title XI of the Merchant Marine Act, 1936, as amended and now recodified at 46 U.S.C. 53701, *et seq*(Title XI). The Sustainable Fisheries Act (SFA) (Pub. L. 104–297) amended section 1104A(a)(7) of Title XI of the Merchant Marine Act (46 U.S.C. App. 1274) and section 303(d)(4) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*) to authorize IFQ financing.

Title XI is the credit authority under which NMFS will make these loans. This authority is subject to the Federal Credit Reform Act of 1990 (FCRA) (2 U.S.C. 661) which requires estimated net loan losses (FCRA cost) to be appropriated at the time Congress authorizes annual loan ceilings.

The amount of annual FCRA credit authority available is a ratio of the FCRA cost rate and the FCRA cost appropriated. The current cost rate estimate based on the historical performance of FFP's loan programs is zero. Consequently, no loan subsidy is required. For Fiscal Year 2010 (FY10),

however, there is appropriated $59,000,000.00 in loan authority for the traditional loan program and $16,000,000.00 for the IFQ loan program.

It is estimated that these credit authorities will fund approximately 31 traditional loans and 54 IFQ loans. Applications will generally be reviewed in the order they are received. The FFP's traditional priorities are:

1. Aquacultural facilities construction, reconstruction, reconditioning, and acquisition

2. Fisheries shoreside facilities construction, reconstruction, reconditioning, and acquisition;

3. Fishing vessel reconstruction, reconditioning and acquisition. The FFP rule, however, prohibits loans that increase existing harvesting capacity, as does the FFP's loan authority appropriations language. FFP loans may not consequently originally finance either vessel construction or reconstruction that increases vessel harvesting capacity. The FFP will not make vessel loans in fisheries listed as overfished or subject to overfishing in the recent Status of the U.S. Fisheries, published by the National Marine Fisheries Service, at the time of application.

B. Catalog of Federal Domestic Assistance

The FFP is listed in the "Catalog of Federal Domestic Assistance" under number 11.415: Fisheries Finance Program.

II. Eligible Applicants

An applicant, either an individual or a business entity must be a citizen of the United States as described in 46 U.S.C. 104, or an entity who is a citizen for the purpose of documenting a vessel in the coastwise trade under 46 U.S.C. 50501.

Applicants for an IFQ loan must be eligible to hold the IFQ in the North Pacific fishery that is subject of the loan.

III. Loan Terms and Conditions

1. *Down payment*. Applicants for financing the purchase of traditional loan assets or IFQ (rather than refinancing) must fund 20 percent of the purchase cost from funds other than loan proceeds. Applications for refinancing a traditional loan can not exceed 80 percent of the project's depreciated actual cost. For IFQ applicants if the current market value of QS, whose purchase cost is being refinanced (rather than financed), is higher than its original purchase price, applicants may need less, or no, down payment. However, if the current value of QS whose purchase cost is being refinanced (rather than financed) is lower than its original purchase price, applicants may be required to provide an additional down payment.

2. *Loan amount*. There is no maximum or minimum loan amount

3. *Interest rate*. Each loan's annual interest rate will be 2 percent higher than the U.S. Treasury's cost of borrowing public funds of an equivalent maturity. For example, the annual loan interest rate would, on January 15, 2010, have been approximately 6.09 percent for a 15-year maturity. Interest is simple interest and the rate is fixed.

4. *Maturity*. Loan maturity may not exceed 25 years, but may be shorter depending on the useful life of the assets being financed and credit and other considerations.

5. *Repayment*. Repayment will be by equal quarterly installments of principal and interest.

6. *Security*. For IFQ loans, the loan QS will, in every case, be the primary security for the loan. For traditional loans, the FFP will require, at a minimum, a pledge of the property being financed or refinanced or adequate substitute collateral. NMFS may require additional collateral to ensure the security position of the primary collateral. NMFS may require all parties with significant ownership interests (eg. the applicant, a corporation or partnership) to personally guarantee the loan repayment. Some credit risks may require additional security.

7. *Application fee*. The application fee is 0.5 percent of the loan amount for which an applicant applies. Half the application fee is fully earned at the time NMFS accepts the application. The other half is fully earned only when NMFS issues an approval in principle letter approving an application. Once it has issued an approval in principle letter, NMFS will not return the second half of the application fee.

IV. Administrative Requirements

1. In accordance with the provisions of the Debt Collection Improvement Act of 1996, a person may not obtain any Federal financial assistance in the form of a loan (other than a disaster loan) or loan guarantee if the person has an outstanding debt (other than a debt under the Internal Revenue Code of 1986) with any Federal agency which is in a delinquent status, as determined under standards prescribed by the Secretary of the Treasury.

2. Applicants may be subject to a name-check review process. Name checks are intended to reveal if any key individuals associated with the applicant have been convicted of or are presently facing such criminal charges as fraud, theft, perjury, or other matters which significantly reflect on the applicant's management honesty or financial integrity.

3. A false statement on an application is grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001.

4. Applicants must submit a completed Form CD–511, "Certifications Regarding Debarment, Suspension and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying," and the following explanations are hereby provided:

i. *Nonprocurement Debarment and Suspension*. Prospective participants (as defined at 15 CFR 26.105) are subject to 15 CFR part 26, "Nonprocurement Debarment and Suspension," and the related section of the certification form applies;

ii. *Anti-Lobbying*. Persons (as defined at 15 CFR 28.105) are subject to the lobbying provisions of 31 U.S.C. 1352. "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions," and the lobbying section of the certification form prescribed above applies to applications/bids for grants, cooperative agreements, and contracts for more than $100,000, and loans and loan guarantees for more than $150,000 the certification form applies.

5. An applicant classified for tax purposes as in individual, partnership, proprietorship, corporation, or medical corporation is required to submit a taxpayer identification number (TIN) (either social security number, employer identification number as applicable, or registered foreign organization number) on Form W–9, "Payers Request for Taxpayer Identification Number." Tax-exempt organizations and corporations (with the exception of medical corporations) are excluded from this requirement. Recipients who either fail to provide their TIN or provide an incorrect TIN may have funding suspended until the requirement is met.

Disclosure of a Recipient's TIN is mandatory for Federal income tax reporting purposes under the authority of 26 U.S.C., Section 6011 and 6109(d), and 26 CFR, Section 301.6109–1. This is to ensure the accuracy of income computation by the IRS. This information will be used to identify an individual who is compensated with DOC funds or paid interest under the Prompt Payment Act.

6. An audit of a Program loan may be conducted at any time. Auditors, selected at the discretion of the Department of Commerce's Office of

Inspector General, shall have access to any and all books, documents, papers and records of the obligor or any other party to a financing, that the auditor(s) deem pertinent, whether written, printed, recorded, produced or reproduced by any mechanical, magnetic or other process or medium.

Classification

Neither the Administrative Procedure Act nor any other law requires prior notice and opportunity for public comment about this document (which concerns loans). Consequently, the Regulatory Flexibility Act does not require a regulatory flexibility analysis.

This notice is not significant for purposes of E.O. 12866.

This notice contains and refers to collection-of-information requirements subject to the Paperwork Reduction Act. The application requirements contained in the Notice have been approved under OMB control number 0648–0012. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

Dated: March 26, 2010.

John Oliver,

Deputy Assistant Administrator For Operations, National Marine Fisheries Service.

[FR Doc. 2010–7264 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Monterey Bay National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applications for the following vacant seats on the Monterey Bay National Marine Sanctuary Advisory Council: Conservation alternate and Education primary. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen for the Education primary should expect to serve until February 2011 and applicants who are chosen for the Conservation alternate should expect to serve until February 2013.

DATES: Applications are due by April 30, 2010.

ADDRESSES: Application kits may be obtained from 299 Foam Street, Monterey, CA 93940 or online at *http://montereybay.noaa.gov/.* Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Nicole Capps, 299 Foam Street, Monterey, CA 93940, (831) 647–4206, *nicole.capps@noaa.gov.*

SUPPLEMENTARY INFORMATION: The MBNMS Advisory Council was established in March 1994 to assure continued public participation in the management of the Sanctuary. Since its establishment, the Advisory Council has played a vital role in decisions affecting the Sanctuary along the central California coast.

The Advisory Council's twenty voting members represent a variety of local user groups, as well as the general public, plus seven local, state and federal governmental jurisdictions. In addition, the respective managers or superintendents for the four California National Marine Sanctuaries (Channel Islands National Marine Sanctuary, Cordell Bank National Marine Sanctuary, Gulf of the Farallones National Marine Sanctuary and the Monterey Bay National Marine Sanctuary) and the Elkhorn Slough National Estuarine Research Reserve sit as non-voting members.

Four working groups support the Advisory Council: The Research Activity Panel ("RAP") chaired by the Research Representative, the Sanctuary Education Panel ("SEP") chaired by the Education Representative, the Conservation Working Group ("CWG") chaired by the Conservation Representative, and the Business and Tourism Activity Panel ("ETAP") chaired by the Business/Industry Representative, each dealing with matters concerning research, education, conservation and human use. The working groups are composed of experts from the appropriate fields of interest and meet monthly, or bi-monthly, serving as invaluable advisors to the Advisory Council and the Sanctuary Superintendent.

The Advisory Council represents the coordination link between the Sanctuary and the state and federal management agencies, user groups, researchers, educators, policy makers, and other various groups that help to focus efforts and attention on the central California coastal and marine ecosystems.

The Advisory Council functions in an advisory capacity to the Sanctuary Superintendent and is instrumental in helping develop policies, program goals, and identify education, outreach, research, long-term monitoring, resource protection, and revenue enhancement priorities. The Advisory Council works in concert with the Sanctuary Superintendent by keeping him or her informed about issues of concern throughout the Sanctuary, offering recommendations on specific issues, and aiding the Superintendent in achieving the goals of the Sanctuary program within the context of California's marine programs and policies.

Authority: 16 U.S.C. 1431, *et seq.* (Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: March 22, 2010.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2010–7001 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Conservation Seat for the Flower Garden Banks National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applications for the following vacant seat on the Flower Garden Banks National Marine Sanctuary Advisory Council: Conservation. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the

area affected by the sanctuary. Applicants who are chosen as members should expect to serve three-year terms, pursuant to the council's Charter.

DATES: Applications are due by May 28, 2010.

ADDRESSES: Application kits may be obtained from Jennifer Morgan, NOA–Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Bldg. 216, Galveston, TX 77551 or downloaded from the sanctuary Web site *http://flowergarden.noaa.gov.* Completed applications should be sent to the same address.

FOR FURTHER INFORMATION CONTACT: Jennifer Morgan, NOAA–Flower Garden Banks National Marine Sanctuary, 4700 Avenue U, Bldg. 216, Galveston, TX 77551, 409–621–5151 ext. 103, *Jennifer.Morgan@noaa.gov.*

SUPPLEMENTARY INFORMATION: Located in the northwestern Gulf of Mexico, the Flower Garden Banks National Marine Sanctuary includes three separate areas, known as East Flower Garden, West Flower Garden, and Stetson Banks. The Sanctuary was designated on January 17, 1992. Stetson Bank was added to the Sanctuary in 1996. The Sanctuary Advisory Council will consist of no more than 21 members; 16 non-governmental voting members and 5 governmental non-voting members. The Council may serve as a forum for consultation and deliberation among its members and as a source of advice to the Sanctuary manager regarding the management of the Flower Garden Banks National Marine Sanctuary.

Authority: 16 U.S.C. Sections 1431, *et seq.* (Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: March 16, 2010.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2010–7002 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Availability of Seats for the Fagatele Bay National Marine Sanctuary Advisory Council

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice and request for applications.

SUMMARY: The ONMS is seeking applications for the following vacant seats on the Fagatele Bay National Marine Sanctuary Advisory Council: Research, Education, Commercial Fishing, Ocean Recreation, Youth, Tutuila: East Side, Tutila: West Side, and Manua Islands. Applicants are chosen based upon their particular expertise and experience in relation to the seat for which they are applying; community and professional affiliations; philosophy regarding the protection and management of marine resources; and possibly the length of residence in the area affected by the sanctuary. Applicants who are chosen as members should expect to serve 3-year terms, pursuant to the council's Charter.

DATES: Applications are due by April 30, 2010.

ADDRESSES: Application kits may be obtained from Emily Gaskin, Fagatele Bay National Marine Sanctuary, American Samoa Department of Commerce Office, Executive Office Building, Utulei. Completed applications should be returned to the same address.

FOR FURTHER INFORMATION CONTACT: Emily Gaskin at (684) 633–5155 ext. 271 or *gaskin.emily@gmail.com.*

SUPPLEMENTARY INFORMATION: The Fagatele Bay National Marine Sanctuary Advisory Council was established in 1986 pursuant to Federal law to ensure continued public participation in the management of the sanctuary. The Sanctuary Advisory Council brings members of a diverse community together to provide advice to the Sanctuary Manager (delegated from the Secretary of Commerce and the Under Secretary for Oceans and Atmosphere) on the management and protection of the Sanctuary, or to assist the National Marine Sanctuary Program in guiding a proposed site through the designation or the periodic management plan review process.

Authority: 16 U.S.C. 1431, *et seq.*

(Federal Domestic Assistance Catalog Number 11.429 Marine Sanctuary Program)

Dated: March 22, 2010.

Daniel J. Basta,

Director, Office of National Marine Sanctuaries, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2010–7000 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–NK–M

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–851]

Certain Preserved Mushrooms From the People's Republic of China: Notice of Initiation of Antidumping Duty New Shipper Reviews

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

SUMMARY: The Department of Commerce (the Department) has received requests for new shipper reviews of the antidumping duty order on certain preserved mushrooms from the People's Republic of China (PRC). *See Notice of Amendment of Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Preserved Mushrooms From the People's Republic of China,* 64 FR 8308 (February 19, 1999). In accordance with section 751(a)(2)(B) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214(d), we are initiating antidumping duty new shipper reviews of Zhangzhou Tongfa Foods Industry Co., Ltd. (Tongfa) and Shandong Fengyu Edible Fungus Corporation Ltd. (Fengyu). The period of investigation (POI) of these new shipper reviews is February 1, 2009 through January 31, 2010.

DATES: *Effective Date:* March 31, 2010.

FOR FURTHER INFORMATION CONTACT: Fred Baker, Scott Hoefke, or Robert James, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, DC 20230, telephone: (202) 482–2924, (202) 482–4947, or (202) 482–0649, respectively.

SUPPLEMENTARY INFORMATION:

Background

On February 19, 1999, the Department published the antidumping duty order on certain preserved mushrooms from the PRC. *See Notice of Amendment of Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Preserved Mushrooms From the People's Republic of China,* 64 FR 8308 (February 19, 1999). Thus, the antidumping duty order on certain preserved mushrooms from the PRC has a February anniversary month. On February 25, 2010 and February 26, 2010, the Department received requests for new shipper reviews from Tongfa and Fengyu, respectively. In their respective requests for reviews, Tongfa and Fengyu identified themselves as both exporters and producers of the

subject merchandise. The Department determined that both requests contained certain deficiencies and requested that both respondents correct their submissions. *See* March 11, 2010 and March 17, 2009 letters from Robert James, Program Manager, to Tongfa and Fengyu, respectively. In accordance with the Department's requests, Tongfa and Fengyu corrected the problems in their initial submissions in revised submissions dated March 18, 2010 and March 23, 2010, respectively. For the purpose of initiating these new shipper reviews, the Department determines that Tongfa and Fengyu's original submissions were timely filed.

Pursuant to the requirements set forth in section 751(a)(2)(B)(i) of the Act and 19 CFR 351.214(b)(2), Tongfa and Fengyu certified that (1) they did not export subject merchandise to the United States during the POI (*see* section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i); (2) since the initiation of the investigation they have never been affiliated with any company that exported subject merchandise to the United States during the POI, including those companies not individually examined during the investigation (*see* section 751(a)(2)(B)(i)(II) and19 CFR 351.214(b)(2)(iii)(A)); and (3) their export activities were not controlled by the central government of the PRC (*see* 19 CFR 351.214(b)(2)(iii)(B)). Additionally, in accordance with 19 CFR 351.214(b)(2)(iv), Tongfa and Fengyu submitted documentation establishing the following: (1) The date on which they first shipped subject merchandise to the United States; (2) the volume of their first shipments; and (3) the date of their first sales to unaffiliated customers in the United States. They also certified they had no shipments to the United States during the period subsequent to their first shipments.

Initiation of Reviews

Based on information on the record and in accordance with section 751(a)(2)(B) of the Act and section 351.214(d) of the Department's regulations, we find that the requests Tongfa and Fengyu submitted meet the statutory and regulatory requirements for initiation of new shipper reviews. *See* Memoranda to the File through Richard Weible, "Initiation of AD New Shipper Review: Certain Preserved Mushrooms from the People's Republic of China (A–570–851)," dated March 31, 2010. Accordingly, we are initiating new shipper reviews of the antidumping duty order on certain preserved mushrooms from the PRC manufactured and exported by Tongfa and Fengyu. These reviews cover the period February 1, 2009 through January 31, 2010. We intend to issue the preliminary results of these reviews no later than 180 days after the date on which these reviews are initiated, and the final results within 90 days after the date on which we issue the preliminary results. *See* section 751(a)(2)(B)(iv) of the Act and 19 CFR 351.214(h)(i).

In cases involving non-market economies, the Department requires that a company seeking to establish eligibility for an antidumping duty rate separate from the country-wide rate provide evidence of *de jure* and *de facto* absence of government control over the company's export activities. *See, e.g., Wooden Bedroom Furniture from the People's Republic of China: Initiation of Antidumping Duty New Shipper Reviews,* 75 FR 10214, 10215 (March 5, 2010). Accordingly, we will issue questionnaires to Tongfa and Fengyu that will include a separate rates section. These reviews will proceed if the response provides sufficient indication that Tongfa and Fengyu are not subject to either *de jure* or *de facto* government control with respect to their exports of preserved mushrooms. However, if Tongfa and Fengyu do not demonstrate eligibility for separate rates, they will be deemed not to have met the requirements of section 751(2)(B)(i) of the Act and 19 CFR 351.214(b)(2)(i), and therefore not separate from the PRC-wide entity. We will therefore rescind the new shipper reviews. *See, e.g., Certain Preserved Mushrooms from the People's Republic of China: Notice of Initiation of Antidumping Duty New Shipper Review,* 74 FR 15698 (April 7, 2009).

We will instruct the CBP to allow, at the option of the importer, the posting, until the completion of the review, of a bond or security in lieu of a cash deposit for certain entries of the subject merchandise produced and exported by Tongfa and produced and exported by Fengyu in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Because Tongfa and Fengyu certified that they both produce and export the subject merchandise, the sales of which form the basis for their new shipper review requests, we will instruct CBP to permit the use of a bond only for entries of subject merchandise which Tongfa and Fengyu both produced and exported.

Interested parties may submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305 and 351.306.

These initiations and this notice are issued and published in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 351.221(c)(1)(i).

Dated: March 26, 2010.

John M. Andersen,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2010–7355 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV57

Marine Mammals; File No. 15206

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Sea World LLC, 9205 South Park Center Loop, Suite 400, Orlando, FL 32819, has applied in due form for a permit to import one beluga whale (*Delphinapterus leucas*) for the purposes of public display.

DATES: Written or telefaxed comments must be received on or before April 30, 2010.

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 713–0376; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

Written comments on this application should be submitted to the Chief, Permits, Conservation and Education Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to *NMFS.Pr1Comments@noaa.gov*. Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits, Conservation and Education Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Kristy Beard, (301) 713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant requests authorization to import one male adult beluga whale from the Vancouver Aquarium Marine Science Center, British Columbia, Canada to Sea World of Texas. The applicant requests this import for the purpose of public display. The receiving facility, Sea World of Texas, 10500 SeaWorld Drive, San Antonio, TX 78251 is: (1) open to the public on regularly scheduled basis with access that is not limited or restricted other than by charging for an admission fee; (2) offers an educational program based on professionally accepted standards of the Association of Zoos and Aquariums and the Alliance for Marine Mammal Parks and Aquariums; and (3) holds an Exhibitor's License, number 58–C–0077, issued by the U.S. Department of Agriculture under the Animal Welfare Act (7 U.S.C. §§ 2131 - 59).

In addition to determining whether the applicant meets the three public display criteria, NMFS must determine whether the applicant has demonstrated that the proposed activity is humane and does not represent any unnecessary risks to the health and welfare of marine mammals; that the proposed activity by itself, or in combination with other activities, will not likely have a significant adverse impact on the species or stock; and that the applicant's expertise, facilities and resources are adequate to accomplish successfully the objectives and activities stated in the application.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: March 26, 2010.

Tammy C. Adams,

Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2010–7260 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XV58

Marine Mammals; File No. 15430

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that the Louisville Zoological Garden, 1100 Trevilian Way, P.O. Box 37250, Louisville, KY 40233, has applied in due form for a permit to import one South African fur seal (*Arctocephalis pusillus*) for the purposes of public display.

DATES: Written or telefaxed comments must be received on or before April 30, 2010

ADDRESSES: The application and related documents are available for review upon written request or by appointment in the following offices:

Permits, Conservation and Education Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 713–2289; fax (301) 713–0376; and

Southeast Region, NMFS, 263 13th Avenue South, Saint Petersburg, FL 33701; phone (727) 824–5312; fax (727) 824–5309.

Written comments on this application should be submitted to the Chief, Permits, Conservation and Education Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713–0376, or by email to*NMFS.Pr1Comments@noaa.gov*. Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits, Conservation and Education Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Jennifer Skidmore or Kristy Beard, (301) 713–2289.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*), and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant requests authorization to import one female adult South African fur seal from the Toronto Zoo, Ontario, Canada to the Louisville Zoological Garden. The applicant requests this import for the purpose of public display. The receiving facility, the Louisville Zoological Garden is: (1) open to the public on regularly scheduled basis with access that is not limited or restricted other than by charging for an admission fee; (2) offers an educational program based on professionally accepted standards of the Association of Zoos and Aquariums; and (3) holds an Exhibitor's License, number 61–C–0106, issued by the U.S. Department of Agriculture under the Animal Welfare Act (7 U.S.C. §§ 2131 - 59).

In addition to determining whether the applicant meets the three public display criteria, NMFS must determine whether the applicant has demonstrated that the proposed activity is humane and does not represent any unnecessary risks to the health and welfare of marine mammals; that the proposed activity by itself, or in combination with other activities, will not likely have a significant adverse impact on the species or stock; and that the applicant's expertise, facilities and resources are adequate to accomplish successfully the objectives and activities stated in the application.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of this application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: March 26, 2010.

Tammy C. Adams,

Acting Chief, Permits, Conservation and Education Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2010–7257 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

International Trade Administration

Civil Nuclear Trade Advisory Committee Public Meeting

AGENCY: International Trade Administration, DOC.

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: This notice sets forth the schedule and proposed agenda of the

next meeting of the Civil Nuclear Trade Advisory Committee (CINTAC). The members will discuss issues outlined in the following agenda.

DATES: The meeting is scheduled for: Thursday, April 15, 2010, from 1 p.m. to 4 p.m. Eastern Daylight Time (EDT).

ADDRESSES: The meeting will be held in Room 4830, U.S. Department of Commerce, Herbert Clark Hoover Building, 1401 Constitution Ave, NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Caliva, Office of Energy & Environmental Industries, International Trade Administration, Room 4053, 1401 Constitution Ave, NW., Washington, DC 20230. (Phone: 202–482–8245; Fax: 202–482–5665; e-mail: *Frank.Caliva@trade.gov*).

SUPPLEMENTARY INFORMATION:

Background: The CINTAC was established under the discretionary authority of the Secretary of Commerce and in accordance with the Federal Advisory Committee Act (5 U.S.C. App.), in response to an identified need for consensus advice from U.S. industry to the U.S. Government regarding the development and administration of programs to expand United States exports of civil nuclear goods and services in accordance with applicable United States regulations, including advice on how U.S. civil nuclear goods and services export policies, programs, and activities will affect the U.S. civil nuclear industry's competitiveness and ability to participate in the international market.

Topics to be considered: The agenda for the April 15, 2010, CINTAC meeting is as follows:

1. Welcome & introduction of members attending for the first time.
2. Discussion of civil nuclear trade priority issues.

Public Participation: The meeting will be open to the public and the room is disabled-accessible. Public seating is limited and available on a first-come, first-served basis. Members of the public wishing to attend the meeting must notify Mr. Frank Caliva at the contact information above by 5 p.m. EST on Friday, April 9, 2010, in order to pre-register for clearance into the building. Please specify any requests for reasonable accommodation at least five business days in advance of the meeting. Last minute requests will be accepted, but may be impossible to fill.

A limited amount of time will be available for pertinent brief oral comments from members of the public attending the meeting. To accommodate as many speakers as possible, the time for public comments will be limited to two (2) minutes per person, with a total public comment period of 30 minutes. Individuals wishing to reserve speaking time during the meeting must contact Mr. Caliva and submit a brief statement of the general nature of the comments and the name and address of the proposed participant by 5 p.m. EST on Friday, April 9, 2010. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration (ITA) may conduct a lottery to determine the speakers. Speakers are requested to bring at least 20 copies of their oral comments for distribution to the participants and public at the meeting.

Any member of the public may submit pertinent written comments concerning the CINTAC's affairs at any time before and after the meeting. Comments may be submitted to the Civil Nuclear Trade Advisory Committee, Office of Energy & Environmental Industries, Room 4053, 1401 Constitution Ave NW., Washington, DC 20230. To be considered during the meeting, comments must be received no later than 5 p.m. EST on Friday, April 9, 2010, to ensure transmission to the Committee prior to the meeting. Comments received after that date will be distributed to the members but may not be considered at the meeting.

Copies of CINTAC meeting minutes will be available within 90 days of the meeting.

Dated: March 25, 2010.

Henry P. Misisco,

Deputy Assistant Secretary for Manufacturing, Acting.

[FR Doc. 2010–7209 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

Bureau of the Census

Census Scientific Advisory Committee

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of public meeting.

SUMMARY: The Bureau of the Census (U.S. Census Bureau) is giving notice of a meeting of the Census Scientific Advisory Committee (C–SAC). The Committee will address policy, research, and technical issues relating to a full range of Census Bureau programs and activities, including communications, decennial, demographic, economic, field operations, geographic, information technology, and statistics. Last minute changes to the agenda are possible, which could prevent giving advance public notice of schedule adjustments.

DATES: April 22–23, 2010. On April 22, the meeting will begin at approximately 8:30 a.m. and adjourn at approximately 5 p.m. On April 23, the meeting will begin at approximately 8:30 a.m. and adjourn at approximately 12 p.m.

ADDRESSES: The meeting will be held at Hilton Crystal City Hotel, 2399 Jefferson Davis Highway, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: Jeri Green, Committee Liaison Officer, Department of Commerce, U.S. Census Bureau, Room 8H182, 4600 Silver Hill Road, Washington, DC 20233, telephone 301–763–6590. For TTY callers, please use the Federal Relay Service 1–800–877–8339.

SUPPLEMENTARY INFORMATION: Members of the C–SAC are appointed by the Director, U.S. Census Bureau. The Committee provides scientific and technical expertise, as appropriate, to address Census Bureau program needs and objectives. The Committee has been established in accordance with the Federal Advisory Committee Act (Title 5, United States Code, Appendix 2, Section 10).

The meeting is open to the public, and a brief period is set aside for public comments and questions. Persons with extensive questions or statements must submit them in writing at least three days before the meeting to the Committee Liaison Officer named above. Seating is available to the public on a first-come, first-served basis.

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should also be directed to the Committee Liaison Officer as soon as known, and preferably two weeks prior to the meeting.

Dated: March 25, 2010.

Thomas L. Mesenbourg,

Deputy Director, Bureau of the Census.

[FR Doc. 2010–7241 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of the Census

Reestablishment of the Census Advisory Committee of Professional Associations

AGENCY: Bureau of the Census, Department of Commerce.

ACTION: Notice of advisory committee reestablishment.

SUMMARY: Notice is hereby given that the Secretary of Commerce has determined that the reestablishment of an advisory committee of technical advisors is necessary and in the public interest. Accordingly, the Bureau of the Census (Census Bureau) has chartered the Census Scientific Advisory Committee (CSAC), which succeeds the Census Advisory Committee of Professional Associations (CACPA). The charter for the CACPA expired on February 1, 2010.

FOR FURTHER INFORMATION CONTACT: Contact Jeri Green, Chief, Census Advisory Committee Office, U.S. Census Bureau, Washington, DC 20233, telephone 301–763–2075, *Jeri.Green@Census.gov.*

SUPPLEMENTARY INFORMATION: The CSAC will advise the Census Bureau's Director on the full range of Census Bureau programs and activities. The CSAC will provide scientific and technical expertise from the following disciplines: Demography, economics, geography, psychology, statistics, survey methodology, social and behavioral sciences, Information Technology and computing, marketing and other fields of expertise, as appropriate, to address Census Bureau program needs and objectives.

The CSAC will function solely as an advisory body and in compliance with provisions of the Federal Advisory Committee Act. Copies of the charter will be filed with the appropriate Committees of the Congress and with the Library of Congress.

Dated: March 25, 2010.

Thomas L. Mesenbourg,

Deputy Director, Bureau of the Census.

[FR Doc. 2010–7250 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

Report to Congress: Retrospective Versus Prospective Antidumping and Countervailing Duty Systems; Request for Comment and Notice of a Public Hearing

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

Background: In the conference report accompanying the 2010 Consolidated Appropriations Act, Public Law: 111–117, the conferees directed the Secretary of Commerce to work with the Secretaries of the Departments of Homeland Security and the Treasury to conduct an analysis of the relative advantages and disadvantages of prospective and retrospective antidumping and countervailing duty systems. The report is currently scheduled to be transmitted to Congress on June 14, 2010. As part of its analysis, the conferees requested that the Department of Commerce (the Department) address the extent to which each type of system would likely achieve the goals of: (1) Remedying injurious dumping or subsidized exports to the United States; (2) minimizing uncollected duties; (3) reducing incentives and opportunities for importers to evade antidumping and countervailing duties; (4) effectively targeting high-risk importers; (5) addressing the impact of retrospective rate increases on U.S. importers and their employees; and (6) creating minimal administrative burden.

To help in its analysis, the Department is inviting the public to comment on the issue and the specific points raised by the conferees as well as identify additional issues or considerations that it believes are deserving of the Department's attention as it prepares its report. The Department is also notifying the public that it will hold a public hearing on April 27, 2010.

Date for Submitting Comments: The Department requests that comments be submitted by 5 p.m., April 20, 2010. Comments should be limited to no more than 25 pages. Comments may be submitted electronically or in writing. Electronic comments should be submitted to *webmaster-support@ita.doc.gov.* If you submit comments electronically, you do not need to also submit comments in writing. People wishing to comment in writing should file, by the date specified above, a signed original and four copies of each set of comments at the address listed below. The Department will not accept nor consider comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason.

All comments will be available for public inspection at Import Administration's Central Records Unit, Room 1117, between the hours of 8:30 a.m. and 5 p.m. on business days. In addition, all comments will be made available to the public in Portable Document Format (PDF) on the Internet at the Import Administration Web site at the following address: *http://www.trade.gov/ia/.* To the extent possible, all comments will be posted within 48 hours. Any questions concerning file formatting, document conversion, access on the Internet, or other electronic filing issues should be addressed to Andrew Lee Beller, Import Administration Webmaster, at (202) 482–0866, e-mail address: *webmaster-support@ita.doc.gov.*

Hearing Date: The hearing will be held on April 27, 2010 starting at 9:30 a.m. in the auditorium at the Department of Commerce, 14th Street and Constitution Avenue, NW., Washington DC.

Hearing Participation: The hearing is open to the public. There are no prerequisites or conditions on participating at the hearing. All are welcome to speak at the hearing subject to the guidelines outlined in this notice. Those wishing to speak at the hearing must notify the Department no later than April 13, 2010. The request can be sent by e-mail to *webmaster-support@ita.doc.gov* or in writing to the address below. Individual presentations will be limited to five minutes to allow for possible questions from the Chair and the panel. Written comments, though strongly encouraged, are not required for those making presentations within the five minute time limit. Anyone requiring additional time for their presentation must seek an extension of the time limit at the time of their notification to the Department. Additional time may be granted as time and the number of participants permits. Also, please be aware that foreign nationals wishing to attend or participate in the hearing may be required to provide certain identification information to the Department by April 23, 2010 in order to gain access to the building. For further information, please contact Kelly Parkhill at (202) 482–3791.

ADDRESSES: Comments may be submitted electronically or in writing. Electronic comments should be submitted to *webmaster-support@ita.doc.gov.* If you submit comments electronically, you do not need to submit comments in writing. People wishing to comment in writing should file a signed original and four copies of each set of comments by 5 p.m., April 20, 2010. Such comments should be addressed to Ronald K. Lorentzen, Deputy Assistant Secretary for Import Administration, Room 1870, Department of Commerce, 14th Street and Constitution Ave., NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: Kelly Parkhill at (202) 482–3791.

New Reporting Requirements: There are no new paperwork or reporting requirements as a result of the action. In addition, all responses to the Department's **Federal Register** notice

requests for information, including this request, are strictly voluntary.

Dated: March 26, 2010.

Ronald K. Lorentzen,

Deputy Assistant Secretary for Import Administration.

[FR Doc. 2010–7217 Filed 3–30–10; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Prepare an Environmental Impact Statement for Basewide Water Infrastructure and Stuart Mesa Bridge Replacement Projects at Marine Corps Base Camp Pendleton, San Diego County, CA

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: In accordance with Section 102(2)(c) of the National Environmental Policy Act (NEPA)of 1969 (42 U.S.C. 4332 (2) (c)), as implemented by the Council on Environmental Quality Regulations (40 CFR Parts 1500–1508), the Department of the Navy intends to prepare an Environmental Impact Statement (EIS) and conduct a public scoping meeting for the proposed replacement of the Stuart Mesa Bridge and installation and operation of water infrastructure improvements throughout Marine Corps Base Camp Pendleton (MCBCP) in San Diego County, California.

DATES: The Department of the Navy will review all comments received during the 30-day public scoping period, which starts with the publication of this Notice of Intent. A public scoping meeting, using an informal open house format, will be held in the San Clemente Community Center, 100 North Calle Seville, San Clemente, California 92672, from 6 p.m. to 8 p.m. on April 16, 2010. The meeting will be announced by notices published in the North County Times and San Clemente Sun Post News. The public is invited to attend the meeting at their convenience during the meeting hours and can view project-related displays and speak with Department of the Navy and MCBCP representatives and resource staff. A court reporter will be available at the meeting to accept oral comments.

ADDRESSES: Written comments on the scope of the MCBCP Basewide Water Infrastructure and Stuart Mesa Bridge Replacement EIS should be directed to: Mr. Jesse Martinez, Naval Facilities Engineering Command (NAVFAC) Southwest, 1220 Pacific Highway, San Diego, California 92132. Written comments may also be submitted via fax at 619–532–4160, or e-mailed to *jesse.w.martinez1@navy.mil.*

FOR FURTHER INFORMATION CONTACT: Mr. Jesse Martinez, NAVFAC Southwest at telephone 619–532–3844, fax 619–532–4160, or e-mail: *jesse.w.martinez1@navy.mil.*

Purpose and Need: The proposed action is needed to modernize and expand the capacity and capability of MCBCP's aging (1940s/1950s era) potable water system and roadway infrastructure. Due to the existing potable water system infrastructure's lack of redundancy/backup and its continued deteriorating condition, portions of MCBCP have experienced more frequent interruptions to water delivery services. Wildfires have also damaged system components (*e.g.* power feeds, pump stations, pipes, *etc.*), with resulting service interruptions. As the potable water system continues to age, and as demand increases, the frequency of the interruptions will also increase, adversely affecting MCBCP's mission. Repairs to and maintenance actions for the system are becoming more frequent and more expensive.

In the case of the roadway system, the Stuart Mesa Bridge, together with nearby roadway segments and the adjacent intersection of Stuart Mesa Road and Vandegrift Boulevard, represents a critical roadway connection on the main internal north-south connector in the southern and western portions of MCBCP. The roadway link has been severed in the past by flooding, underscoring the need for an all-weather solution.

The purpose of the proposed action is to enhance the ability of MCBCP to efficiently meet its mission by developing new or upgraded, reliable, and compliant infrastructure systems necessary to sustain military training and operations and quality of life services on MCBCP. The purpose is to provide (1) secure and more effective use of water resources, improved potable water quality and capacity, treatment and delivery capabilities, and water system redundancy necessary to reliably and efficiently deliver potable water in the northern region of MCBCP; (2) improved delivery of Basewide water services during periods of scheduled, unscheduled, and emergency system interruption; and (3) roadway improvements necessary to maintain efficient all-weather traffic accessibility to key areas in the southern portion of MCBCP that are now severed during periodic flooding in the vicinity of the Stuart Mesa Bridge.

The water infrastructure projects were initially included in the November 12, 2008, Notice of Intent (NOI) for MCBCP's Basewide Utilities Infrastructure project (73 FR 66879). These two water infrastructure projects were removed from that EIS for potential re-design and to develop additional alternatives for analysis. These two water infrastructure projects are independent of the Basewide Utilities Infrastructure projects and meet different needs.

Preliminary Alternatives

The EIS will address the proposed alternative sites, alignments, and construction methods as described below.

Advanced Water Treatment (AWT) North and Associated Facilities (MILCON P–1044)

Four alternatives involving a combination of two AWT sites and two pipeline routes are being evaluated. All alternatives include construction of a 54,000-square-foot AWT facility, 80,000 linear feet (LF) of new and replacement water lines, pump stations with emergency generators, connection to existing reservoirs and distribution system, a brine disposal system, and plant access improvements. The proposed AWT facility would process up to 7.5 million gallons per day (mgd) and would include micro-filtration, granulated activated carbon, and reverse osmosis. The facility would be designed in modular form for ease of expandability; however there are no current plans for expansion.

Alternative 1. Under this alternative the AWT facility would be constructed at a location about 1500 feet south of Basilone Road (Site 6). Raw water, treated water, and brine would be conveyed via new proposed lines. Raw water lines would extend from the existing wells to the AWT facility. Treated water lines would extend from the AWT facility to the west to serve the San Onofre Housing Areas and the 51 Area (San Onofre); to the north to serve the 62 Area (San Mateo), 63 Area (Cristianitos), and 64 Area (Talega); and to the east along Basilone Road to serve the 52 Area (School of Infantry) and 53 Area (Horno). Potable water loops eight inches in diameter would be installed within each cantonment and housing area. Bicycle lanes and/or pedestrian trails could also be included over proposed water lines where feasible. Either horizontal directional drilling (HDD) to extend lines beneath San Onofre Creek and San Mateo Creek or suspension of the pipelines over the

creeks would be incorporated to minimize impacts.

Following water treatment at the AWT, brine would be disposed via ocean outfall and/or injection wells. The brine disposal line would extend from the AWT facility to the south to connect to the proposed injection wells east of Interstate 5 (I–5) and/or to the existing Unit 1 ocean intake pipeline at San Onofre Nuclear Generating Station (SONGS). The line to SONGS would extend beneath I–5 via HDD. Brine disposal would make up approximately 8 to 10 percent of the capacity of the proposed AWT or a maximum volume of approximately 0.6 to 0.75 mgd. The ocean outfall disposal would use the existing SONGS former Unit 1, 12-foot-diameter, 3,200-foot-long cooling water intake structure located on the Pacific Ocean floor. Deep injection wells (approximately 1,000 feet deep) would be located south and east of the existing San Onofre percolation ponds.

Alternative 2. Under this alternative, raw water, treated water, and brine would be conveyed via three proposed new pipelines located primarily in El Camino Real instead of Basilone Road as proposed under Alternative 1.

Alternative 3. Under this alternative, the AWT facility would be located immediately south of Basilone Road (Site 4). Water conveyance pipelines would be the same as Alternative 1.

Alternative 4. Under this alternative, the AWT facility would be located immediately south of Basilone Road (Site 4). Water conveyance pipelines would be the same as Alternative 2.

Connection of North and South Water Systems (MILCON P–1045)

Four alternatives involving different pipeline routes are being evaluated.

Alternative 1. Under this alternative, approximately 90,000 LF of potable water lines sized up to 36 inches in diameter to connect the northern and southern water systems of MCBCP. The water line would start at the new AWT North facility (P–1044) and extend south on an alignment using El Camino Real to Stuart Mesa Road. Dividing at the junction of Stuart Mesa Road and Las Pulgas Road, one branch would run north along Las Pulgas Road to the 43 Area (Las Pulgas). This lateral pipeline would be approximately 10 to 14 inches in diameter and would connect to the Las Pulgas distribution system to link developments in the Las Pulgas, Las Flores, and Stuart Mesa areas to the connected northern and southern water systems. The other branch would continue along Stuart Mesa Road before splitting again into two more branches. One of these branches would extend northeast on the west side of the Santa Margarita River along North River Road, passing east of the 32 Area (Marine Air Control Squadron-1) and 33 Area (Margarita) and west of the 23 Area (Marine Corps Air Station Camp Pendleton) to Basilone Road and on to connect to the AWT South facility at Haybarn Canyon as well as several reservoirs along a ridge above the AWT South (Reservoirs 13151, 13154, 24140, 24174, and 240173). The second branch would continue south along Stuart Mesa Road, passing under or suspending over the Santa Margarita River, to Vandegrift Boulevard before turning north and terminating approximately one mile north at an existing Vandegrift Boulevard/Magazine Road pump station and several nearby reservoirs (Reservoirs 20813, 20814, 20815, 200814, and 200815).

The pipelines would be HDD under or suspended over San Onofre Creek, Las Flores Creek, Aliso Canyon drainage, French Creek, and two locations on the Santa Margarita River to avoid impacts to these areas.

The project would also include the construction and operation of three pump stations along the alignment. One pump station would be located within the footprint of the AWT North and a second pump station would be located within a developed parking lot at the AWT South. A third pump station would be located in an existing parking area on the southwest side of the intersection of El Camino Real and Las Pulgas Road. Bicycle lanes and/or pedestrian trails could also be included over proposed water lines where feasible.

Alternative 2. The proposed north-south pipeline would start at the new AWT North facility (P–1044) and extend south in El Camino Real to Las Pulgas Road and run north in Las Pulgas Road to Basilone Road. The water line would then extend along Basilone Road to Vandegrift Boulevard and run east to connect to the AWT South at Haybarn Canyon as well as several reservoirs along a ridge above the AWT South (Reservoirs 13151, 13154, 24140, 24174, and 240173). This alternative would require two additional pump stations, for a total of five pump stations.

Alternative 3. This alternative would be similar to Alternative 1 except it would not include the segment on the west side of the Santa Margarita River along North River Road and could include a 1.0 mile line connecting to reservoir 32911 at 32 Area (Marine Air Control Squadron-1).

Alternative 4. This alternative would be similar in alignment to Alternative 3, with an additional pipe segment from the Vandegrift Boulevard/Magazine Road pump station east of the 22 Area (Chappo) before connecting to the AWT South at Haybarn Canyon as well as several reservoirs along a ridge above the AWT South (Reservoirs 13151, 13154, 24140, 24174, and 240173).

Stuart Mesa Bridge Replacement and Flood Control Improvements (P–0139)

Four alternatives including a combination of two flood control methods and the use of a temporary bridge during construction are being evaluated. All alternatives include demolition of the existing Stuart Mesa Bridge and construction of a new four lane bridge and flood protection measures.

Alternative 1. Construction would consist of a new cast-in-place prestressed concrete bridge (approximately 1,200 feet long by 56 feet wide) with pile foundations, new approach road and bridge abutments, earthwork and grading, rock protection and revetment, bridge deck, guard rails, night lighting, asphalt pavement, and pavement marking and signs.

The project includes "100-year storm" flood protection control measures to protect Stuart Mesa Road and Vandegrift Boulevard. They consist of levees; toe scour protection along the levee; a storm water drain system consisting of culverts, inlets, outlets, headwalls, channels, and earth and concrete ditches. Supporting activities would include the construction and relocation of utilities (electrical, communications/information lines, water main) during the demolition and construction of the new bridge. Under this alternative, no temporary replacement bridge would be constructed over the Santa Margarita River and traffic would need to utilize alternate routes during this time.

Alternative 2. Under this alternative, a temporary use bridge would be constructed to allow vehicular traffic along Stuart Mesa Road to continue to cross the Santa Margarita River. Bridge construction would be the same as Alternative 1.

Alternative 3. Under this alternative, flood walls would be constructed rather than levees. No temporary replacement bridge would be constructed over the Santa Margarita River. Bridge construction would be the same as Alternative 1.

Alternative 4. This alternative would be similar to Alternative 3, with the exception of a construction phase temporary use bridge, which would allow traffic along Stuart Mesa Road to continue to cross the Santa Margarita River during demolition of the existing

bridge and construction of the new bridge.

Environmental Issues and Resources To Be Examined

The EIS will evaluate the potential environmental effects associated with each of the alternatives. Issues to be addressed include, but are not limited to; geology, topography and soils, hydrology and water quality, biological resources, cultural resources, land use, visual resources, socioeconomics and environmental justice, traffic, air quality, noise, public health and safety, services and utilities, and coastal zone management. Relevant and reasonable measures that could alleviate environmental effects will be considered.

Schedule

Comments on the scope of this EIS must be received by April 30, 2010. The Department of the Navy will publish a Notice of Availability (NOA) in the **Federal Register** and local media when the Draft EIS is issued for public review. A 45-day public comment period will start upon publication of the NOA in the **Federal Register**. The Department of the Navy will consider and respond to all comments received on the Draft EIS when preparing the Final EIS. The Department of the Navy expects to issue the Final EIS in July 2011, which will be available for a 30-day public comment period. The Department of the Navy will consider all comments received on the Final EIS in preparing for the Record of Decision.

Other Agency Involvement

The Department of the Navy will undertake appropriate consultations with regulatory entities pursuant to the Endangered Species Act, Clean Water Act, National Historic Preservation Act, and any other applicable law or regulation. Consultation will include but is not limited to the following Federal, State, and local agencies: U.S. Fish and Wildlife Service; National Oceanic and Atmospheric Administration Fisheries; State Historic Preservation Officer; American Indian Tribes; U.S. Army Corps of Engineers; U.S. Environmental Protection Agency; all local Historic Site Boards and Heritage organizations; California Regional Water Quality Control Board; California Coastal Commission; San Diego Air Pollution Control District; and the County of San Diego, Department of Environmental Health.

Dated: March 25, 2010.

A.M. Vallandingham,

Lieutenant Commander, Judge Advocate Generals Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2010–7183 Filed 3–30–10; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Smaller Learning Communities Program

Catalog of Federal Domestic Assistance (CFDA) Number: 84.215L.

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice of proposed priorities, requirements, definition, and selection criteria.

SUMMARY: The Assistant Secretary for Elementary and Secondary Education proposes priorities, requirements, a definition, and selection criteria under the Smaller Learning Communities (SLC) program. The Assistant Secretary will use these priorities, requirements, definition, and selection criteria, in addition to any other previously established priorities and requirements, for a competition using fiscal year (FY) 2009 funds and may use them in later years. We take this action to focus Federal financial assistance on an identified national need. We intend these priorities, requirements, definition, and selection criteria to enhance the effectiveness of SLC projects in improving academic achievement and helping to prepare students for postsecondary education and careers.

DATES: We must receive your comments on or before April 30, 2010.

ADDRESSES: Address all comments about the proposed priorities, requirements, definition, and selection criteria to Angela Hernandez-Marshall, U.S. Department of Education, 400 Maryland Avenue, SW., LBJ, Room 3E308, Washington, DC 20202–6200.

If you prefer to send your comments through the Internet, use the following address: *smallerlearningcommunities@ed.gov.* You must include the term "SLC Proposed Requirements" in the subject line of your electronic message.

FOR FURTHER INFORMATION CONTACT: Angela Hernandez-Marshall. *Telephone:* (202) 205–1909 or by *e-mail: smallerlearningcommunities@ed.gov.*

If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this notice. To ensure that your comments have maximum effect in developing the notice of final priorities, requirements, definition, and selection criteria, we urge you to identify clearly the specific proposed priority, requirement, definition, or selection criterion that each comment addresses.

We invite you to assist us in complying with the specific requirements of Executive Order 12866 and its overall requirement of reducing regulatory burden that might result from the proposed priorities, requirements, definition, and selection criteria. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this notice in room 3E308, 400 Maryland Avenue, SW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Washington, DC time, Monday through Friday of each week except Federal holidays.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other documents in the public rulemaking record for this notice. If you want to schedule an appointment for this type of accommodation or auxiliary aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Purpose of Program: The SLC program awards discretionary grants to local educational agencies (LEAs) to support the restructuring of large public high schools (*i.e.,* schools with enrollments of 1,000 or more students) into smaller units for the purpose of improving academic achievement in large public high schools. These smaller units include freshman academies, multi-grade academies organized around career interests or other themes, "houses" in which small groups of students remain together throughout high school, and autonomous schools-within-a-school. These structural changes are typically complemented by other personalization strategies, such as student advisories, family advocate systems, and mentoring programs.

Program Authority: 20 U.S.C. 7249.

Applicable Program Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in

34 CFR parts 75, 77, 79, 80, 81, 82, 84, 85, 97, 98, and 99. (b) The final priority, requirements, definitions, and selection criteria published in the **Federal Register** on April 28, 2005 (70 FR 22233) (the 2005 SLC NFP). (c) The notice of final priority, requirements, and selection criteria published in the **Federal Register** on May 18, 2007 (72 FR 28426) (the 2007 SLC NFP).

Background: Creating a more personalized learning experience for students has been a prominent part of high school improvement efforts in recent years. Several evaluations have found, generally, that the implementation of SLCs and complementary personalization strategies can reduce disruptive behavior, create a more orderly environment for learning, and increase student attendance and graduation rates (Lee and Smith 1995; Wasley *et al.,* 2000; McMullan, Sipe, and Wolf, 1994; Quint, 2006; National Research Council, 2004). *Dropout Prevention: A Practice Guide,* published in 2008 by the Institute of Education Sciences' What Works Clearinghouse, recommended that schools implement SLCs and other personalization strategies as part of a comprehensive approach to reducing the dropout rate (Institute of Education Sciences, 2008).

However, evaluation data have not shown that these structural changes and personalization strategies, by themselves, improve student academic achievement and readiness for postsecondary education and careers. Student learning gains have been seen only in those schools that also have made considerable changes in curriculum and instruction (Bernstein, *et al.,* 2005; Kahne, Sporte, *et al.,* 2006; Quint, 2006; Rhodes, Smerdon, 2005). Similarly, some large comprehensive high schools that have not implemented SLCs have significantly increased student achievement in reading or mathematics and narrowed achievement gaps by implementing more rigorous courses, providing extra support to struggling students, and systematically using data to improve instruction (ACT, Inc. and the Education Trust, 2005; Billig, Jaime, *et al.,* 2005; National Center for Educational Accountability, 2005; Robinson, *et al.,* 2005).

For these reasons, we are proposing priorities and selection criteria that are specifically intended to promote the close integration of SLC implementation with systematic efforts to improve curriculum and instruction. We also propose certain other requirements and a definition to clarify statutory provisions, improve the management of grant activities, facilitate the review of applications, and promote the equitable distribution of limited SLC grant funds.

Note: As used in this notice, the terms *smaller learning community* and *large high school* have the meanings assigned to them in the 2005 SLC NFP.

Proposed Priorities: This notice contains two proposed priorities. These proposed priorities would be in addition to the priority established in the 2007 SLC NFP (Preparing All Students to Succeed in Postsecondary Education and Careers).

Proposed Priority 1: Common Planning Time for Teachers

Background: Providing teachers with regular and ongoing opportunities for structured collaboration and planning during or immediately following the school day is considered by many researchers and practitioners to be key to improving instruction and ensuring that students receive the academic and personal supports they need to achieve at high levels. For example, this practice is common among many high-performing schools, including, particularly, those with high concentrations of economically disadvantaged or low-achieving students (Mass Insight Education and Research Institute, 2007; Odden, 2007; Dyke, 2008; Herman, *et al.,* 2008; Education Resource Strategies, 2009; Perlman and Redding, 2009; Strozier, 2009). In these high-performing schools, common planning time is used for a variety of activities, including the analysis of student work and outcome data, collaborative professional development and instructional coaching, and developing or coordinating the implementation of curricula and assessments. By providing teachers with regular and ongoing opportunities for collaboration, these schools also promote a strong sense of shared responsibility among teachers for improving student academic achievement (Louis and Marks, 1998; Symonds, 2004; Mass Insight Education and Research Institute, 2007; Silva, 2009).

For these reasons, we propose a priority to allow grantees to use SLC funds to pay the necessary personnel and other costs associated with increasing common planning time for teachers. Under the proposed priority, applicants could, for example, propose to use grant funds to hire additional teachers, pay substitute teachers, or extend the school day in order to provide teachers with more time for common planning and collaboration.

Under the proposed priority, we would not require that grantees increase common planning time for all teachers within a school. Instead, grantees could choose to focus on a single grade level, such as ninth grade, or on particular content areas.

We believe that this proposed priority will help enhance the effectiveness of SLC projects in improving academic achievement and the preparation of students for postsecondary education and careers by ensuring that students receive the academic and personal supports they need to achieve.

Proposed Priority 1—Common Planning Time for Teachers

This proposed priority would support projects that increase the amount of time regularly provided to teachers who share the same students or teach the same academic subject for common planning and collaboration during or immediately following the school day without decreasing the amount of time provided to teachers for individual planning and preparation. To meet this priority, the common planning time must be used for one or more of the following activities:

(1) Structured examination of student work and outcome data.

(2) Collaborative professional development and coaching, including classroom observation.

(3) Identifying instructional and other interventions for struggling students.

(4) Curriculum and assessment development.

Proposed Priority 2: Persistently Lowest-Achieving Schools—Secondary Schools

Background: The Secretary has established a goal of turning around, over the next five years, the 5,000 lowest-achieving schools nationwide as part of a comprehensive strategy for dramatically reducing the drop-out rate, improving high school graduation rates, and increasing the number of students who graduate prepared for success in college and the workplace.

The SLC program can be an important source of funding to support turnaround efforts in a State's persistently lowest-achieving high schools. For this reason, we propose to establish a priority for SLC projects that include one or more schools that have been identified by a State as a persistently lowest-achieving school.

Proposed Priority 2—Persistently Lowest-Achieving Schools—Secondary Schools

This proposed priority would support SLC projects that include one or more schools that have been identified by a

State as a persistently lowest-achieving school.

For the purpose of this priority, the term "persistently lowest-achieving school" is defined as it is under the Department's State Fiscal Stabilization Fund Program (*see* 74 FR 58436, 58487), School Improvement Grants (*see* 74 FR 65618, 65652), and Race to the Top Fund (*see* 74 FR 59836, 59840).

Types of Priorities:

When inviting applications for a competition using one or more priorities, we designate the type of each priority as absolute, competitive preference, or invitational through a notice in the **Federal Register.** The effect of each type of priority follows:

Absolute priority: Under an absolute priority, we consider only applications that meet the priority (34 CFR 75.105(c)(3)).

Competitive preference priority: Under a competitive preference priority, we give competitive preference to an application by either (1) awarding additional points, depending on the extent to which the application meets the competitive priority (34 CFR 75.105(c)(2)(i)); or (2) selecting an application that meets the priority over an application of comparable merit that does not meet the priority (34 CFR 75.105(c)(2)(ii)).

Invitational priority: Under an invitational priority we are particularly interested in applications that meet the invitational priority. However, we do not give an application that meets the priority a preference over other applications (34 CFR 75.105(c)(1)).

Proposed Requirements: The Assistant Secretary for Elementary and Secondary Education proposes the following requirements for this program. We may apply these requirements in any year in which this program is in effect.

Note: These proposed requirements would be in addition to the application requirements required under title V, part D, subpart 4, section 5441(b) of the ESEA, and the following requirements established in the 2005 SLC NFP and the 2007 SLC NFP:

Requirement	Notice
Consortium Applications and Educational Service Agencies.	2005 SLC NFP.
Student Placement	2005 SLC NFP.
Including All Students	2005 SLC NFP.
Indirect Costs	2007 SLC NFP.
Required Meetings Sponsored by the Department.	2007 SLC NFP.
Previous Grantees	2007 SLC NFP.

Proposed Requirement 1—Budget and Performance Periods

Background: In the 2007 SLC NFP, we established a requirement pursuant to which SLC grant funds were awarded in two increments over a 60-month performance period: An initial award for the first 36 months of the performance period and a continuation award for the remaining 24 months of the performance period. Through this *Proposed Budget and Performance Periods* requirement, we would reduce the duration of the initial award from 36 to 24 months and make continuation awards annually thereafter. We propose this change because making the initial award for a period of 24 months would give grantees until the end of the second school year after the award is made (*i.e.,* the 2011–12 school year) to implement all or most of the components of their projects and demonstrate substantial progress. As we do not expect to make new awards until after the start of the 2010–2011 school year, we recognize that grantees likely will need more than 12 months to implement their projects fully and demonstrate substantial progress. Further, we propose the change to 24 months, based on our belief that, an SLC grantee that requires more than an initial 24 months to show progress is likely experiencing significant management problems and may not merit continued funding. For similar reasons, we are proposing to make continuation awards annually after this initial 24 month budget period. SLC grantees should be able to demonstrate each year that they are continuing to make substantial progress in implementing their projects. In addition, making continuation awards on an annual basis will better ensure that SLC grantees do not receive more funds than they are able to expend to implement their projects. For a variety of reasons, some SLC grantees have been unable to expend all of the funds they requested at the time they submitted their applications. As a result, a number of SLC grantees have returned significant amounts of funds to the United States Treasury when their grants have ended.

Proposed Budget and Performance Periods: Grantees will be awarded implementation grants for a period up to 60 months, with the initial award to provide funding for the first 24 months of the performance period. Funding for the remainder of the performance period will be made annually, contingent on the availability of funds and each grantee's substantial progress toward accomplishing the goals and objectives of the project as described in its approved application.

In its application, the applicant must provide detailed, yearly budget information for the total grant period requested.

Proposed Requirement 2—Maximum Award Amounts and Number of Schools

Background: In order to ensure that applicants have sufficient funding for the personnel expenditures likely needed to meet the requirements of Proposed Priority 1—Common Planning Time for Teachers (*i.e.,* increasing the amount of time that teachers are provided regularly for common planning and collaboration), we are proposing to increase the maximum, 60-month award amounts per school by $750,000. Based on our informal consultations with LEA and school officials in different parts of the country, we believe that this additional $750,000 should be sufficient to support a significant increase in common planning time for teachers in at least one grade level of the school.

In addition, we are proposing to reduce the number of schools that an LEA may apply on behalf of in a single application from eight to five because, in the past, many grantees have experienced great difficulties managing and overseeing project activities at more than five schools. In such cases, implementation progress has been slow and uneven and several grantees decided to remove one or more schools from their grants.

Finally, through this requirement, we are proposing that applications requesting more funds than the maximum amounts specified for any school or for the total grant will not be read as part of the regular application process. In previous SLC competitions, some applicants requested more funds than the amount that we indicated would be available for a grant. These applications included activities that could only be implemented if the applicants received a funding amount that exceeded the maximum amount specified by the Department. This strategy put at a competitive disadvantage other applicants that requested funds within the Department's specified funding range and proposed a less extensive set of activities. For this reason, we propose to review only those applications that request an amount that does not exceed the maximum amounts specified for the grants.

Proposed Maximum Award Amounts and Number of Schools: An eligible LEA may receive, on behalf of a single

school, up to $2,500,000 of SLC grant funds, depending upon student enrollment in the school, for the entire 60-month project period.

The following chart provides the ranges of awards per high school size:

SLC GRANT AWARD RANGES

Student enrollment	Award ranges per school
1,000–2,000 Students	$1,750,000–$2,000,000
2,001–3,000 Students	1,750,000–2,250,000
3,001 and Up	1,750,000–2,500,000

An LEA may include up to five schools in a single application for a SLC grant. Therefore, an LEA applying on behalf of a group of eligible schools would be able to receive up to $12,500,000 for its SLC grant.

Applications requesting more funds than the maximum amounts specified for any school or for the total grant will not be read as part of the regular application process. However, if, after the Secretary selects applications to be funded, it appears that additional funds remain available, the Secretary has the option of reviewing applications that requested funds exceeding the maximum amounts specified. Under this requirement, if the Secretary chooses to fund any of the additional applications, selected applicants will be required to work with the Department to revise their proposed budgets to fit within the appropriate funding range.

Proposed Requirement 3—Performance Indicators

Background: While creating SLCs can appeal to teachers, students, and parents for many reasons, their fundamental purpose is to improve academic achievement and student success after high school. Therefore, it is important that assistance provided under the SLC program support and enhance the efforts of LEAs and schools to improve student academic achievement and preparation for and enrollment in postsecondary education.

In order to ensure that SLC projects ultimately achieve these important outcomes, we must ensure that each funded SLC project measures its progress in improving student academic achievement and related outcomes. For this reason, we propose to continue to measure the progress of grantees using two indicators: (1) Student performance on reading/language arts and mathematics assessments and (2) high school graduation rates (these two indicators are reflected in paragraphs (1) and (2) of the Performance Indicators included in the 2007 SLC NFP). These are the same indicators used by States to measure the progress of LEAs and high schools under Part A of Title I of the ESEA. We propose that performance objectives for these indicators equal or exceed the annual measurable objectives established by the State in its approved accountability plan for Part A of Title I of the ESEA. Because school-level data for these indicators are now available to the Department through using the EDEN Submission System (ESS), it is unnecessary for the Department to continue to collect them directly from grantees.

We also propose to continue measuring the extent to which the graduates of each school included in an SLC grant enter postsecondary education in the semester following high school graduation. Because enrolling in postsecondary education is a nearly universal aspiration among high school students and their parents, we believe that this measurement continues to be useful and we believe that grantees should be held accountable for helping them achieve this goal. We propose that performance objectives for this indicator exceed the baseline level of performance and give particular emphasis to narrowing any gaps between students in general and economically disadvantaged students, students from major racial and ethnic groups, students with disabilities, and students with limited English proficiency. Because data for this indicator are not reported by SEAs through ESS (an electronic system that facilitates the efficient and timely transmission of data from SEAs to the Department), we propose to continue to require grantees to provide these data on an annual basis. We further propose to require grantees to use administrative records that document student enrollment in postsecondary education as the principal source of data for this indicator because these data are likely to be more accurate and less costly to obtain than information gathered through student and parent surveys. Because these administrative records may not provide data on all of a school's graduates (*e.g.,* in the case of most State longitudinal databases, students who enroll in postsecondary education in another State), we propose to permit grantees to supplement the data obtained from administrative records with information gathered through surveys that are administered after high school graduation.

Proposed Performance Indicators: Each applicant must identify in its application the following specific performance indicators as well as the annual performance objectives to be used for each of these indicators. Specifically, each applicant must use the following performance indicators to measure the progress of each school included in its application:

(a) The percentage of students who score at or above the proficient level on the reading/language arts and mathematics assessments used by the State to determine whether a school has made adequate yearly progress under Part A of Title I of the ESEA, as well as these percentages disaggregated by subject matter and the following subgroups:

(1) Major racial and ethnic groups.

(2) Students with disabilities.

(3) Students with limited English proficiency.

(4) Economically disadvantaged students.

(b) The school's graduation rate, as defined in the State's approved accountability plan for Part A of Title I of the ESEA, as well as the graduation rates for the following subgroups:

(1) Major racial and ethnic groups.

(2) Students with disabilities;

(3) Students with limited English proficiency; and

(4) Economically disadvantaged students; and

(c) The percentage of all graduates who enroll in postsecondary education in the semester following high school graduation, as well as the percentage disaggregated by the following subgroups:

(1) Major racial and ethnic groups.

(2) Students with disabilities.

(3) Students with limited English proficiency.

(4) Economically disadvantaged students.

Each applicant must identify in its application its performance objectives for each of these indicators for each year of the project period and provide baseline data for the third indicator (postsecondary enrollment). The Department will obtain baseline data for the first and second performance indicators (student performance on reading/language arts and mathematics assessments and the graduation rate) and data on the extent to which each school included in a grant achieves its annual performance objectives for each year of the project period from the data that are now reported to the Department by SEAs using the EDEN Submission System (ESS). Grantees are not required to provide these data.

Each grantee must report to the Department annually on the extent to which each school in its grant achieves its performance objectives for the third proposed indicator (postsecondary enrollment).

Finally, grantees must use administrative records maintained by State, national, or regional entities that already collect data on student enrollment in postsecondary education as the principal source of data for this performance indicator. These administrative records include, for example, data available through State longitudinal databases or other sources. Grantees may supplement these records with data collected through surveys administered to students or parents after graduation.

Proposed Requirement 4—School Report Cards

Background: In the 2005 SLC NFP, we established a requirement for the SLC program pursuant to which applicants were required to include school report cards with their applications to verify the accuracy of the student achievement they reported. This requirement created a significant paperwork burden for many applicants because, in some States and LEAs, school report cards are expansive, extending over 10 to 20 pages. With school-level student achievement data now available to the Department through ESS, it is no longer necessary to require applicants to provide school report cards to verify the accuracy of the student achievement data they report in their applications.

Proposed School Report Cards Requirement: No applicant is required to include in its application any report card for the schools included in its application.

Proposed Requirement 5—Evidence of Eligibility

Background: We propose to require each applicant to provide, along with its application, the name of, and other identifying information about, each school included in its application and evidence of each such school's enrollment during the current or most recently completed school year. This information is necessary so that the Department can verify that each of the schools in the applicant's application meets the program's eligibility requirements. We propose to require that evidence of enrollment consist of information reported by the LEA to the SEA or produced by the SEA so that there is no ambiguity for applicants about the evidence that they must submit to establish school eligibility.

Proposed Evidence of Eligibility Requirement: LEAs, including schools funded by the Bureau of Indian Education and educational service agencies, applying on behalf of large public high schools, are eligible to apply for a grant. We will not accept applications from LEAs applying on behalf of schools that are being constructed and do not have an active student enrollment at the time of application. LEAs may apply on behalf of no more than five schools. Along with its application, each applicant must provide, for each school included in its application:

(a) The school's name, postal mailing address, and the 12-digit identification number assigned the school by the National Center for Education Statistics; and

(b) Evidence that, during the current school year or the most recently completed school year, the school is a large public high school (*i.e.,* an entity that includes grades 11 and 12 and has an enrollment of 1,000 or more students in grades 9 and above (*see Definitions* in 2005 SLC NFP) and, thus, is eligible to receive assistance under this program.

To meet this requirement, the enrollment figures provided in the evidence must be based upon data from the current school year or the most recently completed school year. In addition, this evidence must include a copy of either:

(a) The form or report that the LEA submits to the SEA to report the school's student enrollment (or student membership, as it is sometimes described) on or around October 1 of each year.

(b) A document provided by the SEA that identifies the school's enrollment on or around October 1 of each year.

Proposed Requirement 6—Evaluation

Background: In the 2005 SLC NFP, we established requirements that each SLC grantee support an independent, formative evaluation of its project that reported its findings to the grantee (*i.e.,* its LEA) on not less than an annual basis. Each grantee was required to provide each annual evaluation report to the Department at the same time it reported annually on its progress in implementing its project. The purpose of this requirement was to provide the project director and other LEA and school personnel information that would be useful in gauging the project's progress and identifying areas for improvement. The Department also provided grantees with technical assistance materials to help them secure qualified evaluators and evaluations that would produce information to more effectively manage their projects. After carefully reviewing the annual evaluation reports that have been submitted by grantees since FY 2006, we have concluded that, generally, this requirement has not achieved its intended purpose. For the most part, grantees have not chosen to commission evaluations that provide them with useful implementation information or have not used the information provided by these evaluations to improve their management of their projects. Instead, many grantees have commissioned evaluations chiefly to comply with our requirement. Given the often considerable cost of these evaluations and their limited usefulness to grantees, we believe it would be prudent to cease to require grantees to commission them. A grantee may still choose to use grant funds to support a project evaluation if the evaluation is related clearly to the goals of the project and necessary for the proper and efficient performance and administration of the grant award.

Proposed Evaluation Requirement: We propose to eliminate the requirement established by the 2005 SLC NFP that each applicant provide assurances that it will support an evaluation of the project that will produce an annual report for each year of the performance period.

Proposed Requirement 7—Grant Award Administration

Background: The responsibilities of a project director for an SLC grant include coordinating grant activities to ensure that they are carried out on time and within budget, overseeing the fiscal management of the project, and fulfilling performance reporting and other requirements established by the Department. We propose to establish a minimum time commitment for this position to ensure that the project director has sufficient time to carry out these responsibilities. In our experience, many of the grants in which the time commitment of the project director was less than the minimum we are proposing have experienced significant implementation delays. In some cases, these grant recipients were unable to implement key elements of their approved applications. We note that under our proposal, applicants could continue to include the salary and other costs of the project director in their proposed budgets.

Proposed Grant Award Administration: Grantees must designate a single project director who will be principally responsible for overseeing the implementation of the proposed project and communicating with the Department.

Each grantee must ensure that its designated project director—for a grant that includes one school—be not less than fifty percent of a full-time equivalent (FTE) position and that the time commitment of a project director

for a grant that includes more than one school be not less than one FTE.

Proposed Requirement 8—Use of Funds for Equipment

Background: While we recognize that equipment can be an effective tool for enhancing instruction and improving student achievement and is essential to carrying out a variety of administrative activities, numerous other sources of funds are available to LEAs and schools to acquire equipment. We, therefore, propose to limit the use of SLC grant funds for the purchase or use of equipment in order to focus grant funds on the personnel, technical assistance, professional development and other costs related to implementing significant structural and instructional reforms that will improve student academic achievement and preparation for postsecondary education.

Proposed Use of Funds for Equipment Requirement: For each budget period of the grant award, a grantee may not use more than one percent of the total grant award for the acquisition of equipment (as that term is defined in this notice).

Proposed Definition:

Background: We are proposing to define the term *equipment* because we propose to limit the use of SLC grant funds for the purchase of equipment elsewhere in this notice. Under Office of Management and Budget Circular A–87, Cost Principles for State, Local, and Indian Tribal Governments, an item is considered to be "equipment" if, among other things, it is nonexpendable, tangible personal property having a useful life of more than one year and has an acquisition cost which equals or exceeds the lesser of the capitalization level established by the governmental unit for financial statement purposes, or $5,000. We are proposing to reduce the acquisition cost threshold to the lesser of the capitalization level established by the governmental unit for financial statement purposes or $500 in order to include laptop and desktop computers, printers, and other office and classroom equipment that some SLC grantees have sought to purchase with grant funds.

Proposed Definition:

In addition to the definitions set out in the authorizing statute, 34 CFR 77.1, and the 2005 SLC NFP, we propose that the following definition also apply to this program:

Equipment means an article of nonexpendable, tangible personal property that has a useful life of more than one year and that has an acquisition cost which equals or exceeds the lesser of the capitalization level established by the governmental unit for financial statement purposes, or $500. It includes, but is not limited to, office equipment and furnishings, modular offices, telephone networks, information technology equipment and systems, air conditioning equipment, reproduction and printing equipment, and motor vehicles.

Proposed Selection Criteria:

The Assistant Secretary for Elementary and Secondary Education proposes the following selection criteria for evaluating an application under this program. We may apply one or more of these criteria in any year in which this program is in effect. These proposed selection criteria are intended to replace the selection criteria established for the SLC program in the 2005 SLC NFP and the 2007 SLC NFP.

In the notice inviting applications or the application package or both we will announce the maximum possible points assigned to each criterion.

(a) *Quality of the Project Design.* In determining the quality of the design of the proposed project, we will consider the extent to which—

(1) Teachers, school administrators, parents, and community stakeholders support the proposed project and have been and will continue to be involved in its development and implementation;

(2) The applicant has carried out sufficient planning and preparatory activities to enable it to implement the proposed project during the school year in which the grant award will be made;

(3) School administrators, teachers, and other school employees will receive effective, ongoing technical assistance and professional development in implementing structural and instructional reforms and providing effective instruction; and

(4) The applicant demonstrates that the proposed project is aligned with and advances a coordinated, district-wide strategy to improve student academic achievement and preparation for postsecondary education and careers without need for remediation.

(b) *Quality of Project Services.* In determining the quality of the services to be provided by the proposed project, we will consider the extent to which the proposed project is likely to be effective in—

(1) Creating an environment in which multiple teachers and other adults within the school know the needs, interests, and aspirations of each student well, closely monitor each student's progress, and provide the academic and other support each student needs to succeed;

(2) Equipping all students with the reading/English language arts, mathematics, and science knowledge and skills they need to succeed in postsecondary education and careers without need for remediation;

(3) Helping students who enter high school with reading/English language arts or mathematics skills that are significantly below grade-level to "catch up" and attain, maintain and exceed proficiency by providing supplemental instruction and supports to these students during the ninth grade and, to the extent necessary, in later grades;

(4) Increasing the amount of time regularly provided to teachers for common planning and collaboration during or immediately following the school day, without decreasing the amount of time provided to teachers for individual planning and preparation;

(5) Ensuring, through technical assistance, professional development, and other means, that teachers use opportunities for common planning and collaboration effectively to improve instruction and student academic achievement;

(6) Increasing the participation of students, particularly low-income students, in Advanced Placement, International Baccalaureate, or dual credit courses (such as dual enrollment or early college programs) that offer students the opportunity to earn simultaneously both high school and college credit; and

(7) Increasing the percentage of students who enter postsecondary education in the semester following high school graduation by delivering comprehensive guidance and academic advising to students and their parents that includes assistance in selecting courses and planning a program of study that will provide the academic preparation needed to succeed in postsecondary education, early and ongoing college awareness and planning activities, and help in identifying and applying for financial aid for postsecondary education.

(c) *Support for Implementation.* In determining the adequacy of the support the applicant will provide for implementation of the proposed project, we will consider the extent to which—

(1) The management plan is likely to achieve the objectives of the proposed project on time and within budget and includes clearly defined responsibilities and detailed timelines and milestones for accomplishing project tasks; and

(2) The project director and other key personnel are qualified and have sufficient authority to carry out their responsibilities, and their time commitments are appropriate and adequate to implement the SLC project effectively.

(d) *Need for the Project.* In determining the need for the proposed

project, we will consider the extent to which the applicant has identified specific gaps and weaknesses in the preparation of all students for postsecondary education and careers without need for remediation, the nature and magnitude of those gaps and weaknesses, and the extent to which the proposed project will address those gaps and weaknesses effectively.

Final Priorities, Requirements, Definition, and Selection Criteria

We will announce the final priorities, requirements, definition, and selection criteria in a notice in the **Federal Register**. We will determine the final priorities, requirements, definitions, and selection criteria after considering responses to this notice and other information available to the Department. This notice does not preclude us from proposing additional priorities, requirements, definitions, and selection criteria, subject to meeting applicable rulemaking requirements.

Note: This notice does not solicit applications. In any year in which we choose to use one or more of these priorities, requirements, definition, and selection criteria, we invite applications through a notice in the **Federal Register.**

Executive Order 12866: This notice has been reviewed in accordance with Executive Order 12866. Under the terms of the order, we have assessed the potential costs and benefits of this regulatory action.

The potential costs associated with this proposed regulatory action are those resulting from statutory requirements and those we have determined as necessary for administering this program effectively and efficiently.

In assessing the potential costs and benefits—both quantitative and qualitative—of this proposed regulatory action, we have determined that the benefits of the proposed priorities, requirements, definition, and selection criteria justify the costs.

We have determined, also, that this regulatory action does not unduly interfere with State, local, and tribal governments in the exercise of their governmental functions.

Discussion of Costs and Benefits: Elsewhere in this notice we discuss the potential costs and benefits, both quantitative and qualitative, of the proposed priorities, requirements, definition, and selection criteria under the background sections to the Priorities, Requirements, Definition, and Selection Criteria.

Paperwork Reduction Act of 1995 (PRA)

Certain sections of the proposed priorities, requirements, definition, and selection criteria for the SLC grant program contain changes to information collection requirements already approved by the Office of Management and Budget (OMB) under OMB control number 1810–0676 (1890–0001). We will be publishing a separate notice in the **Federal Register** requesting comments on these changes.

Intergovernmental Review: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. One of the objectives of the Executive order is to foster an intergovernmental partnership and a strengthened federalism. The Executive order relies on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

This document provides early notification of our specific plans and actions for this program.

Accessible Format: Individuals with disabilities can obtain this document in accessible format (*e.g.,* braille, large print, audiotape, or computer diskette) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: You can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF) on the Internet at the following site: *http://www.ed.gov/news/fedregister.* To use PDF you must have Adobe Acrobat Reader, which is available free at this site.

Note: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available on GPO Access at: *http://www.gpoaccess.gov/nara/index.html.*

Dated: March 26, 2010.

Thelma Meléndez de Santa Ana,

Assistant Secretary for Elementary and Secondary Education.

[FR Doc. 2010–7255 Filed 3–30–10; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Proposed Information Quality Guidelines Policy

AGENCY: U.S. Election Assistance Commission (EAC).

ACTION: Notice and request for public comment on Proposed Information Quality Guidelines Policy.

SUMMARY: The U.S. Election Assistance Commission (EAC) seeks public comment on the Proposed Information Quality Guidelines policy. The policy outlines the EAC's directives and required procedures to implement the OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 FR 8452 ("OMB Guidelines"). The EAC developed the Proposed Information Quality Guidelines to meet its obligations under the OMB Guidelines and to codify its high standards of quality in the production of information disseminated outside the agency.

DATES: Written comments must be submitted on or before 4 p.m. EDT on April 30, 2010.

Comments: Public comments are invited on the information contained in the policy. Comments on the proposed policy should be submitted electronically to *HAVAinfo@eac.gov*. Written comments on the proposed policy can also be sent to the U.S. Election Assistance Commission, 1201 New York Avenue, NW., Suite 300, Washington, DC 20005, ATTN: Proposed Information Quality Guidelines Policy.

Obtaining a Copy of the Policy: To obtain a free copy of the policy: (1) Access the EAC Website at *http://www.eac.gov*; (2) write to the EAC (including your address and phone number) at U.S. Election Assistance Commission, 1201 New York Avenue, NW., Suite 300, Washington, DC 20005, ATTN: Information Quality Guidelines.

FOR FURTHER INFORMATION CONTACT: Ms. Tamar Nedzar, Ms. Karen Lynn-Dyson or Ms. Shelly Anderson at (202) 566–3100.

Thomas R. Wilkey,

Executive Director, U.S. Election Assistance Commission.

[FR Doc. 2010–7134 Filed 3–30–10; 8:45 am]

BILLING CODE 6820–KF–P

ELECTION ASSISTANCE COMMISSION

Notice: Request for Substantive Comments on the EAC's Proposed Requirements for the Testing of Pilot Voting Systems To Serve UOCAVA Voters

AGENCY: United States Election Assistance Commission.

ACTION: Request for public comment on proposed requirements for the testing of

pilot voting systems to be used to serve UOCAVA voters.

SUMMARY: The U.S. Election Assistance Commission (EAC) is publishing for public comment a set of proposed requirements for the testing of pilot voting systems to be used by jurisdictions to serve Uniformed and Overseas voters.

SUPPLEMENTARY INFORMATION:

Background: The Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA) of 1986 protects the right to vote in Federal elections for this defined category of citizens. UOCAVA sets out federal and state responsibilities to assist these voters in exercising their voting rights. The Secretary of Defense is the presidential designee responsible for the Federal functions of the Act. The Federal Voting Assistance Program (FVAP) administers this law on behalf of the Secretary of Defense and works cooperatively with other Federal agencies and state and local election officials to carry out its provisions.

UOCAVA legislation was enacted before the advent of today's global electronic communications technology. Consequently it relied on U.S. domestic and military mail systems as well as foreign postal systems for the worldwide distribution of election materials. By the mid-1990s it became apparent that the mail transit time and unreliable delivery posed significant barriers for many UOCAVA citizens, preventing them from successfully exercising their right to vote. At the same time the Internet was being widely adopted by businesses, governments and the general public. Therefore it was a natural development for FVAP and states to consider the potential of the Internet as an alternative to the "by-mail" UOCAVA process.

FVAP sponsored Voting Over the Internet (VOI), a small pilot project for the November 2000 general election, to examine the feasibility of using Internet technology. Four states participated in this experiment, which enabled voters to use their own personal computers to securely register to vote, request and receive absentee ballots, and return their voted ballots. Following the successful completion of the VOI project, in the Fiscal Year 2002 National Defense Authorization Act (section 1604 of Pub. L. 107–107:115 Stat. 1277), Congress instructed the Secretary of Defense to carry out a larger demonstration project for the November 2002 general election. This project was to be "carried out with participation of sufficient numbers of absent uniformed services voters so that the results are statistically significant".

Since there was not sufficient time to define and implement a large project for 2002, the project was planned for implementation for the November 2004 election. Seven states agreed to participate and worked with FVAP to develop system requirements and operating procedures. However, the Secure Electronic Registration and Voting Experiment (SERVE) was cancelled before it was deployed due to concerns raised by several computer scientists. These individuals contended that the use of personal computers over the Internet could not be made secure enough for voting and consequently called for the project to be terminated. The Department of Defense, citing a lack of public confidence in the SERVE system, decided the project could not continue under these circumstances.

In response to this development, the Fiscal Year 2005 National Defense Authorization Act (section 567 of Pub. L. 108–375;118 Stat. 119) repealed the requirement for the Secretary of Defense to conduct an electronic voting demonstration project "until the first regularly scheduled general election for federal office which occurs after the Election Assistance Commission (EAC) notifies the Secretary that the Commission has established electronic absentee voting guidelines and certifies that it will assist the Secretary in carrying out the project". Pursuant to this legislation, in September 2005, the EAC requested its voting system advisory group, the Technical Guidelines Development Committee (TGDC), to add this subject on their research agenda; however the request was declined.

Since that time legislation dealing with a number of UOCAVA voting issues were under consideration by Congress. Ultimately, passed as part of the Fiscal Year 2010 National Defense Authorization Act (NDAA) (section 581 of Pub. L. 111–84), the Military and Overseas Voters Empowerment Act contains a provision allowing the Secretary of Defense to establish one or more pilot programs to test the feasibility of new election technology for UOCAVA voters. This provision requires the EAC and the National Institute of Standards and Technology (NIST) to provide best practices or standards to support these pilot programs, "in accordance with electronic absentee voting guidelines established under" the earlier FY2005 NDAA. In December 2009, the EAC directed the TGDC to begin this work as a top research priority. The EAC expects this work to result in the comprehensive set of remote electronic voting system guidelines as mandated by the FY2005 NDAA. The TGDC has been tasked to consider the full range of remote voting architectures, including instances where the voter can use his own personal computer for voting. The pilot testing requirements, that the EAC is currently developing, will be provided to the TGDC as the basis and starting point for their research and deliberations.

Project Summary: Since 2008, several states have enacted legislation enabling them to conduct electronic voting projects for UOCAVA voters, beginning with the 2010 elections. To be prepared to support the states with these projects, in July 2009 the EAC convened a UOCAVA Working Group to consider how to adapt the EAC's Testing and Certification Program to accommodate UOCAVA pilot systems. It was concluded that two products were needed: (1) A modified set of system testing requirements; and (2) a revised testing and certification process. It was determined that a working group would assist the EAC in drafting the testing requirements and EAC staff would adapt the certification process to accommodate the UOCAVA pilot program.

The EAC UOCAVA Working Group has taken much the same approach as the state pilot project working groups. The source materials drawn on for this effort included: the Voluntary Voting System Guidelines (VVSG) 1.0 ; the VVSG 1.1; the VVSG 2.0; the VOI, SERVE; FIPS; and NIST Special Publications. One significant difference in the EAC Working Group approach was the technology scope covered by the requirements. The VOI, SERVE and Okaloosa system requirements were tailored specifically for the particular system implementations developed for those projects. However, since many different types of remote voting systems could be submitted to the EAC certification program, the EAC Working Group defined generic system requirements to provide for system design flexibility.

Pilot projects are small in scale and short in duration. Consequently, certification for pilot systems needs to be quicker and less expensive than the regular process currently used for conventional systems with an expected life of more than 10 years. Nevertheless, since actual votes will be cast using the voting systems utilized in the pilot project, the certification process must retain sufficient rigor to provide reasonable assurance that the pilot systems will operate correctly and securely.

There is a fundamental dichotomy in complexity in remote voting architectures: those where the voting

platform is controlled (e.g., provided by the election jurisdiction); and those where it is not controlled (e.g., the voter uses his own personal computer). Since the EAC plans to have the pilot certification process ready for implementation during the first half of 2010, it was decided that the EAC would focus its efforts on controlled platform architectures servicing multiple jurisdictions. This is a highly secure remote voting solution and the Okaloosa Project provides an implementation example for reference. Defining requirements for this class of system architecture was determined to provide a reasonable test case that could be completed within the available timeframe. In addition, most of the core system processing functions are the same for both types of architectures, so a substantial number of requirements will carry over as this work is expanded to include other methods of remote electronic voting.

The UOCAVA Pilot requirements document contains testable requirements for the following areas:

(1) Functional Requirements.
(2) Usability.
(3) Software.
(4) Security.
(5) Quality Assurance.
(6) Configuration Management.
(7) Technical Data Package.
(8) Systems Users Manual.

DATES: Comments must be received on or before 4 p.m. EST on April 15, 2010.

Submission of Comments: The public may submit comments through one of the two different methods provided by the EAC: (1) e-mail submissions to *votingsystemguidelines@eac.gov;* (2) by mail to Voluntary Voting System Guidelines Comments, U.S. Election Assistance Commission, 1201 New York Ave., NW., Suite 300, Washington, DC 20005.

In order to allow efficient and effective review of comments the EAC requests that:

(1) Comments refer to the specific section that is the subject of the comment.

(2) General comments regarding the entire document or comments that refer to more than one section be made as specifically as possible so that EAC can clearly understand to which portion(s) of the documents the comment refers.

(3) To the extent that a comment suggests a change in the wording of a requirement or section of the guidelines, please provide proposed language for the suggested change.

All comments submitted will be published at the end of the comment period on the EAC's Web site at *http://www.eac.gov*. This publication and request for comment is not required under the rulemaking, adjudicative, or licensing provisions of the Administrative Procedures Act (APA). It is a voluntary effort by the EAC to gather input from the public on the EAC's administrative procedures for certifying voting systems to be used in pilot projects. Furthermore, this request by the EAC for public comment is not intended to make any of the APA's rulemaking provisions applicable to development of this or future EAC procedural programs.

An electronic copy of the proposed guidance may be found on the EAC's Web site at *http://www.eac.gov.*

FOR FURTHER INFORMATION CONTACT: Matthew Masterson, Phone (202) 566–3100, e-mail *votingsystemguidelines@eac.gov.*

Alice Miller,

Chief Operating Officer, U.S. Election Assistance Commission.

[FR Doc. 2010–7199 Filed 3–30–10; 8:45 am]

BILLING CODE 6820–KF–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11910–004]

Symbiotics, LLC; AG Hydro, LLC; Notice of Application for Transfer of License, and Soliciting Comments and Motions To Intervene

March 24, 2010.

On March 8, 2010, Symbiotics, LLC (transferor) and AG Hydro, LLC (transferee) filed an application for transfer of license of the Applegate Dam Project, located on the Applegate River in Jackson County, Oregon.

Applicants seek Commission approval to transfer the license for the Applegate Dam from the transferor to the transferee.

Applicant Contact: For both the transferor and transferee is Mr. Brent Smith, 4110 East 300 North, P.O. Box 535, Rigby, ID 83442, phone (208) 745–0834.

FERC Contact: Robert Bell, (202) 502–6062.

Deadline for filing comments and motions to intervene: 30 days from the issuance of this notice. Comments and motions to intervene may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii)(2008) and the instructions on the Commission's Web site under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. For more information on how to submit these types of filings please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp*. More information about this project can be viewed or printed on the eLibrary link of the Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp*. Enter the docket number (P–11910–004) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7143 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 1494–384]

Grand River Dam Authority; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

March 24, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-project use of project lands and waters.

b. *Project No:* 1494–384.

c. *Date Filed:* March 11, 2010, supplemented on March 17, 2010.

d. *Applicant:* Grand River Dam Authority.

e. *Name of Project:* Pensacola Project.

f. *Location:* The proposed non-project use is located on Grand Lake O' the Cherokees in Delaware County, Oklahoma.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Ms. Tamara E. Jahnke, Assistant General Council, Grand Dam River Authority, P.O. Box 409, Vinita, Oklahoma 74301, (918) 256–5545.

i. *FERC Contact:* Any questions on this notice should be addressed to Shana High at (202) 502–8674.

j. *Deadline for filing comments, motions to intervene, and protest:* April 26, 2010.

Comments, Motions to Intervene, and Protests may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions

on the Commission's Web site at *http://www.ferc.gov* under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. For more information on how to submit these types of filings, please go to the Commission's Web site located at *http://www.ferc.gov.filing-comments.asp.* Please include the project number (P–1494–384) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

k. *Description of Request:* GRDA requests Commission authorization to permit BAK, LLC, d/b/a Elk River Landing to expand its current marina. After completing the proposed expansion, the marina would have three docks, with a total of 86 covered boat slips, and a concession dock.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *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. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers.

p. *Agency Comments:* Federal, State, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7145 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 11143–020]

Glen Falls Hydro, LLC; Essex Energy Partners, LLC; Notice of Application for Transfer of License, and Soliciting Comments and Motions To Intervene

March 24, 2010.

On March 8, 2010, Glen Falls Hydro, LLC (transferor) and Essex Energy Partners, LLC (transferee) filed an application for transfer of license of the Glen Falls Project, located on the Moosup River in Windham County, Connecticut.

Applicants seek Commission approval to transfer the license for the Glen Falls Project from the transferor to the transferee.

Applicant Contact: For transferor Mr. John Gauvin, Glen Falls Hydro, LLC, 340 Prospect Street, Moosup, CT 06354, phone (860) 564–7786. For the transferee Mr. Bruce DiGennaro, Essex Energy Partners, LLC, 27 Vaughan Avenue, Newport, RI 02840, phone (401) 619–4872

FERC Contact: Robert Bell, (202) 502–6062.

Deadline for filing comments and motions to intervene: 30 days from the issuance of this notice. Comments and motions to intervene may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii)(2008) and the instructions on the Commission's Web site under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC. 20426. For more information on how to submit these types of filings please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.* More information about this project can be viewed or printed on the eLibrary link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–11143–020) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7142 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 459–297]

Union Electric Company dba Ameren/UE; Notice of Application for Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

March 24, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Non-project use of project lands and waters.

b. *Project No:* 459–297.

c. *Date Filed:* March 18, 2010 .

d. *Applicant:* Union Electric Company dba Ameren/UE.

e. *Name of Project:* Osage Hydroelectric Project.

f. *Location:* The proposed non-project use is located in Linn Creek Cove, on Lake of the Ozarks, in Camden County, Missouri.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contact:* Mr. Mark Jordan, Ameren/UE, P.O. Box 780, MC CP–850, Jefferson City, MO 65102, (573) 681–7246.

i. *FERC Contact:* Any questions on this notice should be addressed to Shana High at (202) 502–8674.

j. *Deadline for filing comments, motions to intervene, and protest:* April 26, 2010.

Comments, Motions to Intervene, and Protests may be filed electronically via the Internet. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. For more information on how to submit these types of filings, please go to the Commission's Web site located at *http://www.ferc.gov.filing-comments.asp.* Please include the project number (P–459–297) on any comments or motions filed.

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of any motion to intervene must also be served upon each representative of the Applicant specified in the particular application.

k. *Description of Request:* The licensee requests Commission authorization to permit Y Investments to construct a 27-slip residential community dock. The dock would serve a planned residential community.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *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. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Any filings must bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE", as applicable, and the Project Number of the particular application to which the filing refers.

p. *Agency Comments:* Federal, state, and local agencies are invited to file comments on the described application. A copy of the application may be obtained by agencies directly from the Applicant. If an agency does not file comments within the time specified for filing comments, it will be presumed to have no comments. One copy of an agency's comments must also be sent to the Applicant's representatives.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7147 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2621–009]

Lockhart Power Company; Notice of Application Accepted for Filing, Soliciting Motions To Intervene and Protests, Ready for Environmental Analysis, and Soliciting Comments, Recommendations, Terms and Conditions, and Prescriptions

March 24, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* P–2621–009.

c. *Date filed:* November 16, 2009.

d. *Applicant:* Lockhart Power Company.

e. *Name of Project:* Pacolet Hydroelectric Project.

f. *Location:* On the Pacolet River, near the Town of Pacolet, Spartanburg County, South Carolina. The project does not occupy Federal Lands.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)—825(r)

h. *Applicant Contact:* Bryan D. Stone, Chief Operating Officer, Lockhart Power Company, P.O. Box 10, 420 River Street, Lockhart, South Carolina 29364; Telephone (864) 545–2211.

i. *FERC Contact:* Lee Emery, Telephone (202) 502–8379, or by e-mail at *lee.emery@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, recommendations, terms and conditions, and prescriptions is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice.

All documents (original and eight copies) may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site (*http://www.ferc.gov/docs-filing/ferconline.asp*) under the "eFiling" link. For a simpler method of submitting text only comments, click on "Quick Comment." For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov;* call toll-free at (866) 208–3676; or, for TTY, contact (202) 502–8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail an original and eight copies to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

The Commission's Rules of Practice require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing and is now is ready for environmental analysis.

l. *Project Description:* The proposed Pacolet Project would consist of two

developments; one that is an existing, licensed development (the Lower Pacolet development) and a new development (Upper Pacolet development). The project would have an annual generation of 8.092 gigawatt-hours. The proposed project would consist of the facilities described below.

The Upper Pacolet development would consist of: (1) An existing 315-foot-long by 18-foot-high concrete and rubble masonry dam, with the addition of 3-foot-high flashboards; (2) an existing 30-acre reservoir, with a useable storage capacity of 90 acre-feet at elevation 519.0 feet North American Vertical Datum 1988 (NAVD 88); (3) new vertical slide intake gates with rack and pinion operators, sluice gates, and trashracks having a 1-inch clear bar spacing with a trash rake; (4) a new 24-foot-wide by 40-foot-long concrete powerhouse that would contain a vertical Kaplan turbine with an estimated generating capacity of 1,100 kilowatts (kW); (5) a tailrace with a 40-foot-long guide wall; (6) a new 200-foot-long, 34 kilovolt (kV) transmission line; (7) a proposed substation; and (8) appurtenant facilities.

The Lower Pacolet development (all existing facilities) would consist of: (1) A 347-foot-long by 24-foot-high concrete and rubble masonry dam, with 4-foot-high flashboards; (2) three sand gates; (3) an 11-acre reservoir, with a useable storage capacity of 44-acre feet at an elevation of 492.0 feet NAVD 88 ; (4) an intake structure equipped with trashracks having a 1.375-inch clear bar spacing and a trash rake; (5) a 100-foot-long by 10-foot-diameter penstock; (6) a 67-foot-long by 32-foot-wide concrete powerhouse, integral with the dam, containing two vertical Leffel Type Z turbines, each generating 400 kilowatts (kW); (7) a tailrace with a 340-foot-long curved training wall; (8) a 250-foot-long, 34.5-kV transmission line; and (9) appurtenant facilities.

m. A copy of the application is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *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.* A copy is also available for inspection and reproduction at the address in item h above.

n. Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

All filings must (1) bear in all capital letters the title "PROTEST", "MOTION TO INTERVENE", "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," "TERMS AND CONDITIONS," or "PRESCRIPTIONS;" (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, terms and conditions or prescriptions must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

o. A license applicant must file no later than 60 days following the date of issuance of this notice: (1) A copy of the water quality certification; (2) a copy of the request for certification, including proof of the date on which the certifying agency received the request; or (3) evidence of waiver of water quality certification.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7146 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 12597–021; Project No. 12598–019]

Turnbull Hydro, LLC; Notice of Application Accepted for Filing, Soliciting Comments, Motions To Intervene and Protests, and Ready for Environmental Analysis; Soliciting Recommendations and Terms and Conditions for the Proposed Changes to the Transmission Line Routes

March 24, 2010.

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Amendment of License.

b. *Project Nos.:* 12597–021 and P–12598–019.

c. *Date Filed:* February 17, 2010, and supplemented March 17 and 23, 2010.

d. *Applicant:* Turnbull Hydro, LLC.

e. *Name of Project:* Lower and Upper Turnbull Drop, respectively.

f. *Location:* The projects are located on the Spring Valley Canal in Teton County, Montana.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Applicant Contact:* Mr. Ted Sorenson, Turnbull Hydro, LLC, 5203 South 11th East, Idaho Falls, ID 83404, (208) 522–8069.

i. *FERC Contact:* Any questions regarding this notice should be directed to Mr. Jeremy Jessup (202) 502–6779 or *Jeremy.Jessup@ferc.gov.*

j. Deadline for filing motions to intervene and protests, comments, recommendations, and preliminary terms and conditions (terms and conditions for transmission line routes only), is 60 days from the issuance of this notice; reply comments are due 105 days from the issuance date of this notice. All documents may be filed electronically via the Internet. *See,* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at *http://www.ferc.gov* under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. For more information on how to submit these types of filings, please go to the Commissions Web site located at *http://ferc.gov.filing-comments.asp.*

Please include the project numbers (P–12597–021 and P–12598–019) on any comments, motions, recommendations,

or preliminary terms and conditions filed.

k. *Description of Request:* At the Lower Turnbull Drop Project, the applicant proposes to (1) change the hydraulic capacity from 600 cfs to 750 cfs; (2) change the authorized installed capacity from 6,150 kW to 7,700 kW; and (3) change from two turbines to a single turbine. At the Upper Turnbull Drop Project, the applicant proposes to (1) change the hydraulic capacity from 600 cfs to 750 cfs; (2) change the authorized installed capacity from 4,100 kW to 5,300 kW; and (3) change from two turbines to a single turbine.

Additionally, at the Lower Turnbull Drop Project, the applicant proposes to (1) change the entire transmission line to 69 kV and eliminate the remote electrical substation and (2) change the length and location of the 69 kV transmission line. At the Upper Turnbull Drop Project, the applicant proposes to (1) change the entire transmission line to 69 kV and eliminate the remote electrical substation and (2) change the length and location of the 69 kV transmission line. The filing of terms and conditions (see section "o" below) are only being requested by this notice for the applicant's proposal regarding changes to the transmission line routes.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502–8371. This filing may also be viewed on the Commission's Web site at *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. You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov,* for TTY, call (202) 502–8659. A copy is also available for inspection and reproduction at the address in item (h) above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* All filings must (1) bear in all capital letters the title "PROTEST", "MOTION TO INTERVENE", "COMMENTS," "REPLY COMMENTS," "RECOMMENDATIONS," or " TERMS AND CONDITIONS" (transmission line routes only); (2) set forth in the heading the name of the applicant and the project numbers of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene or protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene or protests should relate to project works which are the subject of the license amendment. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7144 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 10856–079]

Upper Peninsula Power Company; North American Hydro Holdings, LLC; Notice of Application for Transfer of License, and Soliciting Comments and Motions To Intervene

March 24, 2010.

On March 17, 2010, Upper Peninsula Power Company (transferor) and North American Hydro Holdings, LLC (transferee) filed an application for transfer of license of the AuTrain Project, located on the Upper AuTrain River in Alger County, Michigan.

Applicants seek Commission approval to transfer the license for the AuTrain Project from the transferor to the transferee.

Applicant Contact: For transferor Mr. Terry P. Jensky, Upper Peninsula Power Company, 700 N Adams Street, Green Bay, WI 54307, phone (920) 433–2900. For the transferee Mr. Charles F. Alberg, North American Hydro Holdings, LLC, 116 State Street, Neshkoro, WI 54960, phone (920) 293–4628

FERC Contact: Robert Bell, (202) 502–6062.

Deadline for filing comments and motions to intervene: 30 days from the issuance of this notice. Comments and motions to intervene may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii)(2008) and the instructions on the Commission's website under the "e-Filing" link. If unable to be filed electronically, documents may be paper-filed. To paper-file, an original and eight copies should be mailed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. For more information on how to submit these types of filings please go to the Commission's Web site located at *http://www.ferc.gov/filing-comments.asp.* More information about this project can be viewed or printed on the eLibrary link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–10856–079) in the docket number field to access the document. For assistance, call toll-free 1–866–208–3372.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7141 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings # 1

March 24, 2010.

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC10–55–000.
Applicants: Noble Chateaugay Windpark, LLC, Noble Ellenburg Windpark, LLC, Noble Clinton Windpark I, LLC, Noble Altona Windpark, LLC.
Description: Application for Authorization of Transfer of Certain Limited Interconnection Facilities under Section 203 of the Federal Power Act, and Request for Waivers of Filing Requirements.
Filed Date: 03/24/2010.
Accession Number: 20100324–5032.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER03–198–014.
Applicants: Pacific Gas and Electric Company.
Description: Pacific Gas and Electric Company Notice of Non-Material Change in Status.
Filed Date: 03/24/2010.
Accession Number: 20100324–5037.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Docket Numbers: ER04–449–022.
Applicants: New York Independent System Operator, Inc.
Description: ISO New York Independent System Operator submits proposed modifications.
Filed Date: 03/23/2010.
Accession Number: 20100323–0233.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–495–001.
Applicants: Midwest Independent Transmission System Operator, Inc.
Description: Midwest Independent Transmission System Operator, Inc submits a revised fully executed Amended and Restated Large Generator Interconnection Agreement with Pemeroy Wind Farm, LLC.
Filed Date: 03/22/2010.
Accession Number: 20100323–0202.
Comment Date: 5 p.m. Eastern Time on Monday, April 12, 2010.

Docket Numbers: ER10–662–001.
Applicants: CER Generation, LLC.
Description: CER Generation, LLC submits amendment to application for Blanket Authorizations, Certain Waivers and Order Approving Market Based Rate Tariff and Request for Expedited Consideration.
Filed Date: 03/19/2010.
Accession Number: 20100322–0203.
Comment Date: 5 p.m. Eastern Time on Monday, March 29, 2010.

Docket Numbers: ER10–727–001.
Applicants: AEP Retail Energy Partners LLC.
Description: AEP Retail Energy Partners LLC submits the results of the Commission's market power screen and pivotal supplier screen for the PJM balancing authority to their February 12, 2010.
Filed Date: 03/23/2010.
Accession Number: 20100324–0204.
Comment Date: 5 p.m. Eastern Time on Tuesday, March 30, 2010.

Docket Numbers: ER10–769–002.
Applicants: Glenwood Energy Partners, LTD.
Description: Glenwood Energy Partners, LTD submits petition for acceptance of Initial Rate Schedule, Waivers and Blanket Authority.
Filed Date: 03/23/2010.
Accession Number: 20100324–0206.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–792–001.
Applicants: TC Energy Trading, LLC.
Description: TC Energy Trading, LLC submits Substitute Original Sheet No 3 to its market based rate application.
Filed Date: 03/22/2010.
Accession Number: 20100323–0206.
Comment Date: 5 p.m. Eastern Time on Monday, April 12, 2010.

Docket Numbers: ER10–812–001.
Applicants: Power Choice, Inc.
Description: Amendment to Application of Power Choice Inc.
Filed Date: 03/24/2010.
Accession Number: 20100324–5002.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Docket Numbers: ER10–899–000.
Applicants: Consulting Gasca & Associates, LLC.
Description: Consulting Gasca & Associates, LLC submits a Petition for Acceptance of Initial Tariff, Waivers and Blanket Authority.
Filed Date: 03/24/2010.
Accession Number: 20100324–0215.
Comment Date: 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Docket Numbers: ER10–912–000.
Applicants: NASDAQ OMX Commodities Clearing—Contract Merchant LLC.
Description: NASDAQ OMX Commodities Clearing—Contract Merchant LLC submits application for authorization to make market-based wholesale sales of energy, capacity under FERC Electric Tariff, Original Volume 1, effective 3/24/10.
Filed Date: 03/23/2010.
Accession Number: 20100324–0207.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–913–000.
Applicants: NASDAQ OMX Commodities Clearing—Delivery LLC.
Description: NASDAQ OMX Commodities Clearing—Delivery LLC submits application for authorization to make market based wholesale sales of energy, capacity, etc to be effective 3/24/2010.
Filed Date: 03/23/2010.
Accession Number: 20100324–0208.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–914–000.
Applicants: NASDAQ OMX Commodities Clearing—Finance LLC.
Description: NASDAQ OMX Commodities Clearing—Finance LLC submits its application for authorization to make market-based wholesale sales of energy, capacity, and certain ancillary services etc.
Filed Date: 03/23/2010.
Accession Number: 20100324–0209.
Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–918–000.
Applicants: Maine Public Service Company.
Description: Maine Public Service Company submits Original Sheet No 34 *et al* to FERC Electric Rate Schedule 30 with Algonquin Northern Maine Gen Co.
Filed Date: 03/22/2010.
Accession Number: 20100323–0204.
Comment Date: 5 p.m. Eastern Time on Monday, April 12, 2010.

Docket Numbers: ER10–919–000.
Applicants: ISO New England Inc.
Description: ISO New England, Inc *et al* submits an executed non-confirming Standard Large Generator Interconnection Agreement.
Filed Date: 03/22/2010.
Accession Number: 20100323–0203.
Comment Date: 5 p.m. Eastern Time on Monday, April 12, 2010.

Docket Numbers: ER10–920–000.
Applicants: Maine Public Service Company.
Description: Maine Public Service Company submits revised executed interconnection agreement with Algonquin Northern Maine Gen Co *etc.*
Filed Date: 03/22/2010.
Accession Number: 20100323–0201.
Comment Date: 5 p.m. Eastern Time on Monday, April 12, 2010.

Docket Numbers: ER10–921–000.

Applicants: Indiana Michigan Power Company.

Description: Indiana Michigan Power Company submits Notice of Cancellation of Service Agreement 4, First Revised Sheet 1.

Filed Date: 03/23/2010.

Accession Number: 20100323–0231.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–922–000.

Applicants: Cleco Power LLC.

Description: Cleco Power LLC submits an Electric System Interconnection Agreement.

Filed Date: 03/23/2010.

Accession Number: 20100323–0232.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–924–000.

Applicants: Noble Americas Gas & Power Corp.

Description: Noble Americas Gas & Power Corp submits notice of succession to reflect its succession to and adoption of Noble Energy Marketing & Trades Corp's Rate Schedule No 1.

Filed Date: 03/23/2010.

Accession Number: 20100324–0201.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–925–000.

Applicants: Southwest Power Pool, Inc.

Description: Southwest Power Pool, Inc submits an executed Large Generator Interconnection Agreement with Laredo Ridge Wind, LLC.

Filed Date: 03/23/2010.

Accession Number: 20100324–0202.

Comment Date: 5 p.m. Eastern Time on Tuesday, April 13, 2010.

Docket Numbers: ER10–927–000.

Applicants: PPL Southwest Generation Holdings, LLC.

Description: PPL Southwest Generation Holdings, LLC submits Notice of Cancellation of its FERC Electric Tariff, Original Volume 1.

Filed Date: 03/24/2010.

Accession Number: 20100324–0214.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Docket Numbers: ER10–928–000.

Applicants: WPS Empire State, Inc.

Description: WPS Empire State, Inc submits the Notice of Cancellation re market-based rate tariff, FERC Electric Tariff, Third Revised Volume No. 1.

Filed Date: 03/24/2010.

Accession Number: 20100324–0213.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Docket Numbers: ER10–929–000.

Applicants: ISO New England Inc., New England Power Pool.

Description: ISO New England submits transmittal letter and revised tariff sheets that clarify certain provisions of Market Rule 1 *etc.*

Filed Date: 03/24/2010.

Accession Number: 20100324–0212.

Comment Date: 5 p.m. Eastern Time on Wednesday, April 14, 2010.

Take notice that the Commission received the following open access transmission tariff filings:

Docket Numbers: OA08–62–006.

Applicants: California Independent System Operator Corporation.

Description: California Independent System Operator Corp submits a compliance filing pursuant to the Commission's 1/21/10 Order.

Filed Date: 03/22/2010.

Accession Number: 20100323–0205.

Comment Date: 5 p.m. Eastern Time on Monday, April 12, 2010.

Any person desiring to intervene or to protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. It is not necessary to separately intervene again in a subdocket related to a compliance filing if you have previously intervened in the same docket. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant. In reference to filings initiating a new proceeding, interventions or protests submitted on or before the comment deadline need not be served on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above proceedings are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–7135 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL10–50–000; Docket No. ER10–787–000]

New England Power Generators Association Inc., Complainant v. ISO New England Inc., Respondent; ISO New England Inc. and New England Power Pool; Notice of Complaint

March 24, 2010.

Take notice that on March 23, 2010, pursuant to section 206 of the Rules and Practice and Procedure, 18 CFR 385.206 and sections 206 of the Federal Power Act, 16 U.S.C. 824(e), New England Power Generators Association Inc. (Complainant) filed a formal complaint against ISO New England Inc. (Respondent) alleging that, the Respondent's current and proposed tariffs governing the Forward Capacity market (FCM) are unjust and unreasonable.

The Complainant certifies that copies of the complaint were served on the contacts for the Respondent and the New England Power Pool as listed on the Commission's list of Corporate Officials and on parties and regulatory agencies the Complainant reasonably expects to be affected by this Complaint, including all of the parties that have intervened in Docket ER10–787–000.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date.

The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 14 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the "eLibrary" link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an "eSubscription" link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5 p.m. Eastern Time on April 6, 2010.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7150 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 516–459]

South Carolina Electric and Gas Company, South Carolina; Notice of Availability of Environmental Assessment

March 24, 2010.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission or FERC's) regulations, 18 Code of Federal Regulations (CFR) Part 380 (Order No. 486, 52 FR 47897), the Office of Energy Projects has reviewed South Carolina Electric and Gas Company's application for license for the Saluda Hydroelectric Project (FERC Project No. 516), located on Saluda River in Richland, Lexington, Saluda, and Newberry counties, near Columbia, South Carolina. The project does not occupy any Federal lands.

Staff prepared a draft environmental assessment (EA), which analyzes the potential environmental effects of relicensing the project, and concludes that licensing the project, with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

A copy of the EA is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *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;* toll-free at 1–866–208–3676, or for TTY, 202–502–8659.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via e-mail of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Any comments should be filed within 45 days from the date of this notice and be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. Please affix Project No. 516 to all comments. Comments 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.

For further information, contact Lee Emery by telephone at (202) 502–8379, or by e-mail at *lee.emery@ferc.gov.*

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7148 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER10–904–000]

NFI Solar LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

March 24, 2010.

This is a supplemental notice in the above-referenced proceeding of NFI Solar, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 5, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–7138 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER10–892–000]

Southern Turner Cimarron I, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

March 24, 2010.

This is a supplemental notice in the above-referenced proceeding of Southern Turner Cimarron I, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 13, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–7136 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER10–903–000]

Patriot Power LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

March 24, 2010.

This is a supplemental notice in the above-referenced proceeding of Patriot Power LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is April 13, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–7139 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER10–881–000]

Reliable Power LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

March 24, 2010.

This is a supplemental notice in the above-referenced proceeding of Reliable Power, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR Part 34, of future issuances of securities and assumptions of liability, is April 13, 2010.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access

who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 14 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First St., NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive e-mail notification when a document is added to a subscribed dockets(s). For assistance with any FERC Online service, please e-mail *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2010–7137 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 9907–018]

Mr. Jerry McMillan and Ms. Christine Smith; Notice of Termination of License by Implied Surrender and Soliciting Comments, Protests, and Motions To Intervene

March 24, 2010.

Take notice that the following hydroelectric proceeding has been initiated by the Commission:

a. *Type of Proceeding:* Termination of license by implied surrender

b. *Project No.:* P–9907–018

c. *Licensees:* Mr. Jerry McMillan and Ms. Christine Smith

d. *Name of Project:* Sunshine Power Project

e. *Location:* The Sunshine Power Project is located on Lake Creek in Lemhi County, Idaho.

f. *Issued Pursuant to:* 18 CFR 6.4.

g. *Licensee Contact:* Mr. Jerry McMillan, 1157 North Hughes Street, Centerville, UT 84014, (801) 808–6997.

h. *FERC Contact:* Kelly Houff, (202) 502–6393, *Kelly.Houff@ferc.gov.*

i. *Deadline for filing responsive documents:* April 26, 2010.

Comments, protests, and interventions may be filed electronically via the Internet in lieu of paper; *see* 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the "e-Filing" link. The Commission strongly encourages electronic filings. Please include the project number (P–9907–018) on any documents or motions filed.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person in the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

j. *Description of Existing Facilities:* The project consists of the following facilities: (1) An existing earthfill 10-foot-high Lake Creek diversion dam; (2) an existing 15-inch-diameter, 2,300-foot-long buried PVC penstock; (3) a powerhouse containing one generating unit with a rated capacity of 110 kilowatts; (4) a 200-foot-long, 34.5-kV transmission line connected to Idaho Power Company lines; (5) a wooden fish ladder in a riprap-lined spillway; and (6) appurtenant facilities.

k. *Description of Proceeding:* Section 6.4 of the Commission's regulations (18 CFR 6.4) provides, among other things, that it is deemed to be the intent of a licensee to surrender a license, if the licensee abandons a project for a period of three years.

The Director of Hydropower Licensing issued a 50-year license to A. W. Brown, Co. for the Sunshine Power Project on March 20, 1987 (38 FERC ¶ 62,282). The project was transferred to Mr. Jerry McMillan and Ms. Christine Smith by order on February 23, 1996 (74 FERC ¶ 62,092). On January 26, 2006, Ms. Smith informed the Commission that in August of 2005, Mr. McMillan deeded Ms. Smith his interest in the Sunshine Project. In response, on April 6, 2006, Commission staff requested Ms. Smith file an application for transfer of license with the Secretary of the Commission. Ms. Smith failed to file a transfer application.

On August 13, 2007, Commission staff received a letter from Ms. Smith stating that she had sold the project to Ms. Claudia Burkhart. Commission staff wrote to Ms. Burkhart on August 21, 2008, stating that she needed to file a transfer of license application with the Commission's Secretary. Once again, no transfer application was filed. According to Commission records, the project has not operated since October 1, 2008, and the owner does not intend to bring the project back into operation. On October 19, 2009, Commission staff wrote Ms. Burkhart requesting she file either a detailed plan and schedule to resume generation at the project along with a transfer of license application, or a request to voluntarily surrender the license. No response was filed. On January 13, 2010, Commission staff sent a letter to Mr. McMillan and Ms. Smith, with a copy to Ms. Burkhart, requesting them to show cause why the Commission should not initiate a proceeding for terminating the license based upon implied surrender. No response was filed to the show cause letter.

l. This notice is available for review and reproduction at the Commission in the Public Reference Room, Room 2A, 888 First Street, NE., Washington, DC 20426. The filing may also be viewed on the Web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number, here P–9907–018, in the docket number field to access the document. For assistance, call toll-free 1–866–208–3676 or e-mail *FERCOnlineSupport@ferc.gov.* For TTY, call (202) 502–8659. A copy is also available for review and reproduction at the address in item g above.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. *Comments, Protests, or Motions to Intervene*—Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

o. *Filing and Service of Responsive Documents*—All filings must (1) bear in all capital letters the title "PROTEST", "MOTION TO INTERVENE," "COMMENTS", "RECOMMENDATIONS FOR TERMS AND CONDITIONS: (2) set forth in the heading the project number of the proceeding to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, recommendations, or terms and conditions must set forth their evidentiary basis and otherwise

comply with the requirements of 18 CFR 4.34(b). Any of the above mentioned documents must be filed by providing the original and eight copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. An additional copy must be sent to Director, Division of Hydropower Administration and Compliance, Office of Energy Projects, Federal Energy Regulatory Commission, at the above address.

p. *Agency Comments*—Federal, State, and local agencies are invited to file comments on the described proceeding. If any agency does not file comments within the time specified for filing comments, it will be presumed to have no comments.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7149 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. PL10–4–000]

Enforcement of Statutes, Orders, Rules and Regulations; Notice of Workshops on Penalty Guidelines

March 24, 2010.

The staff of the Federal Energy Regulatory Commission (Commission) will hold three workshops to provide a forum for interested participants to ask questions on the interpretation and application of the Policy Statement on Penalty Guidelines, which the Commission recently issued on March 18, 2010.[1] Staff will hold the first workshop on April 7, 2010, from 9:30 a.m. to 12 p.m. Eastern Daylight Time, in the Commission Meeting Room (2C) at the Commission's Washington, DC headquarters, 888 First Street, NE. To accommodate participants outside of Washington, DC, this workshop will be webcast, but will not be transcribed. All interested parties are invited, and there is no registration list or registration fee to attend.

Staff will also hold similar workshops in Houston, Texas on April 14, 2010, and in San Francisco, California on April 15, 2010. The times and locations of these later workshops will be provided in a subsequent notice. These workshops will not be webcast.

The purpose of the workshops will be to have staff discuss how the Penalty Guidelines will be applied and to answer questions about the Penalty Guidelines. In that regard, questions are being solicited from the public in advance of the workshops. Please submit questions on the Penalty Guidelines to Jeremy Medovoy, Attorney-Advisor, Office of Enforcement, Division of Investigations, by e-mail at *Jeremy.Medovoy@ferc.gov*. Workshop participants will also have an opportunity to ask questions at the workshops, but due to time limitations, questions in advance are encouraged.

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.

Questions about the workshops may be directed to Jeremy Medovoy by e-mail at *Jeremy.Medovoy@ferc.gov* or by telephone at 202–502–6768.

Kimberly D. Bose,

Secretary.

[FR Doc. 2010–7140 Filed 3–30–10; 8:45 am]

BILLING CODE 6717–01–P

[1] *Enforcement of Statutes, Orders, Rules, and Regulations,* 130 FERC ¶ 61,220 (2010).

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0032; FRL–8810–1]

Antimicrobial Pesticide Registration Review Dockets Opened for Review and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has established registration review dockets for the pesticides listed in the table in Unit III.A. With this document, EPA is opening the public comment period for these registration reviews. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency may consider during the course of registration reviews. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before June 1, 2010.

ADDRESSES: Submit your comments identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit III.A., by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.
- *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to the docket ID numbers listed in the table in Unit III.A. for the pesticides you are commenting on. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid

the use of special characters, any form of encryption, and be free of any defects or viruses.

All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact:* The Chemical Review Manager identified in the table in Unit III.A. for the pesticide of interest.

For general information contact: Lance Wormell, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0523; fax number: (703) 308–8090; e-mail address: *wormell.lance@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. Authority

EPA is initiating its reviews of the pesticides identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA section 3(a), a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

A. What Action is the Agency Taking?

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations identified in the table in this unit to assure that they continue to satisfy the FIFRA standard for registration—that is, they can still be used without unreasonable adverse effects on human health or the environment. A pesticide's registration review begins when the Agency establishes a docket for the pesticide's registration review case and opens the docket for public review and comment. At present, EPA is opening registration review dockets for the cases identified in the following table.

TABLE—REGISTRATION REVIEW DOCKETS OPENING

Registration Review Case Name and Number	Docket ID Number	Chemical Review Manager, Telephone Number, E-mail Address
Decyl isononyl dimethyl ammonium chloride (DIDAC) (case 5013)	EPA–HQ–OPP–2010–0005	Monisha Harris (703) 308–0410 harris.monisha@epa.gov
1-(3-chloroally)-3,5,7,-Triaza-1-azoniaadamantane (CTAC)(Case 3069).	EPA–HQ–OPP–2010–0004	K. Avivah Jakob (703) 305–1328 jakob.kathryn@epa.gov
Thymol (5-methyl-2-isopropyl-1-phenol) (case 3143)	EPA–HQ–OPP–2010–0002	Monisha Harris (703) 308–0410 harris.monisha@epa.gov
1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N'-(1,1-dimethylethyl)-6-(methylthio)- (case 5031)	EPA–HQ–OPP–2010–0003	Eliza Blair (703) 308–7279 blair.eliza@epa.gov

B. Docket Content

1. *Review dockets*. The registration review dockets contain information that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

- An overview of the registration review case status.
- A list of current product registrations and registrants.
- **Federal Register** notices regarding any pending registration actions.
- **Federal Register** notices regarding current or pending tolerances.
- Risk assessments.
- Bibliographies concerning current registrations.
- Summaries of incident data.
- Any other pertinent data or information.

Each docket contains a document summarizing what the Agency currently knows about the pesticide case and a preliminary work plan for anticipated data and assessment needs. Additional documents provide more detailed information. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the Agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

2. *Other related information*. More information on these cases, including the active ingredients for each case, may be located in the registration review schedule on the Agency's website at *http://www.epa.gov/oppsrrd1/registration_review/schedule.htm* . Information on the Agency's registration review program and its implementing regulation may be seen at *http://www.epa.gov/oppsrrd1/registration_review*.

3. *Information submission requirements*. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.
- As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

List of Subjects

Environmental protection, Antimicrobials, Pesticides and pests, Decyl isononyl dimethyl ammonium chloride, Dowicil 100, Thymol (5-methyl-2-isopropyl-1-phenol), 1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N'-(1,1-dimethylethyl)-6-(methylthio)-.

Dated: February 23, 2010.

Joan Harrigan Farrelly,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2010–7239 Filed 3–30–10; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0179; FRL–8816–6]

Kasugamycin; Receipt of Application for Emergency Exemption, Solicitation of Public Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received a specific exemption request from the Michigan Department of Agriculture to use the pesticide kasugamycin (CAS No. 6980–18–3 to treat up to 10,000 acres of apples to control fire blight. The applicant proposes the use of a new chemical which has not been registered by EPA. EPA is soliciting public comment before making the decision whether or not to grant the exemption.

DATES: Comments must be received on or before April 15, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0179, by one of the following methods:

- *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200

Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number EPA–HQ–OPP–2010–0179. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Keri Grinstead, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8373; fax number: (703) 605–0781; e-mail address: *grinstead.keri@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Crop production (NAICS code 111).
• Animal production (NAICS code 112).
• Food manufacturing (NAICS code 311).
• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through www.regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What Action is the Agency Taking?

Under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136p), at the discretion of the Administrator, a Federal or State agency may be exempted from any provision of FIFRA if the Administrator determines that emergency conditions exist which require the exemption. Michigan Department of Agriculture has requested the Administrator to issue a specific exemption for the use of kasugamycin on apples to control fire blight.

Information in accordance with 40 CFR part 166 was submitted as part of this request.

As part of this request, the applicant asserts that kasugamycin is needed to control streptomycin-resistant strains of *Erwinia amylovora*, the causal pathogen of fire blight, due to the lack of available alternatives and effective control practices. Without the use of kasugamycin the applicant states that up to 50% of the yield of susceptible apple varieties could be lost in 2010.

The Applicant proposes to make no more than three applications of Kasumin 2L on 10,000 acres of apples between April 20, 2010 and May 31, 2010 in Berrien, Cass, Ionia, Kent, Montcalm, Newaygo, Oceana, Ottawa, and Van Buren counties in Michigan. As currently proposed, the maximum amount of product to be applied would be 15,000 gallons.

This notice does not constitute a decision by EPA on the application itself. The regulations governing section 18 of FIFRA require publication of a notice of receipt of an application for a specific exemption proposing use of a new chemical (i.e., an active ingredient) which has not been registered by EPA. The notice provides an opportunity for public comment on the application.

The Agency will review and consider all comments received during the comment period in determining whether to issue the specific exemption requested by the Michigan Department of Agriculture.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 12, 2010.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2010–6790 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0167; FRL–8811–4]

Bromine Registration Review Final Decision; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's final registration review decision for the pesticide Bromine, case 4015. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without causing unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact*: K. Avivah Jakob, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–1328; fax number: (703) 308–8090; e-mail address: jakob.kathryn@epa.gov.

For general information on the registration review program, contact: Lance Wormell, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 603–0523; fax number: (703) 308–8090; e-mail address: *wormell.lance @epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the pesticide specific contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2009–0167. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

II. Background

A. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58(c), this notice announces the availability of EPA's final registration review decision for bromine, case 4015. Bromine is a bromide releasing antimicrobial pesticide that is registered as a mildewstat/mildewcide, bactericide, fungistate, fungicide, virucide, and insecticide. Bromine is registered for use to control bacteria and fungi on surfaces of agricultural, commercial, institutional, industrial, residential, and public access premises and equipment. It is also registered for use to treat/disinfect potable water (examples of potable water system treatment sites include, but are not restricted to, aboard ships and on oil and gas drilling/production platforms).

Pursuant to 40 CFR 155.57, a registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA. EPA has considered bromine in light of the FIFRA standard for registration. The Final Decision document in the docket describes the Agency's rationale for issuing a registration review final decision for this pesticide.

In addition to the final registration review decision document, the registration review docket for bromine also includes other relevant documents related to the registration review of this case. The combined final work plan and proposed registration review decision was posted to the docket and the public was invited to submit any comments or new information. During the 60–day comment period, no public comments were received.

Pursuant to 40 CFR 155.58(c), the registration review case docket for bromine will remain open until all actions required in the final decision have been completed.

Background on the registration review program is provided at: *http://www.epa.gov/oppsrrd1/registration_review*. Links to earlier documents related to the registration review of this pesticide are provided at: http://www.epa.gov/oppsrrd1/registration_review/bromine/index.htm .

B. What is the Agency's Authority for Taking this Action?

Section 3(g) of FIFRA and 40 CFR part 155, subpart C, provide authority for this action.

List of Subjects

Environmental protection, Registration review, Pesticides and pests, Antimicrobials, Bromine.

Dated: February 3, 2010.

Joan Harrigan Farrelly.

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2010–7045 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2005–0265; FRL–8815–8]

Dicloran; Cancellation Order for Amendment to Terminate a Use of DCNA Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's order for the label amendment, which was voluntarily requested by the registrant and accepted by the Agency, to terminate use on carrots for pesticide registrations listed in Table 1 in Unit II. pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This cancellation order follows a December 2, 2009 (74 FR 63151) **Federal Register** Notice of Receipt of Request from the registrant listed in Table 2 in Unit II. to voluntarily amend to terminate dicloran (DCMA) use on carrots. In its December 2, 2009 Notice, EPA indicated that it would issue an order implementing the cancellation and amendment to terminate the use on carrot, unless the Agency received substantive comments within the 30–day comment period that would merit its further review of these requests, or unless the registrant withdrew their request within this period. The 30–day comment period ended on January 4, 2010, at which time the Agency did not receive any comments on the notice. Further, the registrant did not withdraw their request. Accordingly, EPA hereby issues in this notice a cancellation order granting the requested use termination. Any distribution, sale, or use of the products subject to this cancellation order is permitted only in accordance with the terms of this order, including any existing stocks provisions.

DATES: The cancellations are effective as published in the **Federal Register** on November 2, 2010.

FOR FURTHER INFORMATION CONTACT: James Parker, Pesticides Re-evaluation Division (7508P) , Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0469; fax number: (703) 308–7070; e-mail address: *parker.james@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2005–0265. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

II. What Action is the Agency Taking?

This notice announces the amendment to terminate use on carrots, as requested by registrants, of products registered under section 3 of FIFRA. The affected registrations are listed in sequence by registration number in Table 1 of this unit.

TABLE 1.—DICLORAN REGISTRATION WITH CARROT USE CANCELLATION

EPA Registration Number	Product Name
10163-189	Botran 75-W Fungicide
10163-195	Botran Technical
10163-226	Botran 5-F Fungicide

Table 2 of this unit includes the names and addresses of record for the registrant of the products in Table 1 of this unit, in sequence by EPA company number.

TABLE 2.—REGISTRANTS OF CANCELLED AND AMENDED USE

EPA Company Number	Company Name and Address
10163	Gowan Company P.O. Box 5569 Yuma, AZ 85366-5569

III. Summary of Public Comments Received and Agency Response to Comments

During the public comment period provided, EPA received no comments in response to the December 2, 2009 **Federal Register** notice announcing the Agency's receipt of the request for voluntary cancellation and amendment to terminate use on carrots of products listed in Table 1 in Unit II.

IV. Cancellation Order

Pursuant to FIFRA section 6(f), EPA hereby approves the requested amendment to terminate the carrot use of dicloran registrations identified in Table 1 in Unit II. Accordingly, the Agency for product registrations identified in Table 1 in Unit II. Any distribution, sale, or use of existing stocks of the products identified in Table 1 in Unit II. in a manner inconsistent with any of the Provisions for Disposition of Existing Stocks set forth in Unit VI. will be considered a violation of FIFRA.

V. What is the Agency's Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the Administrator may approve such a request.

VI. Provisions for Disposition of Existing Stocks

EPA's existing stocks policy (56 FR 29362) provides that: "If a registrant requests to voluntarily cancel a registration where the Agency has identified no particular risk concerns, the registrant has complied with all applicable conditions of reregistration, conditional registration, and data call ins, and the registration is not subject to a Registration Standard, Label

Improvement Program, or reregistration decision, the Agency will generally permit a registrant to sell or distribute existing stocks for 1 year after the cancellation request was received. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted."

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The effective date of this use cancellation is November 2, 2010. The cancellation order that is the subject of this notice includes the following existing stock provisions:

The registrant may sell and distribute existing stocks of products listed in Table 1 in Unit II. until November 2, 2010. Persons other than the registrant may sell and distribute existing stocks of products listed in Table 1 in Unit II. until exhausted. Use of the products listed in Table 1 in Unit II. may be exhausted, provided that such use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled product.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 16, 2010.

Richard P. Keigwin, Jr.,

Director, Pesticides Re-evalution Division, Office of Pesticide Programs.

[FR Doc. 2010–6887 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9132–5; Docket ID No. EPA–HQ–ORD–2010–0224]

Draft Toxicological Review of Dichloromethane: In Support of Summary Information on the Integrated Risk Information System (IRIS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Public Comment Period and Listening Session.

SUMMARY: EPA is announcing a 60-day public comment period and a public listening session for the external review draft human health assessment titled, "Toxicological Review of Dichloromethane: In Support of Summary Information on the Integrated Risk Information System (IRIS)" (EPA/635/R–10/003). The draft assessment was prepared by the National Center for Environmental Assessment (NCEA) within EPA's Office of Research and Development (ORD). The public comment period and external peer review meeting, which will be scheduled at a later date and announced in the **Federal Register**, are separate processes that provide opportunities for all interested parties to comment on the assessment. EPA intends to forward the public comments that are submitted in accordance with this notice to the peer review panel prior to the meeting for their consideration. When finalizing the draft assessment, EPA intends to consider any public comments that EPA receives in accordance with this notice.

EPA is also announcing a listening session to be held on May 11, 2010, during the public comment period for this draft assessment. This listening session is a step in EPA's revised IRIS process, announced on May 21, 2009, for developing human health assessments for inclusion in the IRIS database. The purpose of the listening session is to allow all interested parties to present scientific and technical comments on draft IRIS health assessments to EPA and other interested parties during the public comment period and before the peer review meeting. EPA welcomes the comments that will be provided to the Agency by the listening session participants. The comments will be considered by the Agency as it revises the draft assessment in response to the independent SAB peer review and the public comments. All presentations submitted to EPA according to the instructions below will become part of the official public record.

EPA is releasing this draft assessment solely for the purpose of pre-dissemination peer review under applicable information quality guidelines. This assessment has not been formally disseminated by EPA. It does not represent and should not be construed to represent any Agency policy or determination.

DATES: The public comment period begins March 31, 2010, and ends June 1, 2010. Comments should be in writing and must be received by EPA by June 1, 2010.

The listening session on the draft assessment for dichloromethane will be held on May 11, 2010, beginning at 9 a.m. and ending at 4 p.m., Eastern Daylight Time. If you would like to attend the listening session, you should register by May 4, 2010. If you would like to make a presentation at the listening session, you should register by May 4, 2010, indicate that you wish to make oral comments at the session, and indicate the length of your presentation. When you register, please indicate if you will need audio-visual aid (*e.g.,* laptop computer and slide projector). In general, each presentation should be no more than 30 minutes. If, however, there are more requests for presentations than the allotted time allows, then the time limit for each presentation will be adjusted. A copy of the agenda for the listening session will be available at the meeting. If no speakers have registered by May 4, 2010, the listening session will be cancelled, and EPA will notify those registered of the cancellation.

Listening session participants who want EPA to share their comments with the external peer reviewers should also submit written comments during the public comment period using the detailed and established procedures described in the **SUPPLEMENTARY INFORMATION** section of this notice. Comments submitted to the docket prior to the end of the public comment period will be submitted to the external peer reviewers and considered by EPA in the disposition of public comments. All comments received will be submitted to the docket, but comments received after the public comment period closes will not be submitted to the external peer reviewers and will only be considered by EPA if time permits.

ADDRESSES: The draft "Toxicological Review of Dichloromethane: In Support of Summary Information on the Integrated Risk Information System (IRIS)" is available primarily via the Internet on the NCEA home page under the Recent Additions and Publications menus at *http://www.epa.gov/ncea.* A limited number of paper copies are available from the Information Management Team (Address: Information Management Team, National Center for Environmental Assessment (Mail Code: 8601P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone: 703–347–8561; facsimile: 703–347–8691). If you request a paper copy, please provide your name, mailing address, and the assessment title.

Comments may be submitted electronically via *http://www.regulations.gov,* by e-mail, by mail, by facsimile, or by hand delivery/courier. Please follow the detailed instructions provided in the **SUPPLEMENTARY INFORMATION** section of this notice.

The listening session on the draft Dichloromethane assessment will be held at the EPA offices at Potomac Yard

North Building, Room 7100, 2733 South Crystal Drive, Arlington, Virginia 22202. To attend or give verbal comments at the listening session, register by May 4, 2010, via the Internet at *https://www2.ergweb.com/projects/conferences/peerreview/register-dichl.htm.* You may also register via e-mail at *meetings@erg.com* (subject line: Dichloromethane Listening Session), please indicate whether you would like to make oral comments, and include your name, title, affiliation, full address and contact information). You may also register by phone at 781–674–7374 or toll free at 800–803–2833, or by faxing a registration request to 781–674–2906 (please reference the "Dichloromethane Listening Session" and include your name, title, affiliation, full address and contact information). Please note that to gain entrance to this EPA building to attend the meeting, attendees must have photo identification with them and must register at the guard's desk in the lobby. The guard will retain your photo identification and will provide you with a visitor's badge. At the guard's desk, attendees should give the name Christine Ross and the telephone number 703–347–8592 to the guard on duty. The guard will contact Ms. Ross who will meet you in the reception area to escort you to the meeting room. When you leave the building, please return your visitor's badge to the guard and you will receive your photo identification.

A teleconference line will also be available for registered attendees/speakers. The teleconference number is 866–299–3188 and the access code is 926–378–7897, followed by the pound sign (#). The teleconference line will be activated at 8:45 a.m., and you will be asked to identify yourself and your affiliation at the beginning of the call.

Information on Services for Individuals with Disabilities: EPA welcomes public attendance at the "Dichloromethane Listening Session" and will make every effort to accommodate persons with disabilities. For information on access or services for individuals with disabilities, please contact Christine Ross by phone: 703–347–8592 or by e-mail at *ross.christine@epa.gov.* To request accommodation of a disability, please make the proper notification, preferably at least 10 days prior to the meeting, to give EPA as much time as possible to process your request.

FOR FURTHER INFORMATION CONTACT: For information on the public comment period, please contact the Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone: 202–566–1752; facsimile: 202–566–1753; or e-mail: *ORD.Docket@epa.gov.*

For information on the public listening session, please contact Christine Ross, IRIS Staff, National Center for Environmental Assessment (Mail Code: 8601P), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; telephone: 703–347–8592; facsimile: 703–347–8689; or e-mail: *ross.christine@epa.gov.*

If you have questions about the assessment, please contact Glinda S. Cooper, National Center for Environmental Assessment, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., 8601P, Washington, DC 20460, telephone: 703–347–8636; facsimile: 703–347–8689; or e-mail: *cooper.glinda@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Information About IRIS

EPA's IRIS is a human health assessment program that evaluates quantitative and qualitative risk information on effects that may result from exposure to specific chemical substances found in the environment. Through the IRIS Program, EPA provides the highest quality science-based human health assessments to support the Agency's regulatory activities. The IRIS database contains information for more than 540 chemical substances that can be used to support the first two steps (hazard identification and dose-response evaluation) of the risk assessment process. When supported by available data, IRIS provides oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for chronic noncancer health effects and cancer assessments. Combined with specific exposure information, government and private entities use IRIS to help characterize public health risks of chemical substances in a site-specific situation and thereby support risk management decisions designed to protect public health.

II. How To Submit Comments to the Docket at *http://www.regulations.gov*

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2010–0224, by one of the following methods:

- *http://www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *E-mail: ORD.Docket@epa.gov.*
- *Facsimile:* 202–566–1753.
- *Mail:* Office of Environmental Information (OEI) Docket (Mail Code: 2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. The telephone number is 202–566–1752. If you provide comments by mail, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.
- *Hand Delivery:* The OEI Docket is located in the EPA Headquarters Docket Center, EPA West Building, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center's Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is 202–566–1744. Deliveries are only accepted during the docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information. If you provide comments by hand delivery, please submit one unbound original with pages numbered consecutively, and three copies of the comments. For attachments, provide an index, number pages consecutively with the comments, and submit an unbound original and three copies.

EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment and cannot contact you for clarification, EPA may not be able to consider your comment.

Instructions: Direct your comments to Docket ID No. EPA–HQ–ORD–2010–0224. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked "late," and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *http://www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *http://www.regulations.gov* or e-mail. The *http://www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://*

www.regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.*

Docket: All documents in the docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in *http://www.regulations.gov* or in hard copy at the OEI Docket in the EPA Headquarters Docket Center.

Dated: March 25, 2010.

Lynn Flowers,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 2010–7210 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9132–1]

Science Advisory Board Staff Office; Notification of a Public Teleconference and Public Meeting of the SAB Trichloroethylene (TCE) Review Panel

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA Science Advisory Board (SAB) Staff Office announces two public meetings of the SAB Trichloroethylene (TCE) Review Panel: a teleconference and a face-to-face meeting to review EPA's *Toxicological Review of Trichloroethylene in Support of Summary Information on the Integrated Risk Information System (IRIS),* External Review Draft.

DATES: There will be a public teleconference on April 20, 2010 from 2:30 p.m. to 4:30 p.m. (Eastern Time). The public meeting will be held on May 10, 2010 from 9 a.m. to 5 p.m. (Eastern Time), May 11, 2010 from 9 a.m. to 5 p.m. and May 12, 2010 from 9 a.m. to 3 p.m. (Eastern time).

ADDRESSES: The teleconference will be conducted by phone only. The face-to-face meeting on May 10–12, 2010 will be held at The Hilton Embassy Row Hotel, 2015 Massachusetts Avenue, NW., Washington, DC 20036; telephone (202) 265–1600.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing to obtain information concerning the public teleconference and/or public meeting may contact Dr. Marc Rigas, Designated Federal Officer (DFO), EPA Science Advisory Board Staff Office (1400F), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; by telephone/voice mail at (202) 343–9978 or at *rigas.marc@epa.gov.* General information about the SAB, as well as any updates concerning the meeting announced in this notice, may be found on the EPA Web site at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA), 5 U.S.C., App. 2, notice is hereby given that the SAB Trichloroethylene Review Panel will hold a public teleconference to discuss the plans for the subsequent public face-to-face meeting to conduct a peer review of the EPA's *Toxicological Review of Trichloroethylene in Support of Summary Information on the Integrated Risk Information System (IRIS),* External Review Draft (October 2009). The SAB was established pursuant to 42 U.S.C. 4365 to provide independent scientific and technical advice to the Administrator on the technical basis for Agency positions and regulations. The SAB is a Federal Advisory Committee chartered under FACA. The SAB will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

Background: EPA's Integrated Risk Information System (IRIS) is an electronic database containing descriptive and quantitative toxicological information on human health effects that may result from chronic exposure to various substances in the environment. This information supports human health risk assessments and includes hazard identification, dose-response data and derivations of oral reference doses (RfDs) and inhalation reference concentrations (RfCs) for noncancer effects and oral slope factors and oral and inhalation unit risks for cancer effects. IRIS is prepared and maintained by EPA's National Center for Environmental Assessment (NCEA) within the Office of Research and Development (ORD).

In 2001, ORD developed a draft IRIS Toxicological Assessment for TCE, which was released for public comment and external peer review. In 2002, the Environmental Health Committee of the SAB reviewed the draft TCE Assessment and made several recommendations to strengthen the dose-response assessment. In 2004, in preparation for development of a new TCE assessment, the National Research Council (NRC) was requested to provide a scientific consultation on key scientific issues related to assessing the human health risks of TCE, including those relevant to hazard characterization/mode of action, physiologically-based pharmacokinetic (PBPK) modeling, and dose-response assessment. ORD has taken the recommendations and conclusions included in the NRC's report, which was released in 2006, into account as it developed a new revised draft IRIS Toxicological Assessment for TCE. ORD has requested that the SAB review its revised draft assessment.

In response to ORD's request, the SAB Staff Office solicited nominations of experts and formed a review panel for TCE [**Federal Register** Notice dated October 22, 2009 (74 FR 54563–54564)]. The panel will conduct a review of EPA's October 2009 External Review Draft of its *Toxicological Review of Trichloroethylene in Support of Summary Information on the Integrated Risk Information System (IRIS).* Specifically, the panel is being asked to provide recommendations on physiologically-based pharmacokinetic (PBPK) modeling, meta-analysis for cancer epidemiology, components of the TCE hazard assessment and dose-response assessment. The purpose of the teleconference is for the panel to receive a briefing on the assessment and for members to clarify the charge to the panel. During the face-to-face meeting, the panel will review the assessment.

Availability of Meeting Materials: Agendas and materials in support of these meetings will be placed on the EPA Web site at *http://www.epa.gov/sab* in advance of each meeting. For technical questions and information concerning EPA's draft document, please contact Dr. Weihsueh Chiu at (703) 347–8607, or *chiu.weihsueh@epa.gov.*

Procedures for Providing Public Input: Interested members of the public may submit relevant written or oral

information for the SAB Trichloroethylene Review Panel to consider during this advisory activity. *Oral Statements:* In general, individuals or groups requesting an oral presentation at a public teleconference will be limited to three minutes per speaker, with no more than a total of 30 minutes for all speakers. At the face-to-face meeting, presentations will be limited to five minutes, with no more than a total of one hour for all speakers. Each person making an oral statement should consider providing written comments as well as their oral statement so that the points presented orally can be expanded upon in writing. Interested parties should contact Dr. Marc Rigas, DFO, in writing (preferably via e-mail) at the contact information noted above by April 13, 2010 for the teleconference and by May 3, 2010 for the face-to-face meeting, to be placed on the list of public speakers. *Written Statements:* Written statements should be supplied to the DFO via e-mail at the contact information noted above by April 13, 2010 for the teleconference and by May 3, 2010 for the face-to-face meeting so that the information may be made available to the Committee members for their consideration. Written statements should be supplied in one of the following electronic formats: Adobe Acrobat PDF, MS Word, MS PowerPoint, or Rich Text files in IBM–PC/Windows 98/2000/XP format. Submitters are requested to provide versions of signed documents, submitted with and without signatures, because the SAB Staff Office does not publish documents with signatures on its Web sites.

Accessibility: For information on access or services for individuals with disabilities, please contact Dr. Marc Rigas at (202) 343–9978 or *rigas.marc@epa.gov*. To request accommodation of a disability, please contact Dr. Rigas preferably at least ten days prior to each meeting to give EPA as much time as possible to process your request.

Dated: March 24, 2010.

Vanessa T. Vu,

Director, EPA Science Advisory Staff Office.

[FR Doc. 2010–7229 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0936; FRL–8806–9]

Antimicrobial Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register new antimicrobial pesticide products containing new active ingredients, pursuant to the provisions of section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. EPA is publishing this notice of such applications, pursuant to section 3(c)(4) of FIFRA.

DATES: Comments must be received on or before April 30, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number specified for the pesticide of interest as shown in Unit II., by one of the following methods:

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

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to the docket ID number specified for the pesticide of interest as shown in the registration application summary. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: A contact person is listed at the end of each registration application summary and may be contacted by telephone or e-mail. The mailing address for each contact person listed is: Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number). If you are commenting in a docket that addresses multiple products, please indicate to which registration number(s) your comment applies.

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA received applications as follows to register new antimicrobial pesticide products containing new active ingredients pursuant to the provisions of section 3(c) of FIFRA, and is publishing this notice of such applications pursuant to section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

1. *Registration Number/File Symbol*: 1258–RGEE. *Docket ID Number*: EPA–HQ–OPP–2009–0999. *Company name and address*: Arch Chemicals Inc., 501 Merrit 7, Norwalk, CT 06856. *Active ingredient*: Copper 2-pyridinethiol-1-/oxide. *Proposed Use*: For formulation of antifoulant paints. *Contact*: Martha Terry, (703) 308–217; *terry.martha@epa.gov*.

2. *Registration Number/File Symbol*: 2693–EER. *Docket ID Number*: EPA–HQ–OPP–2009–0998. *Company name and address*: International Paint LLC, 2270 Morris Ave., Union, NJ 07083. *Active ingredient*: Copper pyrithione; Cuprous oxide. *Proposed Uses*: For antifoulant paint to be used below the waterline on fiberglass, wood, and properly primed metal boat hulls and parts in fresh, salt, and brackish waters. *Contact*: Martha Terry, (703) 308–6217; *terry.martha@epa.gov*.

3. *Registration Number/File Symbol*: 5383–RGI. *Docket ID Number*: EPA–HQ–OPP–2009–1000. *Company name and address*: Troy Chemical, Inc., 8 Vreeland Rd., P.O. Box 955, Florham Park, NJ 07932–4200. *Active ingredient*: Terbutryn. *Proposed Uses*: Manufacturing use product for joint compound, masonry coatings, paints, roof coatings, sealants, stuccos, and plastic and wood protection stains. *Contact*: Jacqueline Campbell-McFarlane, (703) 308–6416, *campbell-mcfarlane.jacqueline@epa.gov*.

4. *Registration Number/File Symbol*: 5383–RGO. *Docket ID Number*: EPA–HQ–OPP–2009–1006. *Company name and address*: Troy Chemical, Inc., 8 Vreeland Rd., P.O. Box 955, Florham Park, NJ 07932–4200. *Active ingredient*: Terbutryn. *Proposed Uses*: End use product for joint compound, masonry coatings, paints, roof coatings, sealants, stuccos, and plastic and wood protection stains. *Contact*: Jacqueline Campbell-McFarlane, (703) 308–6416, *campbell-mcfarlane.jacqueline@epa.gov*.

5. *Registration Number/File Symbol*: 63838–RN. *Docket ID Number*: EPA–HQ–OPP–2009–0996. *Company name and address*: Enviro Tech Chemical Services, Inc., 500 Winmoore Way, Modesto, CA 95358. *Active ingredient*: Potassium hypochlorite. *Proposed Uses*: Use on porous food and non-food contact surfaces, treatment of sewage and wastewater effluent, disinfection of drinking water, pulp and paperboard water treatment, farm premises treatment, treatment of laundry, and agricultural and aquacultural uses. *Contact*: Wanda Henson (703) 308–6345; *henson.wanda@epa.gov*.

6. *Registration Number/File Symbol*: 67071–R. *Docket ID Number*: EPA–HQ–OPP–2009–1001. *Company name and address*: Acti-Chem Specialties, Inc., 56 Quarry Rd., Trumbell, CT 06611. *Active ingredient*: Tetramethyiol acetylenediruea. *Proposed Uses*: Material preservative in adhesives, building materials, lattices, paints, and coatings. *Contact*: Demson Fuller, (703) 308–8062; *fuller.demson@epa.gov*.

7. *Registration Number/File Symbol*: 85249–R. *Docket ID Number*: EPA–HQ–OPP–2009–1012. *Company name and address*: HeiQ Materials AG. Agent (Gaughan Consulting), 1369 Gwynedale Way, Lansdale, PA 19446. *Active ingredient*: Silver. *Proposed Uses*: Antimicrobial and preservative additive used to treat fibers, plastics, polymers, latex products, and ceramics. *Contact*: Demson Fuller, (703) 308–8062; *fuller.demson@epa.gov*.

8. *Registration Number/File Symbol*: 85808–R. *Docket ID Number*: EPA–HQ–OPP–2009–0997. *Company name and address*: Schulke & Mayr GMBH Agent (Technology Sciences Group, Inc.), 1150 18th St., NW., Suite 1000, Washington, DC 20036. *Active ingredient*: *N, N,-methalylenbis* [5-methyloxazolidin]. *Proposed Uses*: Oilfield muds, fuels, and metalworking fluid preservative. *Contact*: Demson Fuller, (703) 308–8062; *fuller.demson@epa.gov*.

List of Subjects

Environmental protection, Antimicrobial pesticides and pest.

Dated: March 15, 2010.

Joan Harrigan Farrelly,

Director, Antimicrobial Division, Office of Pesticide Programs.

[FR Doc. 2010–6792 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–0935; FRL–8807–1]

Antimicrobial Pesticide Products; Registration Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register new uses for pesticide products containing currently registered active ingredients, pursuant to the provisions of section 3(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. EPA is publishing this notice of such applications, pursuant to section 3(c)(4) of FIFRA.

DATES: Comments must be received on or before April 30, 2010.

ADDRESSES: Submit your comments, identified by docket identification (ID) number specified within the table below, by one of the following methods:

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

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to docket ID number specified for the pesticide of interest as shown in the registration application summaries. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: A contact person is listed at the end of each registration application summary and may be contacted by telephone or e-mail. The mailing address for each contact person listed is: Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

• Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number). If you are commenting in a docket that addresses multiple products, please indicate to which registration number(s) your comment applies.

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Registration Applications

EPA received applications as follows to register new uses of pesticide products containing currently registered active ingredients pursuant to the provisions of section 3(c) of FIFRA, and is publishing this notice of such applications pursuant to section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

1. *Registration Number/File Symbol*: 100–1233. *Docket ID. Number*: EPA–HQ–OPP–2009–0970. *Company name and address*: Syngenta Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419. *Active ingredient*: Propiconazole. *Proposed Uses*: Materials preservative for latex paint, coatings and stains. *Contact*: Stacey Grigsby, (703) 305–6440; *rigsby.stacey@epa.gov*.

2. *Registration Number/File Symbol*: 464–682. *Docket ID. Number*: EPA–HQ–OPP–2009–0992. *Company name and address*: Dow Chemical Co., 1803 Bldg., Midland, MI 48674. *Active ingredient*: 2,6-Dimethyl-m-dioxan-4-ol acetate *Proposed Uses*: Material preservative for adhesive, paints, coatings, textiles and leather. *Contact*: Martha Terry, (703) 308–6217; *terry.martha@epa.gov*.

3. *Registration Number/File Symbol*: 707–307. *Docket ID. Number*: EPA–HQ–OPP–2009–0953. *Company name and address*: Rohm & Haas, 100 Independence Mall West, Philadelphia, PA 19106. *Active ingredient*: 4,5-Dichloro-2-n-octyl-4-isothiazolin-3 one *Proposed Uses*: Wood preservative intended for use in aquatic environments. *Contact*: Demson Fuller (703) 308–8063; *fuller.demson@epa.gov*.

4. *Registration Number/File Symbol*: 1043–REL *Docket ID. Number*: EPA–HQ–OPP–2009–0954. *Company name and address*: Steris Corporation, 7501 Page Ave, St Louis, MO 63133. *Active ingredient*: Tetra-acetyl-ethyllenediamine. *Proposed Uses*: Disinfectant for use on hard non-porous surfaces in institutional settings *Contact*: Demson Fuller (703) 308–8063; *fuller.demson@epa.gov*.

5. *Registration Number/File Symbol*: 1258–RGEO. *Docket ID. Number*: EPA–HQ–OPP–2009–0973. *Company name and address*: Arch Chemical Co, 1955 Lake Park Dr., Suite 100, Smyrna, GA 30080.*Active ingredient*: Calcium hypochlorite; Zinc sulfate monohydrate. *Proposed Uses*: Swimming pool water sanitizer. *Contact*: Wanda Henson, (703) 308–6345; *henson.wanda@epa.gov*.

6. *Registration Number/File Symbol*: 1258–RGGR. *Docket ID. Number*: EPA–HQ–OPP–2009–0993. *Company name and address*: Arch Chemical Co, 1955 Lake Park Dr., Suite 100, Smyrna, GA 30080. *Active ingredient*: Calcium hypochlorite; Zinc sulfate monohydrate. *Proposed Uses*: Swimming pool water sanitizer. *Contact*: Wanda Henson (703) 308–6345; *henson.wanda@epa.gov*.

7. *Registration Number/File Symbol*: 1258–1249. *Docket ID. Number*: EPA–HQ–OPP–2009–0975. *Company name and address*: Arch Chemical Co, 1955 Lake Park Dr., Suite 100, Smyrna, GA 30080. *Active ingredient*: N-Butyl-1,2-Benzisothiazol-3-one. *Proposed Uses*: Material preservative for plastic, metalworking fluids, rubber and coatings. *Contact*: Martha Terry, (703) 308–6217; *terry.martha@epa.gov*.

8. *Registration Number/File Symbol*: 1258–1286. *Docket ID. Number*: EPA–HQ–OPP–2009–0994. *Company name and address*: Arch Chemical Co, 1955 Lake Park Dr., Suite 100, Smyrna, GA 30080 *Active ingredient*: N-Butyl-1,2-Benzisothiazol-3-one *Proposed Uses*: Material preservative for plastic, metalworking fluids, rubber and coatings. *Contact*: Martha Terry, (703) 308–6217; *terry.martha@epa.gov*.

9. *Registration Number/File Symbol*: 1624–RGN. *Docket ID. Number*: EPA–HQ–OPP–2009–0972. *Company name and address*: US Borax Inc c/o Delta Analytical Corp., 12510 Prosperity Dr., Suite 160, Silver Spring, MD 20904. *Active ingredient*: Boric acid. *Proposed Uses*: Material preservative for paints, coatings, stains and ink dyes. *Contact*: Stacey Grigsby, (703) 305–6440; *grigsby.stacey@epa.gov*.

10. *Registration Number/File Symbol*: 1839–155. *Docket ID. Number*: EPA–HQ–OPP–2009–0955. *Company name and address*: Stepan Chemical, 22 W Frontage Rd, Northfield, Il 60093. *Active ingredient*: Alkyl dimethyl ethylbenzyl ammonium chloride. *Proposed Uses*: Food contact surface sanitizer in public eating establishments. *Contact*: Jacqueline Campbell-McFarlane, (703) 308–6416, *campbell-mcFarlane.jacqueline@epa.gov*.

11. *Registration Number/File Symbol*: 4582–TE. *Docket ID. Number*: EPA–HQ–OPP–2009–0971. *Company name and address*: Colgate-Palmolive, 909 River Rd, P.O. Box 1343, Piscataway, NJ 08855–1343. *Active ingredient*: L-Lactic acid. *Proposed Uses*: Dishwashing Detergent/Sanitizer *Contact*: Stacey Grigsby, (703) 305–6440; *Grigsby.Stacey@epa.gov*.

12. *Registration Number/File Symbol*: 5383–89. *Docket ID. Number*: EPA–HQ–OPP–2009–0939. *Company name and address*: Troy Chemical Corp., 8 Vreeland Rd, PO Box 955, Florham Park, NJ 07932–4200. *Active ingredient*: Carbamic acid. *Proposed Uses*: Metal working fluid. *Contact*: ShaRon Carlisle, (703) 308–6427; *carlisle.sharon@epa.gov*.

13. *Registration Number/File Symbol*: 5383–135. *Docket ID. Number*: EPA–HQ–OPP–2009–0950. *Company name and address*: Troy Chemical, Inc., 8 Vreekand Rd, PO Box 955, Floraham Park, NJ 07932. *Active ingredient*: 1,2-Benziosthiazolin. *Proposed Uses*: Material preservative for paint with public health claims. *Contact*: Demson Fuller, (703) 308–8063; *fuller.demson@epa.gov*.

14. *Registration Number/File Symbol*: 39967–25. *Docket ID. Number*: EPA–HQ–OPP–2009–0947. *Company name and address*: Lanxess Corp., 111 RDC Park West Drive, Pittsburgh, PA 15275–1112. *Active ingredient*: Sodium p-chloro-m-creosolate. *Proposed Uses*: Materials preservative for industrial lubricants. *Contact*: Heather Garvie, (703) 308–0034; *garvie.heather@epa.gov*.

15. *Registration Number/File Symbol*: 47371–161. *Docket ID. Number*: EPA–HQ–OPP–2009–0940. *Company name and address*: H&S Chemical Division, 90 Boroline Rd., Allendale, NJ 07401. *Active ingredient*: n-Alkyl(C14 50%, C12 40%, C16 10%) dimethyl benzyl ammonium chloride. *Proposed Uses*: Material preservative for treatment of sponges. *Contact*: Tracy Lantz, (703) 308–6415; *lantz.tracy@epa.gov*.

16. *Registration Number/File Symbol*: 63838–2. *Docket ID. Number*: EPA–HQ–OPP–2009–0991. *Company name and address*: Enviro Tech Chemical Services, P.O. Box 577470, Modesto, CA 95357. *Active ingredient*: Hydrogen peroxide; Peroxyacetic acid. *Proposed Uses*: Treatment of wastewater and sewage. *Contact*: Karen Leavy, (703) 308–6237; *Leavy.Karen@epa.gov*.

17. *Registration Number/File Symbol*: 68660–RG. *Docket ID. Number*: EPA–HQ–OPP–2009–0995. *Company name and address*: Solvay Chemical Inc., 3333 Richmond Ave, Houston, TX 77098. *Active ingredient*: Hydrogen peroxide. *Proposed Uses*: Sterilant for aseptic food packaging. *Contact*: Demson Fuller, (703) 308–8062; *fuller.demson@epa.gov*.

18. *Registration Number/File Symbol*: 70087–E. *Docket ID. Number*: EPA–HQ–OPP–2009–0944. *Company name and address*: Coating Systems Laboratories Inc, 211 E. Clinton Dr. Chandler, AZ 85225. *Active ingredient*: 3-(tri-hydroxysilyl) propyl ammonium chloride. *Proposed Uses*: Algicide for closed system ponds and swimming pools/spas. *Contact*: Jacqueline Campbell-McFarlane, (703) 308–6416; *campbell-mcFarlane.jacqueline@epa.gov*.

19. *Registration Number/File Symbol*: 71227–7. *Docket ID. Number*: EPA–HQ–OPP–2009–0951. *Company name and address*: Sinanen Company, LTD Agent (Agion Technologies Inc.), 60 Audubon Rd., Wakeffield, MA 01880. *Active ingredient*: Elemental copper; silver. *Proposed Uses*: Materials preservative in water bottle dispensers, ice trays, water bottles. *Contact*: Demson Fuller, (703) 308–8062; *fuller.demson@epa.gov*.

20. *Registration Number/File Symbol*: 71654–6. *Docket ID. Number*: EPA–HQ–OPP–2009–0938. *Company name and address*: E.I. Dupont De Nemours and Ccompany, Dupont Chemical Solutions Enterprises, PO Box 80402, Wilmington, Delaware 19880–0402. *Active ingredient*: Potassium peroxymonosulfate; Sodium chlorite. *Proposed Uses*: Food use in presence of farm animals; first food use to control viruses, bacteria, fungi, and algae in poultry and swine feeding sites while animals are present. *Contact*: ShaRon Carlisle, (703) 308–6427; *Carlisle.Sharon@epa.gov*.

21. *Registration Number/File Symbol*: 72920–R. *Docket ID. Number*: EPA–HQ–OPP–2009–0948. *Company name and address*: Vorigen, Inc., 5076 CR # 342, Navosota, TX 77868. *Active ingredient*: Silver. *Proposed Uses*: Control of legionella in water systems. *Contact*: Demson Fuller, (703) 308–8063; *fuller.demson@epa.gov*.

22. *Registration Number/File Symbol*: 72992–RL. *Docket ID. Number*: EPA–HQ–OPP–2009–0974. *Company name and address*: Lewis & Harrison c/o Chrysal International BV, 122 C Street, NW Suite 740, Washington DC 20001. *Active ingredient*: Silver nitrate. *Proposed Uses*: Material preservative for textile, plastic, metals, rubber and coatings. *Contact*: Martha Terry, (703) 308–6217; *terry.martha@epa.gov*.

23. *Registration Number/File Symbol*: 84526–G. *Docket ID. Number*: EPA–HQ–OPP–2009–0976. *Company name and address*: Lewis & Harrison c/o Sanosil USA, LLC, 122 C Street, NW, Suite 740, Washington DC 20001. *Active ingredient*: Hydrogen peroxide; Silver. *Proposed Uses*: For microbial control in re-circulating cooling water systems and industrial process water systems. *Contact*: Martha Terry (703) 308–6217; *terry.martha@epa.gov*.

24. *Registration Number/File Symbol*: 82544–E. *Docket ID. Number*: EPA–HQ–OPP–2009–0968. *Company name and address*: Samsung Electronics Co.,Ltd., Agent (Keller and Heckman LLP) 101 G Street, N.W., Suite 500 West, Washington, D.C. 20001. *Active ingredient*: Silver asmetallic. *Proposed Uses*: Silver use in washing machine *Contact*: Karen Leavy, (703) 308–6237; *leavy.karen@epa.gov*.

25. *Registration Number/File Symbol*: 82544–R. *Docket ID. Number*: EPA–HQ–OPP–2009–0969. *Company name and address*: Samsung Electronics Co.,Ltd., Agent (Keller and Heckman LLP) 101 G Street, N.W., Suite 500 West, Washington, D.C. 20001. *Active ingredient*: Silver as metallic. *Proposed Uses*: Silver use in washing machine. *Contact*: Karen Leavy, (703) 308–6237; *leavy.karen@epa.gov*.

26. *Registration Number/File Symbol*: 84545–I. *Docket ID. Number*: EPA–HQ–OPP–2009–0945. *Company name and address*: SBiomed LLC, 1272 South 1280 West Orem, Utah 84058. *Active ingredient*: Hydrogen peroxide; Peroxyacetic acid . *Proposed Uses*: Use as sporicidal decontaminant. *Contact*: Karen Leavy, (703) 308–6237; *leavy.karen@epa.gov*.

27. *Registration Number/File Symbol*: 84545–O. *Docket ID. Number*: EPA–HQ–OPP–2009–0967. *Company name and address*: SBiomed LLC, 1272 South 1280 West Orem, Utah 84058. *Active ingredient*: Silver. *Proposed Uses*: Use as sporicidal decontaminant. *Contact*: Karen Leavy, (703) 308–6237; *leavy.karen@epa.gov*.

28. *Registration Number/File Symbol*: 84622–1. *Docket ID. Number*: EPA–HQ–OPP–2009–0946. *Company name and address*: SBiomed LLC, 1272 South 1280 West Orem, Utah 84058. *Active ingredient*: Hydrogen peroxide; Peroxyacetic acid. *Proposed Uses*: Control of Bacillus anthracis on hard non-porous surfaces. *Contact*: Karen Leavy, (703) 308–6237; *leavy.karen@epa.gov*.

29. *Registration Number/File Symbol*: 84630–E. *Docket ID. Number*: EPA–HQ–OPP–2009–0943. *Company name and address*: Transtex Technologies, 9600 Rue Ingnace, Suite D, Brossard, Quebec, Canada J4Y 2R4. *Active ingredient*: n-Alkyl(C14 50%, C12 40%, C16 10%) dimethyl benzyl ammonium chloride and Silver. *Proposed Uses*: Material preservative for natural and synthetic fibers and textiles. *Contact*: Jacqueline Campbell-McFarlane, (703) 308–6416, *campbell-mcFarlane.jacqueline @epa.gov*.

30. *Registration Number/File Symbol*: 86256–R. *Docket ID. Number*: EPA–HQ–OPP–2009–0941. *Company name and address*: AbTech Industries Inc, 4110 N Scottsdale Rd., Suite 235, Scottsdale, AZ 85251. *Active ingredient*: 3-(trimethoxylsilyl) propyldimethyloctadecyl ammonium chloride. *Proposed Uses*: Sponge for treatment of industrial, municipal and storm water. *Contact*: Tracy Lantz (703) 308–6415; *lantz.tracy@epa.gov*.

List of Subjects

Environmental protection, Antimicrobial pesticides and pest.

Dated: March 15, 2010.

Joan Harrigan Farrelly,

Director, Antimicrobial Division, Office of Pesticide Programs.

[FR Doc. 2010–6793 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2007–1026; FRL–8816–2]

Bacillus subtilis; Registration Review Final Decision; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's final registration review decision for the pesticide *Bacillus subtilis*, case 6012. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, that the pesticide can perform its intended function without causing unreasonable adverse effects on human health or the environment. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information, contact*: Susanne Cerrelli, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8077; fax number: (703) 308–7026; e-mail address: *cerrelli.susanne@epa.gov.*

For general information on the registration review program, contact: Kevin Costello, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5026; fax number: (703) 308–8090; e-mail address: *costello.kevin @epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a

wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the pesticide specific contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–1026. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

II. Background

A. What Action is the Agency Taking?

In accordance with 40 CFR 155.58(c), this notice announces the availability of EPA's final registration review decision for *Bacillus subtilis*, case 6012. The *Bacillus subtilis* case consists of four strains: Strain GB03; Strain MBI 600; Strain QST 713; and *var. amyloliquefaciens* Strain FZB24. All four strains occur ubiquitously in the environment: *Bacillus subtilis* strain GB03 is used to prevent, control and suppress plant disease on barley, berries, bulb vegetables, cole crops, cotton, cucurbits, fruiting vegetables, herbs, leafy crops, legumes, ornamental plants and cuttings, peanuts, root/tuber and corm vegetables, soybeans, tomatoes, trees, tropical plants, turf, and wheat. *Bacillus subtilis* strain GB03 is applied as an irrigation application, pre-plant soak, overhead spray, soil drench, seed dressing, tank mix, or hydroponic system treatment; *Bacillus subtilis* strain MBI 600 is used to suppress disease organisms such as *Botrytis, Alternaria, Rhizoctonia, and Fusarium* and is also used to promote more effective nodulation by nitrogen-fixing bacteria to improve yields. It is used as a seed and in-furrow treatment on cotton, seed and pod vegetables, peanuts, soybeans, alfalfa, forage and turf grasses, wheat, barley, corn, and canola. It is also used in greenhouses to treat peat moss and soil intended for seeding, potting, or transplanting non-bearing fruit and vegetable seedlings and as a foliar spray on asparagus, cole crops, bulb vegetables, berry crops, cucurbits, flowers, bedding plants, ornamentals, tropical plants, fruiting vegetables, grape, leafy vegetables, pome fruit, stone fruit, strawberry, tuber/root and corm vegetables, turf, sod, lawns, trees, and shrubs. *Bacillus subtilis* strain QST 713 is used to prevent or reduce several types of fungal and bacterial pests on artichoke, asparagus, avocado, beans, beets, berries, brassica crops, bulb vegetables, celery, cereal grains, citrus, coffee, corn, cucurbits, beans, eggplant, grapes, herbs/spices, hops, kiwi, kohlrabi, leafy vegetables, legumes, melons, oil seed crops, oil palm, okra, peanuts, peppers, pome fruit, rice, root/tuber crops, silage crops, stone fruits, tomatoes, tree nuts, tropical fruits, field roses, forestry seedlings, lawns, ornamental flowering plants, ornamental foliage plants, ornamental trees and shrubs, seed production crops, sod, tobacco, and turf. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is used for plant strengthening, enhancing growth, increasing yields and suppressing soil-borne fungal diseases such as *Rhizoctonia* and *Fusarium* as a dip for seedlings, transplants, plugs, tubers, bulbs, corms, cuttings and roots of ornamentals, shrubs and trees, and as a spray over furrows for ornamentals, shrubs, trees, turf, vegetables, herbs and spices, and other crops. It is also incorporated into soils, soil-less growing media and mushroom spawn media and as a drench for interiorscapes and potted orchids and ferns.

In accordance with 40 CFR 155.57, a registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA. EPA has considered *Bacillus subtilis* in light of the FIFRA standard for registration. The *Bacillus subtilis* Final Decision document in the docket describes the Agency's rationale for issuing a registration review final decision for this pesticide.

In addition to the final registration review decision document, the registration review docket for *Bacillus subtilis* also includes other relevant documents related to the registration review of this case. The proposed registration review decision was posted to the docket and the public was invited to submit any comments or new information. During the comment period, the public comments received were not substantive and did not affect the Agency's final decision.

In accordance with 40 CFR 155.58(c), the registration review case docket for *Bacillus subtilis* will remain open until all actions required in the final decision have been completed.

Background on the registration review program is provided at: *http://www.epa.gov/oppsrrd1/registration_review*. Links to earlier documents related to the registration review of this pesticide are provided at: *http:/www.epa.gov/oppsrrd1/registration_review/bacillus_subtilis/index.htm.*

B. What is the Agency's Authority for Taking this Action?

Section 3(g) of FIFRA and 40 CFR part 155, subpart C, provide authority for this action.

List of Subjects

Environmental protection, Bacillus subtilis, Pesticide and pest, Registration review.

Dated: March 24, 2010.

Keith A. Matthews,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2010–7237 Filed 3–30–10; 8:45 a.m.]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0118; FRL–8816–1]

Registration Review; Biopesticides Dockets Opened for Review and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has established registration review dockets for the pesticides listed in the table in Unit III.A. With this document, EPA is opening the public comment period for these registration reviews. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency may consider during the course of registration reviews. Through this program, EPA is ensuring that each

pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before June 1, 2010.

ADDRESSES: Submit your comments identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit III.A., by one of the following methods:

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

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

Instructions: Direct your comments to the docket ID numbers listed in the table in Unit III.A. for the pesticides you are commenting on. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at *http://www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through regulations.gov or e-mail. The regulations.gov website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through regulations.gov, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact*: The Regulatory Action Leader (RAL) identified in the table in Unit III.A. for the pesticide of interest.

For general information contact: Kevin Costello, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5026; fax number: (703) 308–8090; e-mail address: *costello.kevin@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments*. When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticide(s) discussed in this document, compared to the general population.

II. Authority

EPA is initiating its reviews of the pesticides identified in this document in accordance with section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

A. What Action is the Agency Taking?

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations identified in the table in this unit to assure that they continue to satisfy the FIFRA standard for registration—that is, they can still be used without unreasonable adverse effects on human health or the environment. A pesticide's registration review begins when the Agency establishes a docket for the pesticide's registration review case and opens the docket for public review and comment. At present, EPA is opening registration review dockets for the cases identified in the following table.

TABLE—REGISTRATION REVIEW DOCKETS OPENING

Registration Review Case Name and Number	Docket ID Number	RAL, Telephone Number, E-mail Address
Vegetable and flower oils (case # 8201)	EPA–HQ–OPP–2009–0904	Menyon Adams, (703) 347–8496, *adams.menyon@epa.gov*
Menthol (case # 4063)	EPA–HQ–OPP–2009–0900	Colin Walsh, (703) 308–0298, *walsh.colin@epa.gov*
Agrobacterium radiobacter (case number 4101)	EPA–HQ–OPP–2009–0878	Ann Sibold, (703) 305–6502, *sibold.ann@epa.gov*

B. Docket Content

1. *Review dockets*. The registration review dockets contain information that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

- An overview of the registration review case status.
- A list of current product registrations and registrants.
- **Federal Register** notices regarding any pending registration actions.
- **Federal Register** notices regarding current or pending tolerances.
- Risk assessments.
- Bibliographies concerning current registrations.
- Summaries of incident data.
- Any other pertinent data or information.

Each docket contains a document summarizing what the Agency currently knows about the pesticide case and a preliminary work plan for anticipated data and assessment needs. Additional documents provide more detailed information. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the Agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

2. *Other related information*. More information on these cases, including the active ingredients for each case, may be located in the registration review schedule on the Agency's website at *http://www.epa.gov/oppsrrd1/registration_review/schedule.htm*. Information on the Agency's registration review program and its implementing regulation may be seen at *http://www.epa.gov/oppsrrd1/registration_review*.

3. *Information submission requirements*. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

List of Subjects

Environmental protection, Pesticides and pests, Vegetable and flower oils, Menthol and Agrobacterium radiobacter.

Dated: March 25, 2010.

Keith A. Matthews,

Acting Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2010–7234 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0128; FRL–8814–4]

Registration Review; Pesticide Dockets Opened for Review and Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has established registration review dockets for the pesticides listed in the table in Unit III.A. With this document, EPA is opening the public comment period for these registration reviews. Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. Registration review dockets contain information that will assist the public in understanding the types of information and issues that the Agency may consider during the course of registration reviews. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment. This document also announces the Agency's intent not to open a registration review docket for pirimicarb. This pesticide does not currently have any actively registered pesticide products and is therefore not scheduled for review under the registration review program.

DATES: Comments must be received on or before June 1, 2010.

ADDRESSES: Submit your comments identified by the docket identification (ID) number for the specific pesticide of interest provided in the table in Unit III.A., by one of the following methods:

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

• *Mail*: Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

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Docket: All documents in the docket are listed in the docket index available at *http://www.regulations.gov*. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at *http://www.regulations.gov*, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact*: The Chemical Review Manager identified in the table in Unit III.A. for the pesticide of interest.

For general information contact: Kevin Costello, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5026; fax number: (703) 308–8090; e-mail address: *costello.kevin @epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

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This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farmworker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI*. Do not submit this information to EPA through regulations.gov or e-mail. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

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iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

3. *Environmental justice*. EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Authority

EPA is initiating its reviews of the pesticides identified in this document pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

A. What Action is the Agency Taking?

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registrations identified in the table in this unit to assure that they continue to satisfy the FIFRA standard for registration—that is, they can still be used without unreasonable adverse effects on human health or the environment. A pesticide's registration review begins when the Agency establishes a docket for the pesticide's registration review case and opens the docket for public review and comment. At present, EPA is opening registration review dockets for the cases identified in the following table.

TABLE—REGISTRATION REVIEW DOCKETS OPENING

Registration Review Case Name and Number	Docket ID Number	Chemical Review Manager, Telephone Number, E-mail Address
Amitraz (0234)	EPA–HQ–OPP–2009-1015	James Parker, (703) 306–0469 *parker.james@epa.gov*
Sodium acifluorfen (2605)	EPA–HQ–OPP–2010–0135	Christina Scheltema, (703) 308–2201 *scheltema.christina@epa.gov*
Allethrin stereoisomers (0437)	EPA–HQ–OPP–2010-0022	Molly Clayton, (703) 603–0522 *clayton.molly@epa.gov*
Bentazon (0182)	EPA–HQ–OPP–2010–0117	Joy Schnackenbeck, (703) 308–8072 *schnackenbeck.joy@epa.gov*
Clofencet (7015)	EPA–HQ–OPP–2009-0760	Wilhelmena Livingston, (703) 308–8025 *livingston.wilhelmena@epa.gov*
Chlorpyrifos-methyl (8011)	EPA–HQ–OPP–2010-0119	Katie Weyrauch, (703) 308–0166 *weyrauch.katie@epa.gov*
Deltamethrin (7414)	EPA–HQ–OPP–2009-0637	Jill Bloom, (703) 308–8019 *bloom.jill@epa.gov*
Hexazinone (0266)	EPA–HQ–OPP–2009–0755	Dana Friedman, (703) 347–8827 *friedman.dana@epa.gov*
Hymexazol (7016)	EPA–HQ–OPP–2010-0127	Kelly Ballard, (703) 305–8126 *ballard.kelly@epa.gov*
Tralomethrin (7400)	EPA–HQ–OPP–2010–0116	Joy Schnackenbeck, (703) 308–8072 *schnackenbeck.joy@epa.gov*

EPA is also announcing that it will not be opening a docket for pirimicarb because this pesticide is not included in any products actively registered under FIFRA section 3. The Agency will take separate actions to cancel any remaining FIFRA section 24(c) Special Local Needs registrations with this active ingredient and to propose revocation of any affected tolerances that are not supported for import purposes only.

B. Docket Content

1. *Review dockets*. The registration review dockets contain information that the Agency may consider in the course of the registration review. The Agency may include information from its files

including, but not limited to, the following information:

• An overview of the registration review case status.

• A list of current product registrations and registrants.

• **Federal Register** notices regarding any pending registration actions.

• **Federal Register** notices regarding current or pending tolerances.

• Risk assessments.

• Bibliographies concerning current registrations.

• Summaries of incident data.

• Any other pertinent data or information.

Each docket contains a document summarizing what the Agency currently knows about the pesticide case and a preliminary work plan for anticipated data and assessment needs. Additional documents provide more detailed information. During this public comment period, the Agency is asking that interested persons identify any additional information they believe the Agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

2. *Other related information*. More information on these cases, including the active ingredients for each case, may be located in the registration review schedule on the Agency's website at *http://www.epa.gov/oppsrrd1/registration_review/schedule.htm*. Information on the Agency's registration review program and its implementing regulation may be seen at *http://www.epa.gov/oppsrrd1/registration_review*.

3. *Information submission requirements*. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

• To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.

• The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

• Submitters must clearly identify the source of any submitted data or information.

• Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: March 22, 2010.

Richard P. Keigwin, Jr.,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

[FR Doc. 2010–6888 Filed 3–30–10; 8:45 am]

BILLING CODE 6560–50–S

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission, Comments Requested

March 25, 2010.

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(s), as required by the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501 – 3520. 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; (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, and (e) ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently 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 (PRA) that does not display a currently valid OMB control number.

DATES: Written Paperwork Reduction Act (PRA) comments should be submitted on or before June 1, 2010. If you anticipate that you will be submitting PRA comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the FCC contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, Office of Management and Budget, via fax at 202–395–5167 or via the Internet at Nicholas_A._Fraser@omb.eop.gov and to the Federal Communications Commission via email to PRA@fcc.gov.

FOR FURTHER INFORMATION CONTACT: Judith B. Herman, Office of Managing Director, (202) 418–0214. For additional information, contact Judith B. Herman, 202–418–0214, judth–b.herman@fcc.gov.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0710.

Title: Policy and Rules Under Parts 1 and 51 Concerning Implementation of the Local Competition Provisions in the Telecommunications Act of 1996, CC Docket No. 96–98.

Form No.: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for profit.

Number of Respondents and Responses: 15,282 responses; 1,067,987 responses.

Estimated Time Per Response: .50 – 2,880 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. sections 1 – 4, 201 – 205, 214, 224, 251, 252, 303(r) and 601.

Total Annual Burden: 645,798 hours.

Total Annual Cost: N/A.

Privacy Act Impact Assessment: N/A.

Nature and Extent of Confidentiality: The Commission is not requesting respondents to submit confidential information to the Commission. If the respondents wish to submit information which they believe is confidential, they may request confidential treatment of

such information under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: The Commission will submit this expiring information collection to the Office of Management and Budget (OMB) after this comment period in order to obtain the full three year clearance from them. There is no change in the reporting, recordkeeping and/or third party disclosure requirements. However, there is a significant decrease of 409,352 total annual burden hours and a $625,000 decrease in annual costs. This is due to several reasons including 1) re–calculations of each burden estimate; 2) re–estimate of the estimated time burden for some of the information collection categories; and 3) less time per response due to familiarity gained over the years of performing these functions.

The Commission adopted rules and regulations to implement parts of Sections 251 and 252 that affect local competition. Incumbent local exchange carriers (LECs) are required to offer interconnection, unbundled network elements, transport and termination and wholesale rates for certain services to new entrants. Incumbent LECs must price such services at rates that are cost–based and just and reasonable and provide access to right–of–way as well as establish reciprocal compensation arrangements for the transport and termination of telecommunications traffic.

Federal Communications Commission.

Bulah P. Wheeler,

Acting Associate Secretary,

Office of the Secretary,

Office of Managing Director.

[FR Doc. 2010–7168 Filed 3–30–10; 8:45 am]

BILLING CODE 6712–01–S

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Issuance of Exposure Draft on Accrual Estimates for Grant Programs

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

Board Action: Pursuant to 31 U.S.C. 3511(d), the Federal Advisory Committee Act (Pub. L. 92–463), as amended, and the FASAB Rules of Procedure, as amended in April, 2004, notice is hereby given that the Accounting and Auditing Policy Committee (AAPC) has issued an Exposure Draft of a new Federal Financial Accounting Technical Release entitled *Accrual Estimates for Grant Programs.* The proposed Technical Release provides guidance supporting cost-effective development of reasonable estimates of accrual liabilities for grant programs.

The Exposure Draft is available on the FASAB home page *http://www.fasab.gov/exposure.html.* Copies can be obtained by contacting FASAB at (202) 512–7350.

Respondents are encouraged to comment on any part of the exposure draft. Written comments are requested by April 22, 2010, and should be sent to:

Wendy M. Payne, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street, NW., Suite 6814, Mail Stop 6K17V, Washington, DC 20548.

FOR FURTHER INFORMATION CONTACT: Wendy Payne, Executive Director, at (202) 512–7350.

Authority: Federal Advisory Committee Act, Pub. L. 92–463.

Dated: March 26, 2010.

Charles Jackson,

Federal Register Liaison Officer.

[FR Doc. 2010–7248 Filed 3–30–10; 8:45 am]

BILLING CODE 1610–02–P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: *Background.* On June 15, 1984, the Office of Management and Budget (OMB) delegated to the Board of Governors of the Federal Reserve System (Board) its approval authority under the Paperwork Reduction Act (PRA), as per 5 CFR 1320.16, to approve of and assign OMB control numbers to collection of information requests and requirements conducted or sponsored by the Board under conditions set forth in 5 CFR Part 1320 Appendix A.1. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instruments are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Request for Comment on Information Collection Proposals

The following information collections, which are being handled under this delegated authority, have received initial Board approval and are hereby published for comment. At the end of the comment period, the proposed information collections, along with an analysis of comments and recommendations received, will be submitted to the Board for final approval under OMB delegated authority. Comments are invited on the following:

a. Whether the proposed collection of information is necessary for the proper performance of the Federal Reserve's functions; including whether the information has practical utility;

b. The accuracy of the Federal Reserve's estimate of the burden of the proposed information collection, including the validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected; and

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Comments must be submitted on or before June 1, 2010.

ADDRESSES: You may submit comments, identified by FR 2046, FR 2060, FR 2572, FR 4006, FR 4008, FR 4010, FR 4011, FR 4012, FR 4017, FR 4019, FR 4023, FR 4013, or FR 4014 by any of the following methods:

- *Agency Web Site: http://www.federalreserve.gov.* Follow the instructions for submitting comments at *http:/www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm.*
- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: regs.comments@federalreserve.gov.* Include the OMB control number in the subject line of the message.
- *FAX:* 202–452–3819 or 202–452–3102.
- *Mail:* Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551.

All public comments are available from the Board's web site at *http://www.federalreserve.gov/generalinfo/foia/ProposedRegs.cfm* as submitted, unless modified for technical reasons.

Accordingly, your comments will not be edited to remove any identifying or contact information. Public comments may also be viewed electronically or in paper form in Room MP–500 of the Board's Martin Building (20th and C Streets, NW.) between 9 a.m. and 5 p.m. on weekdays.

Additionally, commenters should send a copy of their comments to the OMB Desk Officer by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street, NW., Washington, DC 20503 or by fax to 202–395–6974.

FOR FURTHER INFORMATION CONTACT: A copy of the PRA OMB submission, including the proposed reporting form and instructions, supporting statement, and other documentation will be placed into OMB's public docket files, once approved. These documents will also be made available on the Federal Reserve Board's public Web site at: *http://www.federalreserve.gov/boarddocs/reportforms/review.cfm* or may be requested from the agency clearance officer, whose name appears below.

Michelle Shore, Federal Reserve Board Clearance Officer (202–452–3829), Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may contact (202–263–4869).

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, With Revision, of the Following Reports

1. Report title: Report of Selected Balance Sheet Items for Discount Window Borrowers.

Agency form numbers: FR 2046.

OMB control number: 7100–0289.

Frequency: On occasion.

Reporters: Depository institutions.

Annual reporting hours: Primary and Secondary Credit, 1 hour; Seasonal Credit, 386 hours.

Estimated average hours per response: Primary and Secondary Credit, 0.75 hour; Seasonal Credit, 0.25 hour.

Number of respondents: Primary and Secondary Credit, 1; Seasonal Credit, 103.

General description of report: This information collection is required to obtain a benefit pursuant to section 10B and 19(b)(7) of the Federal Reserve Act (12 U.S.C. 347b and 461(b)(7)) and is given confidential treatment (5 U.S.C. 552(b)(4)).

Abstract: The Federal Reserve's Regulation A, Extensions of Credit by Federal Reserve Banks, requires that the Federal Reserve review balance sheet data in determining whether to extend credit and to help ascertain whether undue use is made of such credit. Borrowers report certain balance sheet data for a period that encompasses the dates of borrowing.

Current Actions: The Federal Reserve proposes to revise the FR 2046 consistent with the 2009 revisions to the Weekly Report of Selected Assets and Liabilities of Domestically Chartered Commercial Banks and U.S. Branches and Agencies of Foreign Banks (FR 2644; OMB No. 7100–0075). FR 2046 respondents that also file the FR 2644 need not report data items that are common to both reports. The recent changes to the FR 2644 included new reporting of total deposits and the elimination of a separate data item for total loans. As a result, FR 2046 respondents that also file the FR 2644 or the weekly Report of Transaction Accounts, Other Deposits and Vault Cash (FR 2900; OMB No. 7100–0087) need not provide data on total deposits, but must provide data on total loans.

2. Report title: Report of Terms of Credit Card Plans and the Report of Terms of Credit Card Plans Supplemental Survey.

Agency form numbers: FR 2572 and FR 2572S, respectively.

OMB control number: 7100–0239.

Frequency: FR 2572, Semi-annual; and FR 2572S, one-time.

Reporters: Commercial banks, savings banks, industrial banks, and savings and loans associations.

Annual reporting hours: FR 2572, 75 hours; and FR 2572S, 263 hours.

Estimated average hours per response: FR 2572, 0.25 hours; and FR 2572S, 1.50 hours.

Number of respondents: FR 2572, 150; and FR 2572S, 175.

General description of report: This information collection is authorized pursuant section 136(b) of the Truth in Lending Act, 15 U.S.C. 1646(b). Reporting the FR 2572 is required of the 25 largest issuers; other financial institutions participate voluntarily. The data are not considered confidential. Reporting the FR 2572S data is mandatory and the identity of survey respondents is considered confidential (5 U.S.C 552(b)(4)).

Abstract: The FR 2572 collects data on credit card pricing and availability from a sample of at least 150 financial institutions that offer credit cards to the general public. The information collected on the FR 2572 is reported to Congress and made available to the public in order to promote competition within the industry. The FR 2572S gathers information on the number of creditors that have engaged in one or more of the practices identified in Section 505 of the Credit Card Act.

Current Actions: The Federal Reserve proposes to discontinue collection of the FR 2572S data. As directed by the Section 505 of the Credit Card Act, the Federal Reserve Board conducted a one-time survey regarding the extent to which credit card issuers adjust consumer credit lines or interest rates based on certain factors. The Credit Card Act required the Federal Reserve Board to complete the survey and submit a report to Congress by May 22, 2010. For this reason, the Federal Reserve is proposing to discontinue the FR 2572S.

Proposal To Approve Under OMB Delegated Authority the Extension for Three Years, Without Revision, of the Following Reports

1. *Report title:* Survey to Obtain Information on the Relevant Market in Individual Merger Cases.

Agency form number: FR 2060.

OMB control number: 7100–0232.

Frequency: On occasion.

Reporters: Small businesses and consumers.

Annual reporting hours: 9 hours.

Estimated average hours per response: Small businesses, 10 minutes; Consumers, 6 minutes.

Number of respondents: 25 small businesses and 50 consumers per survey.

General description of report: This information collection is voluntary pursuant to the Change in Bank Control Act (12 U.S.C. 1817(j)(7)(A) and (B)), the Bank Merger Act (12 U.S.C. 1828(c)(5)), and section 3(c)(1) of the Bank Holding Company Act (BHC Act) (12 U.S.C. 1842(c)(1)). Individual responses are confidential pursuant to the Freedom of Information Act (5 U.S.C. 552 (b)(4) and (b)(6)) for small businesses and consumers, respectively.

Abstract: The Federal Reserve uses this information to define relevant banking markets for specific merger and acquisition applications and to evaluate changes in competition that would result from proposed transactions.

2. *Report title:* Request for Extension of Time to Dispose of Assets Acquired in Satisfaction of Debts Previously Contracted.

Agency form number: FR 4006.

OMB control number: 7100–0129.

Frequency: Annual.

Reporters: BHCs.

Annual reporting hours: 505 hours.

Estimated average hours per response: 5 hours.

Number of respondents: 101.

General description of report: This information collection is required to

obtain a benefit pursuant to sections 4(a) and 4(c)(2) of the BHC Act [12 U.S.C. 1843(a) and (c)(2)] and may be given confidential treatment upon request. The Federal Reserve has established a procedure for requesting an extension in its Regulation Y [12 CFR 225.22(d)(1) and 225.140].

Abstract: BHC that acquired voting securities or assets through foreclosure in the ordinary course of collecting a debt previously contracted may not retain ownership of those shares or assets for more than two years without prior Federal Reserve approval. There is no formal reporting form and each request for extension must be filed at the appropriate Reserve Bank of the BHC. The Federal Reserve uses the information provided in the request to fulfill its statutory obligation to supervise BHCs.

3. *Report title:* Stock Redemption Notification.

Agency form number: FR 4008.

OMB control number: 7100–0131.

Frequency: On occasion.

Reporters: BHCs.

Annual reporting hours: 155 hours.

Estimated average hours per response: 15.5 hours.

Number of respondents: 10

General description of report: This information collection is mandatory pursuant to Sections 5(b) and (c) of the BHC Act (12 U.S.C. 1844(b) and (c)) and is generally not given confidential treatment. However, a respondent may request that the information be kept confidential on a case-by-case basis.

Abstract: The BHC Act and Regulation Y generally require a BHC to seek prior Federal Reserve approval before purchasing or redeeming its equity securities. Given that a BHC is exempt from this requirement if it meets certain financial, managerial, and supervisory standards, only a small portion of proposed stock redemptions actually require the prior approval of the Federal Reserve. There is no formal reporting form. The Federal Reserve uses the information provided in the redemption notice to fulfill its statutory obligation to supervise BHCs.

4. *Report title:* Information Collections Related to the Gramm-Leach-Bliley (GLB) Act.

Agency form number: FR 4010, FR 4011, FR 4012, FR 4017, FR 4019, and FR 4023.

OMB control number: 7100–0292.

Frequency: On occasion.

Reporters: BHCs, foreign banking organizations (FBOs), and state member banks (SMBs).

Annual reporting hours: 3,485 hours.

Estimated average hours per response: FR 4010: BHC 3 hours, FBOs 3.5 hours; FR 4011: 10 hours; FR 4012: BHCs decertified as financial holding companies (FHCs) 1 hour, FHCs back into compliance 10 hours; FR 4017: 4 hours; FR 4019: Regulatory relief requests 1 hour, Portfolio company notification 1 hour; and FR 4023: 50 hours.

Number of respondents: FR 4010: BHC 35, FBOs 6; FR 4011: 6; FR 4012: BHCs decertified as FHCs 80, FHCs back into compliance 20; FR 4017: 3; FR 4019: Regulatory relief requests 5, Portfolio company notification 2; FR 4023: 60.

General description of report: The FR 4010 is required to obtain a benefit and is authorized under Section 4(l)(1)(C) of the BHC Act, 12 U.S.C. 1843(l)(1)(C); section 8(a) of the International Banking Act, 12 U.S.C. 3106(a); and sections 225.82 and 225.91 of Regulation Y, 12 CFR 225.82 and 225.91.

The FR 4011 is voluntary and is authorized under Sections 4(j) and 4(k) of the BHC Act, 12 U.S.C. 1843(j) through (k); and sections 225.88, and 225.89, of Regulation Y, 12 CFR 225.88, and 225.89.

The FR 4012 is mandatory and is authorized under Section 4(l)(1) and 4(m) of the BHC Act, 12 U.S.C. 1843(l)(1) and (m); section 8(a) of the International Banking Act, 12 U.S.C. 3106(a); and sections 225.83 and 225.93 of Regulation Y, 12 CFR 225.83 and 225.93.

The FR 4017 is required to obtain a benefit and is authorized under Section 9 of the Federal Reserve Act, 12 U.S.C. 335; and section 208.76 of Regulation H, 12 CFR 208.76.

The FR 4019 is required to obtain a benefit and is authorized under Section 4(k)(7) of the BHC Act, 12 U.S.C. 1843(k)(7); and sections 225.171(e)(3), 225.172(b)(4), and 225.173(c)(2) of Regulation Y, 12 CFR 225.171(e)(3), 225.172(b)(4), and 225.173(c)(2).

The FR 4023 is mandatory and is authorized under Section 4(k)(7) of the BHC Act, 12 U.S.C. 1843(k)(7); and sections 225.171(e)(4) and 225.175 of Regulation Y, 12 CFR 225.171(e)(4) and 225.175.

For the FR 4010, FR 4011, FR 4017, FR 4019, and information related to a failure to meet capital requirements on the FR 4012, a company may request confidential treatment of the information contained in these information collections pursuant to section (b)(4) and (b)(6) of the Freedom of Information Act (FOIA)(5 U.S.C. 552 (b)(4) and (b)(6)). Information related to a failure to meet management requirements on the FR 4012 is confidential and exempt from disclosure under section (b)(4), because the release of this information would cause substantial harm to the competitive position of the entity, and (b)(8) if the information is related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions. Since the Federal Reserve does not collect the FR 4023, no issue of confidentiality under the FOIA arises. FOIA will only be implicated if the Board's examiners retained a copy of the records in their examination or supervision of the institution, and would likely be exempt from disclosure pursuant to FOIA (5 U.S.C. 552(b)(4), (b)(6), and (b)(8)).

Abstract: Each BHC or FBO seeking FHC status must file the FR 4010 declaration, which includes information needed to verify eligibility for FHC status. By filing the FR 4011, a requestor may ask the Board to determine that an activity is financial in nature, to issue an advisory opinion that an activity is within the scope of an activity previously determined to be financial in nature, or to approve engagement in an activity complementary to a financial activity. Any FHC ceasing to meet capital or managerial prerequisites for FHC status must notify the Board of the deficiency by filing the FR 4012 and often must submit plans to the Board to cure the deficiency. Any SMB seeking to establish a financial subsidiary must seek the Board's prior approval by submitting the FR 4017. Any FHC seeking to extend the 10-year holding period for a merchant banking investment must submit the FR 4019 to apply for the Board's prior approval, and a FHC also must notify the Board if it routinely manages or operates a portfolio company for more than nine months. All FHCs engaging in merchant banking activities must keep records of those activities, and make them available to examiners as specified in the FR 4023 requirements.

There are no formal reporting forms for these collections of information, which are event generated, though in each case the type of information required to be filed is described in the Board's regulations. These collections of information are required pursuant to amendments made by the GLB Act to the BHC Act or the Federal Reserve Act, or Board regulations issued to carry out the GLB Act.

5. *Report title:* Notice Claiming Status as an Exempt Transfer Agent.

Agency form number: FR 4013.

OMB control number: 7100–0137.

Frequency: On occasion.

Reporters: BHCs, and certain trust companies.

Annual reporting hours: 20 hours.

Estimated average hours per response: 2 hours.

Number of respondents: 10.

General description of report: This information collection is mandatory pursuant to section 17A(c) of the Securities Exchange Act of 1934 (15 U.S.C. 78q–1(c)) as amended by the Securities Acts Amendments of 1975. The Federal Reserve is authorized to collect these data from state member banks or their subsidiaries, and BHCs or their subsidiaries (except national banks and state nonmember banks that are insured by the FDIC) by 15 U.S.C. 78c(a)(34)(B)(ii). The data collected are not given confidential treatment.

Abstract: Banks, BHCs, and trust companies subject to the Federal Reserve's supervision that are low-volume transfer agents voluntarily file the notice on occasion with the Federal Reserve. Transfer agents are institutions that provide securities transfer, registration, monitoring, and other specified services on behalf of securities issuers. The purpose of the notice, which is effective until the agent withdraws it, is to claim exemption from certain rules and regulations of the Securities and Exchange Commission (SEC). The Federal Reserve uses the notices for supervisory purposes because the SEC has assigned to the Federal Reserve responsibility for collecting the notices and verifying their accuracy through examinations of the respondents. There is no formal reporting form and each notice is filed as a letter.

6. *Report title:* Investment in Bank Premises Notification.

Agency form number: FR 4014.

OMB control number: 7100–0139.

Frequency: On occasion.

Reporters: SMBs.

Annual reporting hours: 7 hours.

Estimated average hours per response: 30 minutes.

Number of respondents: 13.

General description of report: This information collection is required to obtain a benefit pursuant to Section 24A(a) of the Federal Reserve Act (12 U.S.C. 371d(a)) and is not given confidential treatment. However, a respondent may request confidential treatment for all or part of a notification, which would be reviewed on a case-by-case basis.

Abstract: The Federal Reserve Act requires an SMB to seek prior Federal Reserve approval before making an investment in bank premises that exceeds certain thresholds. There is no formal reporting form, and each required request for prior approval must be filed as a notification with the appropriate Reserve Bank of the SMB. The Federal Reserve uses the information provided in the notice to fulfill its statutory obligation to supervise SMBs.

Board of Governors of the Federal Reserve System, March 26, 2010.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 2010–7164 Filed 3–30–10; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications 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 26, 2010.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Bank Applications Officer) 33 Liberty Street, New York, New York 10045–0001:

1. Morgan Stanley, New York, New York; to acquire 100 percent of the voting shares of Morgan Stanley Private Bank, N.A., Jersey City, New Jersey, as a result of converting Morgan Stanley Trust into a national bank and thereby merging it with Morgan Stanley Bank, N.A., which will be relocated to Purchase, New York.

Board of Governors of the Federal Reserve System, March 26, 2010.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2010–7182 Filed 3–30–10; 8:45 am]

BILLING CODE 6210–01–S

FEDERAL TRADE COMMISSION

[File No. 082 3153]

Dave & Buster's, Inc.; Analysis of Proposed Consent Order to Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Proposed Consent Agreement.

SUMMARY: The consent agreement in this matter settles alleged violations of federal law prohibiting unfair or deceptive acts or practices or unfair methods of competition. The attached Analysis to Aid Public Comment describes both the allegations in the draft complaint and the terms of the consent order — embodied in the consent agreement — that would settle these allegations.

DATES: Comments must be received on or before April 26, 2010.

ADDRESSES: Interested parties are invited to submit written comments electronically or in paper form. Comments should refer to "Dave & Buster's, File No. 082 3153" to facilitate the organization of comments. Please note that your comment — including your name and your state — will be placed on the public record of this proceeding, including on the publicly accessible FTC website, at (*http://www.ftc.gov/os/publiccomments.shtm*).

Because comments will be made public, they should not include any sensitive personal information, such as an individual's Social Security Number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. Comments also should not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, comments should not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential. . . .," as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and Commission Rule 4.10(a)(2), 16 CFR 4.10(a)(2). Comments containing

material for which confidential treatment is requested must be filed in paper form, must be clearly labeled "Confidential," and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c).[1]

Because paper mail addressed to the FTC is subject to delay due to heightened security screening, please consider submitting your comments in electronic form. Comments filed in electronic form should be submitted by using the following weblink: (*https://public.commentworks.com/ftc/daveandbusters*) and following the instructions on the web-based form. To ensure that the Commission considers an electronic comment, you must file it on the web-based form at the weblink: (*https://public.commentworks.com/ftc/daveandbusters*). If this Notice appears at (*http://www.regulations.gov/search/index.jsp*), you may also file an electronic comment through that website. The Commission will consider all comments that regulations.gov forwards to it. You may also visit the FTC website at (*http://www.ftc.gov/*) to read the Notice and the news release describing it.

A comment filed in paper form should include the "Dave & Buster's, File No. 082 3153" reference both in the text and on the envelope, and should be mailed or delivered to the following address: Federal Trade Commission, Office of the Secretary, Room H-135 (Annex D), 600 Pennsylvania Avenue, NW, Washington, DC 20580. The FTC is requesting that any comment filed in paper form be sent by courier or overnight service, if possible, because U.S. postal mail in the Washington area and at the Commission is subject to delay due to heightened security precautions.

The Federal Trade Commission Act ("FTC Act") and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at (*http://www.ftc.gov/os/publiccomments.shtm*). As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act, may be found in the FTC's privacy policy, at (*http://www.ftc.gov/ftc/privacy.shtm*).

FOR FURTHER INFORMATION CONTACT: Katrina Blodgett (202-326-3158), Bureau of Consumer Protection, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580.

SUPPLEMENTARY INFORMATION: Pursuant to section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46(f), and § 2.34 the Commission Rules of Practice, 16 CFR 2.34, notice is hereby given that the above-captioned consent agreement containing a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of thirty (30) days. The following Analysis to Aid Public Comment describes the terms of the consent agreement, and the allegations in the complaint. An electronic copy of the full text of the consent agreement package can be obtained from the FTC Home Page (for March 25, 2010), on the World Wide Web, at (*http://www.ftc.gov/os/actions.shtm*). A paper copy can be obtained from the FTC Public Reference Room, Room 130-H, 600 Pennsylvania Avenue, NW, Washington, D.C. 20580, either in person or by calling (202) 326-2222.

Public comments are invited, and may be filed with the Commission in either paper or electronic form. All comments should be filed as prescribed in the **ADDRESSES** section above, and must be received on or before the date specified in the **DATES** section.

Analysis of Agreement Containing Consent Order to Aid Public Comment

The Federal Trade Commission has accepted, subject to final approval, a consent agreement from Dave & Buster's, Inc. ("Dave & Buster's").

The proposed consent order has been placed on the public record for thirty (30) days for receipt of comments by interested persons. Comments received during this period will become part of the public record. After thirty (30) days, the Commission will again review the agreement and the comments received, and will decide whether it should withdraw from the agreement and take appropriate action or make final the agreement's proposed order.

Dave & Buster's owns and operates 53 restaurant and entertainment complexes in the United States. Consumers may pay for purchases at these locations with credit and debit cards (collectively, "payment cards") or cash. In conducting its business, Dave & Buster's routinely collects information from consumers to obtain authorization for payment card purchases, including the credit card account number, expiration date, and an electronic security code for payment authorization. This information is particularly sensitive because it can be used to facilitate payment card fraud and other consumer fraud.

The Commission's complaint alleges that since at least April 2007, Dave & Buster's engaged in a number of practices that, taken together, failed to provide reasonable and appropriate security for personal information on its computer networks. Among other things, Dave & Buster's: (a) failed to employ sufficient measures to detect and prevent unauthorized access to computer networks or to conduct security investigations, such as by employing an intrusion detection system and monitoring system logs; (b) failed to adequately restrict third-party access to its networks, such as by restricting connections to specific IP addresses or granting temporary, limited access; (c) failed to monitor and filter outbound traffic from its networks to identify and block export of sensitive personal information without authorization; (d) failed to use readily available security measures to limit access between in-store networks, such as by using firewalls or isolating the payment card system from the rest of the corporate network; and (e) failed to use readily available security measures to limit access to its computer networks through wireless access points on the networks.

The complaint further alleges that between April 30, 2007 and August 28, 2007, an intruder, exploiting some of these vulnerabilities, connected to Dave & Buster's networks numerous times without authorization, installed unauthorized software, and intercepted personal information in transit from in-store networks to its credit card processing company. The breach compromised approximately 130,000 unique payment cards used by consumers in the United States.

The proposed order applies to personal information Dave & Buster's collects from or about consumers. It contains provisions designed to prevent Dave & Buster's from engaging in the future in practices similar to those alleged in the complaint.

Part I of the proposed order requires Dave & Buster's to establish and maintain a comprehensive information

[1] The comment must be accompanied by an explicit request for confidential treatment, including the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. The request will be granted or denied by the Commission's General Counsel, consistent with applicable law and the public interest. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

security program in writing that is reasonably designed to protect the security, confidentiality, and integrity of personal information collected from or about consumers. The security program must contain administrative, technical, and physical safeguards appropriate to Dave & Buster's size and complexity, the nature and scope of its activities, and the sensitivity of the personal information collected from or about consumers. Specifically, the order requires Dave & Buster's to:

- Designate an employee or employees to coordinate and be accountable for the information security program.
- Identify material internal and external risks to the security, confidentiality, and integrity of personal information that could result in the unauthorized disclosure, misuse, loss, alteration, destruction, or other compromise of such information, and assess the sufficiency of any safeguards in place to control these risks.
- Design and implement reasonable safeguards to control the risks identified through risk assessment, and regularly test or monitor the effectiveness of the safeguards' key controls, systems, and procedures.
- Develop and use reasonable steps to select and retain service providers capable of appropriately safeguarding personal information they receive from respondents, and require service providers by contract to implement and maintain appropriate safeguards.
- Evaluate and adjust its information security program in light of the results of the testing and monitoring, any material changes to its operations or business arrangements, or any other circumstances that it knows or has reason to know may have a material impact on the effectiveness of its information security program.

Part II of the proposed order requires that Dave & Buster's obtain within 180 days, and on a biennial basis thereafter for ten (10) years, an assessment and report from a qualified, objective, independent third-party professional, certifying, among other things, that it has in place a security program that provides protections that meet or exceed the protections required by Part I of the proposed order; and its security program is operating with sufficient effectiveness to provide reasonable assurance that the security, confidentiality, and integrity of consumers' personal information is protected.

Parts III through VII of the proposed order are reporting and compliance provisions. Part III requires Dave & Buster's to retain documents relating to its compliance with the order. For most records, the order requires that the documents be retained for a five-year period. For the third-party assessments and supporting documents, Dave & Buster's must retain the documents for a period of three years after the date that each assessment is prepared. Part IV requires dissemination of the order now and in the future to principals, officers, directors, and managers at corporate headquarters, regional offices, and at each store having responsibilities relating to the subject matter of the order. Part V ensures notification to the FTC of changes in corporate status. Part VI mandates that Dave & Buster's submit an initial compliance report to the FTC, and make available to the FTC subsequent reports. Part VII is a provision "sunsetting" the order after twenty (20) years, with certain exceptions.

The purpose of the analysis is to aid public comment on the proposed order. It is not intended to constitute an official interpretation of the proposed order or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark

Secretary

[FR Doc. 2010–7127 Filed 3–30–10: 1:29 pm]

BILLING CODE 6750–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Call for Co-Sponsors for Office of Healthcare Quality's Programs to Strengthen Coordination and Impact National Efforts in the Prevention of Healthcare-Associated Infections (HAIs)

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Healthcare Quality.

ACTION: Notice.

SUMMARY: The U.S. Department of Health and Human Services (HHS), Office of Public Health and Science (OPHS), Office for Healthcare Quality (OHQ) announces the opportunity to collaborate with the U.S. Department of Health and Human Services (HHS). HHS invites public and private professional health related organizations to participate as collaborating co-sponsors in the development and implementation of an innovative program that advances the goals enumerated in the HHS Action Plan to prevent Healthcare-Associated Infections.

DATES: Expressions of interest for FY 2010–11 must be received no later than cob April 15, 2010.

ADDRESSES: Expressions of interest, comments, and questions may be submitted by e-mail to *ohq@hhs.gov;* by regular mail to Office of Healthcare Quality, Department of Health and Human Services, 200 Independence Ave., SW., Room 716G, Washington, DC 20201, or via fax to 202–401–9547.

FOR FURTHER INFORMATION CONTACT: Daniel Gallardo via electronic mail to *Daniel.Gallardo@hhs.gov*; or by phone at 202–690–2470.

SUPPLEMENTARY INFORMATION: Healthcare-associated infections (HAIs) exact a significant toll on human life. They are among the leading causes of preventable death in the United States, accounting for an estimated 1.7 million infections and 99,000 associated deaths in 2002. In hospitals, they are a significant cause of morbidity and mortality. In addition to the substantial human suffering caused by healthcare-associated infections, the financial burden attributable to the infections is staggering. It is estimated that healthcare-associated infections cause $28 to $33 billion in excess healthcare costs each year. For these reasons, the prevention and reduction of healthcare-associated infections is a top priority for the U.S. Department of Health and Human Services (HHS).

The HHS Steering Committee for the Prevention of Healthcare-Associated Infections, led by Dr. Don Wright, Deputy Assistant Secretary for Healthcare Quality, was established in July 2008. The Steering Committee was charged with developing a comprehensive strategy to prevent and reduce healthcare-associated infections and issuing a plan which establishes national goals for healthcare-associated infection prevention and outlines key actions for achieving identified short- and long-term objectives. The plan, released in January 2009 as the HHS Action Plan, is also intended to enhance collaboration with external stakeholders to strengthen coordination and impact of national efforts.

Therefore, OHQ is interested in establishing partnerships with private and public professional health organizations in order to further the efforts in the prevention of Healthcare-Associated Infections. As partners with OHQ, professional health related organizations can bring their ideas, expertise, administrative capabilities, and resources in the development of a program(s) that promotes the reduction and prevention of Healthcare-

Associated Infections at the National level.

Given OHQ's objective, entities which have similar goals and consistent interests, appropriate expertise and resources, and which would like to pursue a Co-Sponsorship opportunity with OHQ, are encouraged to reply to this notice with a program proposal. Working together, these partnerships will provide opportunities to promote the prevention and reduction of healthcare-associated infections.

Dated: March 22, 2010.

Don Wright,

Deputy Assistant Secretary for Healthcare Quality, Office of Healthcare Quality, Office of Public Health and Science.

[FR Doc. 2010–7227 Filed 3–30–10; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Policy Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Policy Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on a policy framework for the development and adoption of a nationwide health information technology infrastructure that permits the electronic exchange and use of health information as is consistent with the Federal Health IT Strategic Plan and that includes recommendations on the areas in which standards, implementation specifications, and certification criteria are needed.

Date and Time: The meeting will be held on April 21, 2010, from 10 a.m. to 4 p.m./Eastern Time.

Location: The Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC. The hotel telephone number is 202–234–0700.

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202–205–4528, Fax: 202–690–6079, e-mail: *judy.sparrow@hhs.gov.* Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups, including the Meaningful Use Workgroup, the Certification/Adoption Workgroup, the NHIN Workgroup, the Privacy & Security Policy Workgroup, and the Strategic Plan Workgroup. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posed on ONC's Web site after the meeting, at *http://healthit.hhs.gov*.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 13, 2010. Oral comments from the public will be scheduled between approximately 3:30 p.m. to 4 p.m. Time allotted for each presentation is limited to three minutes. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://healthit.hhs.gov* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: March 18, 2010.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2010–6601 Filed 3–30–10; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the National Coordinator for Health Information Technology; HIT Standards Committee Advisory Meeting; Notice of Meeting

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

ACTION: Notice of meeting.

This notice announces a forthcoming meeting of a public advisory committee of the Office of the National Coordinator for Health Information Technology (ONC). The meeting will be open to the public.

Name of Committee: HIT Standards Committee.

General Function of the Committee: To provide recommendations to the National Coordinator on standards, implementation specifications, and certification criteria for the electronic exchange and use of health information for purposes of adoption, consistent with the implementation of the Federal Health IT Strategic Plan, and in accordance with policies developed by the HIT Policy Committee.

Date and Time: The meeting will be held on April 28, 2010, from 9 a.m. to 4 p.m./Eastern Time.

Location: The Omni Shoreham Hotel, 2500 Calvert Street, NW., Washington, DC. The hotel telephone number is 202–234–0700.

Contact Person: Judy Sparrow, Office of the National Coordinator, HHS, 330 C Street, SW., Washington, DC 20201, 202–205–4528, Fax: 202–690–6079, e-mail: *judy.sparrow@hhs.gov.* Please call the contact person for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice.

Agenda: The committee will hear reports from its workgroups, including the Clinical Operations, Clinical Quality, Privacy & Security, and Implementation Workgroups. ONC intends to make background material available to the public no later than two (2) business days prior to the meeting. If ONC is unable to post the background

material on its Web site prior to the meeting, it will be made publicly available at the location of the advisory committee meeting, and the background material will be posed on ONC's Web site after the meeting, at *http://healthit.hhs.gov*

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 20, 2010. Oral comments from the public will be scheduled between approximately 3 p.m. and 3:30 p.m./Eastern Time. Time allotted for each presentation will be limited to three minutes each. If the number of speakers requesting to comment is greater than can be reasonably accommodated during the scheduled open public hearing session, ONC will take written comments after the meeting until close of business.

Persons attending ONC's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

ONC welcomes the attendance of the public at its advisory committee meetings. Seating is limited at the location, and ONC will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Judy Sparrow at least seven (7) days in advance of the meeting.

ONC is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://healthit.hhs.gov* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App. 2).

Dated: March 18, 2010.

Judith Sparrow,

Office of Programs and Coordination, Office of the National Coordinator for Health Information Technology.

[FR Doc. 2010–6600 Filed 3–30–10; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Establishment of the Presidential Commission for the Study of Bioethical Issues

AGENCY: Office of Public Health and Science, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

Authority: Executive Order 13251, dated November 24, 2009. The Presidential Commission for the Study of Bioethical Issues will be governed by provisions of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees.

SUMMARY: The U.S. Department of Health and Human Services announces establishment of the Presidential Commission for the Study of Bioethical Issues (the "Commission"), as directed by Executive Order 13521.

FOR FURTHER INFORMATION CONTACT: Ms. Diane M. Gianelli, Acting Executive Director, Presidential Commission on the Study of Bioethical Issues; Department of Health and Human Services; and/or Ms. Judith E. Crawford, Administrative Director, Presidential Commission on the Study of Bioethical Issues; Department of Health and Human Services. Both Ms. Gianelli and Ms. Crawford work in the Commission's office located at: 1425 New York Avenue, NW., Suite C100; Washington, DC 20005; Telephone: (202) 233–3960; Fax: (202) 233–3990.

SUPPLEMENTARY INFORMATION: Under Executive Order 13521, the President directed that the Commission shall be established within the Department of Health and Human Services (HHS). To comply with the authorizing directive and guidelines under the Federal Advisory Committee Act (FACA), a charter has been filed with the Committee Management Secretariat in the General Services Administration (GSA), the appropriate committees in the Senate and U.S. House of Representatives, and the Library of Congress to establish the Commission as a non-discretionary Federal advisory committee. The charter was filed on March 10, 2010.

Objectives and Scope of Activities. The Commission shall advise the President on bioethical issues that may emerge as consequences of advances in biomedicine and related areas of science and technology. The Commission shall pursue its work with the goal of identifying and promoting policies and practices that ensure scientific research, healthcare delivery, and technological innovation are conducted in an ethically responsible manner. The Commission shall not be responsible for the review and approval of specific projects. The Commission may accept suggestions of issues for consideration from executive departments and agencies and the public as it deems appropriate to support its mission.

Membership and Designation. The Commission shall be an expert panel composed of not more than 13 members, who will be drawn from fields of bioethics, science, medicine, technology, engineering, law, philosophy, theology, and other areas of the humanities or social sciences. Commission members shall be appointed by the President. The President shall designate a Chair and Vice Chair from among the members of the Commission. At least one, and not more than three members, may be bioethicists or scientists drawn from the executive branch, as designated by the President; members who are selected from the Federal sector to fill these positions on the Commission will be classified as regular government employees. The Commission members who are selected from the public and/or private sector will be classified as special government employees.

Administrative Management and Support. HHS will provide funding and administrative support for the Commission to the extent permitted by law within existing appropriations. Staff will be assigned to a program office established to support the activities of the Commission. Management and oversight for support services provided to the Commission will be the responsibility of the Office of Public Health and Science, which is a staff division within HHS Office of the Secretary. All executive departments and agencies and all entities within the Executive Office of the President shall provide information and assistance to the Commission as the Chair may request for purposes of carrying out the Commission's functions, to the extent permitted by law.

The Commission has been established to replace the President's Council on Bioethics. The Council was established by Executive Order 13237, dated November 28, 2001. Council operations were terminated on September 30, 2009. The authorizing directive for the Commission, Executive Order 13521, supersedes Executive Order 13237.

A copy of the Commission charter can be obtained from the designated contacts or by accessing the FACA database that is maintained by the GSA Committee Management Secretariat. The Web site for the FACA database is *http://fido.gov/facadatabase/.*

Dated: March 25, 2010.

Howard K. Koh,

Assistant Secretary for Health, Office of Public Health and Science.

[FR Doc. 2010–7232 Filed 3–30–10; 8:45 am]

BILLING CODE 4154–06–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–10AJ]

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) 639–5960 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) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Evaluation of Childhood Obesity Prevention and Control Initiative: New York City Health Bucks Program —New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Childhood obesity is a major public health concern. One out of every five children is affected by overweight or obesity in the United States, making it the most prevalent nutritional disease of this population. Although increased consumption of fruits and vegetables has been found to reduce long-term obesity risk, as well as risk of heart disease and some cancers, relatively few children and adolescents consume the USDA recommended minimum standard of five servings a day of fruits and vegetables.

In response to this growing public health crisis, the Division of Nutrition, Physical Activity, and Obesity (DNPAO) at the Centers for Disease Control and Prevention (CDC), is working to identify promising local programs and policies designed to prevent childhood obesity. Priority is being given to programs and policies targeting improved eating habits and physical activity levels among children in low-income communities.

The New York City Health Bucks program, operated by the New York City Department of Health and Mental Hygiene (DOHMH), is one example of this type of initiative. The program operates in three high-need, underserved New York City neighborhoods: The South Bronx, North and Central Brooklyn, and East and Central Harlem. Through the program, targeted neighborhood residents are provided with $2 "Health Bucks" that can be redeemed at local farmers' markets for the purchase of fresh, locally-grown fruits and vegetables. The Health Bucks program is intended to increase fresh fruit and vegetable purchases and consumption, and to increase access at the community level by attracting local farmers to these underserved areas.

CDC plans to sponsor an evaluation of the NYC Health Bucks program in 2010. Information will be collected from five groups of respondents: Local community organizations involved in distributing Health Bucks to individuals (200 respondents); farmers' market managers operating New York City farmers' markets (90 respondents); farmers' market vendors selling at New York City farmers' markets (474 respondents); farmers' market consumers at New York City farmers' markets (2,348 respondents); and residents of neighborhoods in which the NYC Health Bucks program operates (1,000 respondents).

The evaluation plan calls for local community organizations to complete a web-based questionnaire at the conclusion of the farmers' market season. Farmers' market managers will complete a written survey during the farmers' market season, with in-person follow up by trained interviewers on site at farmers' markets for managers who do not respond to the initial mailing. Farmers' market vendors will complete a written survey administered by trained interviewers on site at farmers' markets, and trained interviewers will also conduct written point-of-purchase intercept surveys with farmers' market consumers. Finally, telephone interviews will be conducted with a random sample of residents in neighborhoods in which the NYC Health Bucks program operates, and in-depth information will be collected from farmers' market consumers and vendors through focus groups.

The results of the evaluation study will be used to: Assess the program's ability to improve nutrition behaviors among targeted participants; identify factors serving as barriers and facilitators to program implementation and expected outcomes; provide feedback to the DOHMH for the purposes of program improvement; and share results with other entities interested in implementing similar programs.

Information collection will be conducted in English and Spanish. There are no costs to respondents other than their time, and participation is voluntary. The total estimated annualized burden hours are 660.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form type	Number of respondents	Number of responses per respondent	Average burden (in hours)
Local Community Organizations	Local Community Organization Survey	200	1	10/60
Farmers' Market Managers	Farmers' Market Managers Survey	90	1	8/60
Farmers' Market Vendors	Farmers' Market Vendor Survey	450	1	7/60
	Farmers' Market Vendor Focus Group	24	1	2
Farmers' Market Consumers	Consumer Point-of-Purchase Survey	2,300	1	7/60
	Consumer Focus Group	48	1	2
NYC Health Bucks Neighborhood Residents	Neighborhood Resident Survey	1,000	1	9/60

Dated: March 22, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2010–7171 Filed 3–30–10; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Studying the Implementation of a Chronic Care Toolkit and Practice Coaching In Practices Serving Vulnerable Populations." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on February 1, 2010 and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by April 30, 2010.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Studying the Implementation of a Chronic Care Toolkit and Practice Coaching In Practices Serving Vulnerable Populations

An important part of AHRQ's mission is to disseminate information and tools that can support improvement in quality and safety in the U.S. health care community. This proposed information collection supports that part of AHRQ's mission by further refining the practice coaching delivered in conjunction with a previously developed toolkit, Implementing Integrating Chronic Care and Business Strategies in the Safety Net: A Toolkit for Primary Care Practices and Clinics. AHRQ requests that the Office of Management and Budget approve, under the Paperwork Reduction Act of 1995, AHRQ's intention to collect information needed to determine whether practice coaching is effective in facilitating adoption of the Chronic Care Model (CCM) for improving treatment and management of chronic medical conditions by primary care physicians, especially those who care for underserved populations. This project is being conducted pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to quality measurement and improvement and with respect to clinical practice, including primary care and practice-oriented research. 42 U.S.C. 299a(a)(2) and (4). This project will be conducted by AHRQ through a contract with the University of Minnesota.

Although 1,500 physician practices in the U.S. and internationally have been involved in CCM quality improvement efforts, most patients still do not receive their chronic care in accordance with CCM. One factor affecting CCM implementation has been that having teams attend collaborative meetings (three two-day meetings over a nine-month period) is burdensome, especially for under-resourced providers. An attempt to use the Internet as a virtual collaborative met with disappointing results. Another barrier to adoption of the CCM in settings that serve vulnerable populations is the scarcity of resources to implement and sustain the CCM. In 2006 AHRQ contracted with the RAND Corporation, Group Health's MacColl Institute, and the California Health Care Safety Net Institute (SNI) to develop a toolkit that informs safety net providers on how to redesign their systems of care along the lines of the Chronic Care Model while attending to their financial realities. The result was Implementing Integrating Chronic Care and Business Strategies in the Safety Net: A Toolkit for Primary Care Practices and Clinics. The Toolkit was piloted in two California safety net clinics. Recognizing that merely distributing the Toolkit was unlikely to foster adoption of CCM, the intervention included six months of practice coaching delivered by the MacColl Institute. Practice Coaches (PC) are health care or related professionals who help primary care practices in a variety of quality improvement and research activities. PCs made two site visits to each site and participated in weekly team meetings by phone. They also interacted with the sites through e-mail and phone contact.

The lack of documentation available on coaching led to the development of a practice coaching manual, which was funded by AHRQ through a contract with the RAND Corporation. Development of the Coaching Manual entailed conducting a literature review, interviewing practice coaching experts, and incorporating evaluation results from the coaching provided in conjunction with the Toolkit. The Coaching Manual was published in the winter of 2009. The literature review and interviews revealed that there are a number of different models of practice coaching. However, knowledge is scant about how practice coaching is best performed, under what conditions practice coaching is most successful, and the costs of coaching and being coached. Pilot testing the Toolkit with a low-intensity practice coaching strategy proved insufficient to encourage practices to use the Toolkit independently. The Toolkit was subsequently streamlined based on pilot sites' reports that the initial Toolkit was not easy to use. This project will explore the implementation of the revised Toolkit along with a more intensive practice coaching strategy, providing lessons on methods to improve chronic care in clinical practices that serve vulnerable populations.

Method of Collection

This project will include the following data collections:

(1) Key Informant Interviews with providers, staff and practice coaches from 20 safety net practices that participate in the practice coaching intervention. These will be used to describe the process and content of practice coaching, perceived changes from the coaching intervention at the practice, provider and patient levels, factors that impeded or facilitated the coaching intervention and implementation of practice changes

through the coaching process, overall satisfaction with practice coaching, and recommendations for improvement.

(2) Primary Care Practice Profile (PCPP). This questionnaire will be completed by a single individual at each site, either the medical director or chief administrator, and will provide an overview of each replication site that will help place intervention activities and outcomes in context for each site. It covers demographics of patients served, patient flow, disease health outcomes, most frequent diagnoses, most frequent referrals, number of staff by discipline, staff and patient satisfaction, processes of care, and organizational processes.

(3) Physician Practice Connections-Readiness Survey (PPC–RS)—This questionnaire asks about the presence of 53 practice systems in 5 of the 6 domains of the Chronic Care Model: Clinical information systems (information systems, presence of registry or organized database, and systematic monitoring of patient population); decision support (clinician reminders and alerts for lab tests, and visits or guidelines related to individual patient care), delivery system redesign (services for managing patients with chronic illness involving multiple clinicians and care between visits), health care organization (performance tracking and feedback, process of using clinical information systems to aggregate and report on key indicators, and use of data for benchmarking performance and informing QI activities), and clinical quality improvement (presence of formal processes to assess care, develop interventions, and use data to monitor the effects).

(4) Assessment of Chronic Illness Care (ACIC)—The ACIC is contained in the Toolkit and yields subscale scores and a total score. Subscale scores reflect CCM components and include: Community linkages, self-management support, decision support, delivery system design, information systems, and organization of care.

(5) Change Process Capability Questionnaire (CPCQ)—The CPCQ assesses 30 factors and strategies that experienced quality improvement leaders ranked as most important for successful implementation. A recent validation study found good predictive validity. Items correlating with the PPC–RS were eliminated after the initial validation study so there is little to no overlap across the two measures. In addition to changes in the content of care (CCM components), these also include organizational will for change (Priority) and capacity and skill in the conduct of the actual change processes and strategies.

(6) Patient Assessment of Chronic Illness Care (PACIC)—The 20-item PACIC consists of five subscales which assess components of the CCM: Patient activation, delivery system design/decision support, goal setting, problem-solving/contextual counseling, and followup and coordination.

(7) Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult—This questionnaire assesses patient experiences in three areas: Getting appointments and healthcare when needed; how well doctors communicate, and courteous and helpful office staff.

(8) Primary Care Staff Satisfaction Survey—This questionnaire assesses staff satisfaction with their work environment. It consists of 8 4-point likert scale items and 2 open-ended questions, and was developed by the Institute for Healthcare Improvement.

(9) Chart Audits—Chart audits will be conducted at baseline, the end of the 10-month coaching intervention, and at 3-month follow-up to assess changes in patient care quality over the course of the intervention. A chart abstraction form will be developed to collect these data. This data collection will be performed by the project staff and will not impose a burden on the participating sites. Therefore, OMB clearance is not required for this data collection.

Clinic staff will be provided with a paper version of the surveys as well as the option to complete the surveys on line using a secure on-line survey program. With the exception of the staff surveys, no special information technology will be used to collect information, since many of the data collection forms are standardized instruments available in hard-copy form, and special permission from the developers would be required to create electronic versions of these forms. The information collection is a one-time only project; thus, there would be little benefit in reduced burden from automated information collection tools for the other instruments.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this two-year study. Key informant interviews will be conducted with practice coaches at midpoint in the intervention and again at the end of the intervention. Key informant interviews will also be conducted with up to 3 primary care providers and 2 other staff members from each of the 20 practices (10 per year) prior to start of the intervention, and again at 3-month follow-up after the intervention is completed. Each interview takes about 1 hour.

The Primary Care Practice Profile will be administered once and will be completed by one staff person from each practice and takes 30 minutes to complete. The Physician Practice Connections-Readiness Survey (PPC–RS) will be completed pre, post and at 3-month follow-up by three individuals from each of the 20 practices (individuals with the appropriate knowledge to complete the survey will be identified by the medical director of each site). It takes 90 minutes to complete. The Assessment of Chronic Illness Care (ACIC) will be completed by 4 staff and 4 primary care providers per practice at pre, post and 3-month follow-up and takes 30 minutes to complete. The Change Process Capability Questionnaire (CPCQ) will be completed by 4 staff and 4 primary care providers per practice at pre, post and 3-month follow-up and takes 15 minutes to complete. The Primary Care Staff Satisfaction Survey (PCSSS) will be completed by 4 staff and 4 primary care providers per practice at pre, post and 3-month follow-up and takes 15 minutes to complete. The Patient Assessment of Chronic Illness Care (PACIC) will be completed by 3,000 adult patients (1,500 annually) with chronic illness and requires 15 minutes to complete. The Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult (CAHPS) will be completed by 3,000 adult patients (1,500 annually) with chronic illness and requires 45 minutes to complete. Both patient surveys will be administered to adult patients with a chronic disease who receive care at the practices during a 2-day data collection period immediately before, immediately after, and at 3-month follow-up. The surveys will be administered during the post visit period in the wait room, by a bi-lingual Spanish-English research assistant. The total annualized burden hours are estimated to be 1,984 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondent's time to participate in this study. The total annualized cost burden is estimated to be $60,714.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Key informant interviews with practice coaches	2	2	1	4
Key informant interviews with providers (3 per practice interviewed twice)	10	6	1	60
Key informant interviews with staff (2 per practice interviewed twice)	10	4	1	40
Primary Care Practice Profile (PCPP)	10	1	30/60	5
Physician Practice Connections—Readiness Survey (PPC–RS) (3 per practice × 3 times)	10	9	1.5	135
Assessment of Chronic Illness Care (ACIC) (8 per practice × 3 times)	10	24	30/60	120
Change Process Capability Questionnaire (CPCQ) (8 per practice × 3 times)	10	24	15/60	60
Primary Care Staff Satisfaction Survey (PCSSS) (8 per practice 3 × times)	10	24	15/60	60
Patient Assessment of Chronic Illness Care (PACIC)	1,500	1	15/60	375
Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult (CAHPS)	1,500	1	45/60	1,125
Total	3,072	na	na	1,984

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Key informant interviews with practice coaches	2	4	$42.00	$168
Key informant interviews with providers	10	60	77.64	4,658
Key informant interviews with staff	10	40	32.64	1,306
Primary Care Practice Profile (PCPP)	10	5	77.64	388
Physician Practice Connections—Readiness Survey (PPC–RS)	10	135	77.64	10,481
Assessment of Chronic Illness Care (ACIC)	10	120	** 55.14	6,617
Change Process Capability Questionnaire (CPCQ)	10	60	** 55.14	3,308
Primary Care Staff Satisfaction Survey	10	60	** 55.14	3,308
Patient Assessment of Chronic Illness Care (PACIC)	1,500	375	20.32	7,620
Consumer Assessment of Healthcare Providers and Systems—Primary Care Adult (CAHPS)	1,500	1,125	20.32	22.860
Total	3,072	1,984	na	60,714

* Based upon the mean of the average wages, May 2008 National Occupational and Wage Estimates accessed on December 14, 2009 at: *http://www.bls.gov/oes/current/oes_nat.htm#b29–0000.*
National Compensation Survey:
** Average for 4 staff ($32.64/hr) and 4 physician clinicians ($77.64/hr).

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated total and annualized cost to conduct this research. The total cost over two years is estimated to be $600,000.

EXHIBIT 3—ESTIMATED TOTAL AND ANNUALIZED COST

Cost component	Total cost	Annualized cost
Project Development	$162,744	$81,372
Data Collection Activities	92,994	46,497
Data Processing and Analysis (20%)	92,994	46,497
Publication of Results	23,248	11,624
Project Management	92,994	46,497
Overhead	135,026	67,513
Total	600,000	300,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of

automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–6776 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Reductions of Infection Caused by Carbapenem Resistant Enterobacteriaceae (KPC) Producing Organisms through the Application of Recently Developed CDC/HICPAC Recommendations." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by June 1, 2010.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Reductions of Infection Caused by Carbapenem Resistant Enterobacteriaceae (KPC) Producing Organisms Through the Application of Recently Developed CDC/HICPAC Recommendations

Healthcare Acquired Infections (HAIs) caused almost 100,000 deaths among the 2.1 million people who acquired infections while hospitalized in 2000, and HAI rates have risen relentlessly since then. On March 20, 2009, the Centers for Disease Control (CDC) and the Healthcare Infections Control Practices Advisory Committee (HICPAC) developed infection control (IC) guidance for Klebsiella pneumonia carbapenemase-producing (KPC) isolates, as they have been rapidly emerging as a significant challenge in healthcare settings. The danger of these bacteria is that they are resistant to carbapenem (a class of beta-lactam antibiotics with a broad spectrum of antibacterial activity) and cannot be treated by the most commonly prescribed antibiotics. Limited treatment options mean that infections caused by carbapenem resistant bacteria result in substantial mortality and morbidity.

The CDC and HICPAC recommendations draw on infection control strategies which have been applied to these pathogens in other settings, and other evidence based strategies in infection control. There has been little research, however, on the implementation of control strategies to prevent the spread of these KPC infections. The goal of this project is to understand how these recommendations can best be implemented and how effective these recommendations will be in practice. This research will advance private and public efforts to improve health care quality by improving measures to control the spread of a dangerous organism. This research will also provide data for the development of an implementation toolkit that hospitals can use to prevent the spread of carbapenem resistant bacteria. The toolkit may include the following types of resources: General information about the implementation of evidenced-based clinical practices, resource materials, and tools and methods that users can adopt to conduct point prevalence surveys, protocols and tools that users can adopt to specify when active KPC surveillance is needed, and resources for approaching the problem as a team-based quality-improvement effort.

OMB clearance will be sought for this toolkit once it is developed.

This study is being conducted by AHRQ through its contractor, Boston University, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of healthcare services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

This project will include the following data collections from the intensive care unit (ICU) staff within each of three participating hospitals:

(1) Pre-intervention focus groups will be conducted separately with managers and staff. The purpose of these focus groups is to identify potential problems in the implementation that can be addressed through various means (*e.g.,* additional education, other changes in process). Another purpose is to understand the existing approach to quality improvement, the connection(s) between overall approach to quality improvement and to KPC infection control practices, current practices at the hospital of quality reporting and accountability, and constraints and obstacles to quality improvement as seen in their roles. Staff members identified for the focus groups will be those with the most first-hand knowledge of existing quality improvement efforts, and KPC infection control practices.

(2) Clinical staff survey. Factors identified in the pre-intervention focus groups will be used to inform the development of a self-administered survey of staff knowledge of and attitudes toward KPC surveillance and infection control procedures. Respondents will be health care workers on the units where these new guidelines have been implemented. Findings from the survey will be used to assess barriers perceived by the staff, potential differences across units, and potential differences by employee/occupational group.

(3) Post-intervention focus groups (6 months after implementation of new KPC IC guidelines) will be conducted separately with managers and staff. The purpose of these focus groups is to identify actual problems experienced in the initial implementation and possible measures to address, and to identify successful practices to include in a toolkit that hospitals can use to implement the CDC and HICPAC recommendations.

In addition to developing a toolkit, AHRQ plans to disseminate the lessons

learned from this project about how hospitals can best implement the CDC guidance for KPC screening and infection control, in order to inform efforts to change practice in this area.

Estimated Annual Respondent Burden

The estimated annualized burden hours for respondents to participate in this two year research project are presented in Exhibit 1. Pre-intervention focus groups with clinical staff will be conducted with 18 staff members (an average of 9 per year for 2 years) from each of the 3 participating hospitals and will take about 1 hour. Pre-intervention focus groups with also be conducted with 2 managers (an average of 1 per year for 2 years) from each hospital and will take about an hour to complete.

The clinical staff survey will be administered to 20 clinical staff (an average of 10 per year for 2 years) from each hospital and will take 15 minutes to complete.

Finally, respondents from the pre-intervention focus groups will participate in post-intervention focus groups approximately four months after the initiation of the intervention. They will not last more than an hour each. The total annualized burden hours are estimated to be 68 hours.

Exhibit 2 shows the estimated annualized cost burden associated with the respondents' time to participate in this research. The total annualized cost burden is estimated to be $3,108.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Pre-intervention focus groups with clinical staff *	3	9	1	27
Pre-intervention focus groups with managers *	3	1	1	3
Clinical staff survey	3	10	15/60	8
Post-intervention focus groups with clinical staff *	3	9	1	27
Post-intervention focus groups with managers *	3	1	1	3
Total	15	n/a	n/a	68

* Individuals that cannot attend the focus groups will be interviewed one-on-one. Clinical staff includes IC leaders, QI team members and unit staff. Managers include the chief nursing officer and chief medical officer.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
Pre-intervention focus groups with clinical staff	3	27	* $36.73	$992
Pre-intervention focus groups with managers	3	3	** 138.38	415
Clinical staff survey	3	8	* 36.73	294
Post-intervention focus groups with clinical staff	3	27	* 36.73	992
Post-intervention focus groups with managers	3	3	** 138.38	415
Total	15	68	na	3,108

* Based upon the mean hourly wage for Registered Nurses in Nassau and Suffolk County, NY as reported by the Bureau of Labor Statistics in May 2008.

** Based on report of a private survey of HR departments conducted in November 2009 in New York, NY published by *http://www.salary.com;* 3 chief nursing officers at $101.14/hr and 3 chief medical officers at $175.61/hour.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the annualized and total cost to the federal government for this two year research project. Project development covers steps taken to revise the research plan and begin implementation. The total cost is estimated to be $500,001.

EXHIBIT 3—ANNUALIZED AND TOTAL COST TO THE FEDERAL GOVERNMENT

Cost component	Annualized cost	Total cost
Project Management	$125,526	$251,052
Project Development	54,622	109,244
Data Collection Activities	41,864	83,728
Travel	4,000	8,000
Overhead	23,754	47,507
Total	250,001	500,001

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–6778 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: "Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Health Plan Survey Comparative Database." In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3520, AHRQ invites the public to comment on this proposed information collection.

This proposed information collection was previously published in the **Federal Register** on January 25th, 2010 and allowed 60 days for public comment. No comments were received. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by April 30, 2010.

ADDRESSES: Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by e-mail at *OIRA_submission@omb.eop.gov* (*attention:* AHRQ's desk officer).

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by e-mail at *doris.letkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Collection of Information for Agency for Healthcare Research and Quality's (AHRQ) Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey Comparative Database

The Agency for Healthcare Research and Quality (AHRQ) requests that the Office of Management and Budget (OMB) approve, under the Paperwork Reduction Act of 1995, AHRQ's collection of information for the AHRQ Consumer Assessment of Healthcare Providers and Systems (CAHPS) Database for Health Plans. The CAHPS Health Plan Database consists of data from the AHRQ CAHPS Health Plan Survey.

Health plans in the U.S. are asked to voluntarily submit data from the survey to AHRQ, through its contractor, Westat. The CAHPS Database was developed by AHRQ in 1998 in response to requests from health plans, purchasers, and the Centers for Medicare & Medicaid Services (CMS) to provide comparative data to support public reporting of health plan ratings, health plan accreditation and quality improvement.

The CAHPS Health Plan Survey is a tool for collecting standardized information on enrollees' experiences with health plans and their services. The development of the CAHPS Health Plan Survey began in 1995, when AHRQ awarded the first set of CAHPS grants to Harvard, RTI, and RAND. In 1997 the CAHPS 1.0 survey was released by the CAHPS Consortium. The CAHPS Consortium refers to the research organizations involved in the development, dissemination, and support of CAHPS products. The current Consortium includes AHRQ, CMS, RAND, Yale School of Public Health, and Westat.

Since that time, the Consortium has clarified and updated the survey instrument to reflect field test results; feedback from industry experts; reports from health plan participants, data collection vendors, and other users; and evidence from cognitive testing and focus groups. In November 2006, the CAHPS Consortium released the latest version of the instrument: The CAHPS Health Plan Survey 4.0. The development of this update to the Health Plan Survey has been part of the "Ambulatory CAHPS (A–CAHPS) Initiative," which arose as a result of extensive research conducted with users. AHRQ released the CAHPS Health Plan Survey 4.0, along with guidance on how to customize and administer it. The National Quality Forum endorsed the 4.0 version of the Health Plan Survey in July 2007.

The CAHPS Health Plan Database uses data from AHRQ's standardized CAHPS Health plan survey to provide comparative results to health care purchasers, consumers, regulators and policy makers across the country. The Database also provides data for AHRQ's annual National Healthcare Quality and National Healthcare Disparities Reports. Voluntary participants include public and private employers, State Medicaid agencies, State Children's Health Insurance Programs (SCHIP), CMS, and individual health plans.

The collection of information for the CAHPS Database for Health Plans is being conducted pursuant to AHRQ's statutory authority to conduct and support research on health care and systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services. *See* 42 U.S.C. 299a(a)(1).

Method of Collection

Information for the CAHPS Health Plan Database has been collected by AHRQ through its contractor Westat on an annual basis since 1998. Health plans are asked to voluntarily submit their data to the comparative database in June of each year. The data are cleaned with standardized programs, then aggregated and used to produce comparative results for commercial (adult and child), Medicaid (adult and child), and Medicare (adult) populations for the two most recent years. In addition, individual participant reports are produced that display the participating organizations' own results compared to appropriate comparisons derived from the National, regional and product-type distributions on a password-protected section of the online reporting system.

The CAHPS Health Plan Database receives the data from three sources. First, commercial health plan data is purchased by the CAHPS Health Plan Database directly from the National Committee for Quality Assurance (NCQA). The data is collected by NCQA from those who participate in its accreditation program. Second, Medicare data is provided by CMS through an agency data use agreement. The Medicare data is collected by CMS

and their contractor from beneficiaries who were enrolled in a managed care health plan. Third, Medicaid data is collected by the CAHPS Health Plan Database. Medicaid agencies and their vendors directly submit their Medicaid health plan survey data to the CAHPS Health Plan Database through an online data submission system. Data submitted by Medicaid plans are compiled along with the data received from CMS and NCQA to comprise the CAHPS Health Plan Survey comparative database.

Estimated Annual Respondent Burden

Each year State Medicaid agencies and individual health plans decide whether to participate in the database and prepare their materials and dataset for submission to the CAHPS Health Plan Database. Participating organizations are typically State Medicaid agencies with multiple health plans. However, individual health plans are also encouraged to submit their data to the CAHPS Database. The number of data submissions per registrant varies from participant to participant and year to year because some participants submit data for multiple health plans, while others may only submit survey data for one plan.

Each organization that decides to participate in the database must have their POC complete a registration form providing their contact information for access to the on-line data submission system, sign and submit a data use agreement (DUA), and provide health plan characteristics such as health plan name, product type, type of population surveyed, health plan state, and plan name to appear in the reporting of their results.

Each vendor that submits files on behalf of a Medicaid agency or individual health plan must also complete the registration form in order to obtain access to the on-line submission system. The vendor, on behalf of their client, may also complete additional information about survey administration (CAHPS survey version used, mode of survey administration, total enrollment count, description of how the sample was selected), submit a copy of the questionnaire used, and submit one data file per health plan. Commercial health plan data is received directly from NCQA. Medicare health plan data is received from CMS.

The burden hours and costs below pertain only to the collection of Medicaid data from State Medicaid agencies and individual Medicaid health plans because those are the only entities that submit data through the data submission process (other data are obtained directly from NCQA and CMS as noted earlier in Section 2). In 2009, a total of 60 participants, representing 45 individual organizations and 15 vendors, submitted data for 244 health plans (an average of about 4 health plans per participant).

Exhibits 1 and 2 are based on the estimated number of individual participants (participating organizations and/or vendors) who will complete the database submission steps and forms in the coming years, and is not based on the total number of health plans that are submitted. The number of respondents and burden hours are based on an estimated slight increase in the number of participants to 70 in 2010 and 2011.

In Exhibit 1, the 70 participants that will complete the registration form and submit information to the CAHPS Health Plan Database are a combination of an estimated 50 State Medicaid agencies and individual health plans, and 20 estimated vendors. The 50 State Medicaid agencies or individual health plans will sign and submit a DUA. Vendors do not sign or submit DUAs. Health plan information and data files are submitted for each health plan. Exhibit 1 shows an estimated total of 280 health plans (70 estimated participants with 4 health plans per participant). The total burden hours for completing the registration, DUA and data submission process are estimated to be 722 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents/ POCs	Number of responses per POC	Hours per response	Total burden hours
Registration Form and Data Submission *	70	1	7.6	532
Data Use Agreement **	50	1	1	50
Health Plan Information ***	70	4	30/60	140
Total	190	NA	NA	722

* The online Registration Form requires about 5 minutes to complete; however over 7 hours is required to plan/prepare for the data submission. This includes the amount of time the participating organization, and others (CEO, lawyer, vendor) typically spend deciding whether to participate in the database and preparing their materials and dataset for submission to the CAHPS Health Plan Database and performing the submission.

** The Data Use Agreement requires about 3 minutes to complete; however about 57 minutes is required for the participating organization to review the agreement prior to signing. This includes the review by the organization's CEO or legal department.

*** A few health plans may submit their data directly, however most health plan data will be submitted by the POC.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete the submission process. The cost burden is estimated to be $31,046 annually.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate **	Total cost burden
Registration Form and Data Submission *	70	532	$43.00	$22,876
Data Use Agreement	50	50	43.00	2,150
Health Plan Information	70	140	43.00	6,020

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN—Continued

Form name	Number of respondents	Total burden hours	Average hourly wage rate**	Total cost burden
Total	190	722	NA	31,046

*Wage rates were calculated using the mean hourly wage based on occupational employment and wage estimates from the Dept of Labor, Bureau of Labor Statistics' May 2008 National Industry-Specific Occupational Employment and Wage Estimates NAICS 622000—located at *http://www.bls.gov/oes/current/oes_nat.htm.*

**Wage rate of $43.00 is based on the mean hourly wages for Medical and Health Services Managers. Wage rate of $42.67 is the weighted mean hourly wage for: Medical and Health Services Managers ($42.67 × 2.6 hours = $110.95), Lawyers ($59.98 × .5 hours = $29.99), Chief Executives ($89.16 × .5 hours = $44.58), and Computer programmer ($35.32 × 4 hours = $141.28) [Weighted mean = ($110.95 + 29.99 + 44.58 = 141.28)/7.6 hours = $326.80/7.6 hours = $43.00/hour].

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the estimated annualized cost to the government for developing, maintaining and managing the Health Plan Database and analyzing the data and reporting results. The cost is estimated to be $260,000 annually. Annualized costs for collecting and processing the CAHPS Health Plan Database are based upon 10 years of historical project costs. Start-up costs were present in the early years of the database only.

EXHIBIT 3—ESTIMATED ANNUALIZED COST

Cost component	Annualized cost
Database Maintenance	$50,000
Data Submission	100,000
Data Analysis and Reporting	110,000
Total	260,000

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ healthcare research and healthcare information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) 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 upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–6780 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

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 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.

Proposed Project: The Health Education Assistance Loan (HEAL) Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915–0204)—Extension

The Health Education Assistance Loan (HEAL) program provided federally-insured loans to students in schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, and graduate students in health administration or clinical psychology through September 30, 1998. Eligible lenders, such as banks, savings and loan associations, credit unions, pension funds, State agencies, HEAL schools, and insurance companies, made new refinanced HEAL loans which are insured by the Federal Government against loss due to borrower's death, disability, bankruptcy, and default. The basic purpose of the program was to assure the availability of funds for loans to eligible students who needed to borrow money to pay for their educational loans. Currently, the program monitors the federal liability, and assists in default prevention activities.

The HEAL borrower, the borrower's physician, and the holder of the loan completes the Physician's Certification form to certify that the HEAL borrower meets the total and permanent disability provisions. The Department uses this form to obtain detailed information about disability claims which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, (2) pertinent information supplied by the certifying physician, (3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death, and (4) information from the

lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability claim. No changes have been made to the current form.

The estimate of burden for the Physician's Certification form is as follows:

Type of respondent	Number of respondents	Responses per respondent	Number of responses	Minutes per response	Total burden hours
Borrower	75	1	75	5	6
Physician	75	1	75	30	38
Loan Holder	13	6	78	10	13
Total	163		228		57

E-mail comments to *paperwork@hrsa.gov* or mail the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 25, 2010.

Sahira Rafiullah,

Director, Division of Policy and Information Coordination.

[FR Doc. 2010–7251 Filed 3–30–10; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0161]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export of Food and Drug Administration Regulated Products: Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements imposed on firms that intend to export to countries that require an export certificate as a condition of entry for FDA-regulated products, pharmaceuticals, biologics, and devices as indicated in the Federal Food, Drug, and Cosmetic Act (the act) as amended.

DATES: Submit written or electronic comments on the collection of information by June 1, 2010.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.Capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Export of Food and Drug Administration Regulated Products: Export Certificates (OMB Control Number 0910–0498)—Extension

In April 1996, a law entitled "The FDA Export Reform & Enhancement Act of 1996" (FDAERA) amended sections 801(e) and 802 of the act (21 U.S.C. 381(e) and 382). It was designed to ease restrictions on exportation of unapproved pharmaceuticals, biologics, and devices regulated by FDA. Section 801(e)(4) of the FDAERA provides that persons exporting certain FDA-regulated products may request FDA to certify that the products meet the requirements of 801(e) and 802 or other requirements of the act. This section of the law requires FDA to issue certification within 20 days of receipt of the request and to charge firms up to $175 for the certifications.

This new section of the act authorizes FDA to issue export certificates for regulated pharmaceuticals, biologics, and devices that are legally marketed in the United States, as well as for these same products that are not legally marketed but are acceptable to the importing country, as specified in sections 801(e) and 802 of the act. FDA has developed five types of certificates that satisfy the requirements of section 801(e)(4)(B) of the act: (1) Certificates to Foreign Governments, (2) Certificates of Exportability, (3) Certificates of a Pharmaceutical Product, (4) Non-Clinical Research Use Only Certificates, and (5) Certificates of Free Sale. Table 1 of this document lists the different certificates and details their use:

TABLE 1.—EXPORT CERTIFICATES

Type of Certificate	Use
"Supplementary Information Certificate to Foreign Government Requests" "Exporter's Certification Statement Certificate to Foreign Government" "Exporter's Certification Statement Certificate to Foreign Government (For Human Tissue Intended for Transplantation)"	For the export of products legally marketed in the United States
"Supplementary Information Certificate of Exportability Requests" "Exporter's Certification Statement Certificate of Exportability"	For the export of products not approved for marketing in the United States (unapproved products) that meet the requirements of sections 801(e) or 802 of the act
"Supplementary Information Certificate of a Pharmaceutical Product" "Exporter's Certification Statement Certificate of a Pharmaceutical Product"	Conforms to the format established by the World Health Organization and is intended for use by the importing country when the product in question is under consideration for a product license that will authorize its importation and sale or for renewal, extension, amending, or reviewing a license
"Supplementary Information Non-Clinical Research Use Only Certificate" "Exporter's Certification Statement Non-Clinical Research Use Only)"	For the export of a non-clinical research use only product, material, or component that is not intended for human use which may be marketed in, and legally exported from the United States under the act
Certificate of Free Sale	For food, cosmetic products, and dietary supplements that may be legally marketed in the United States

FDA will continue to rely on self-certification by manufacturers for the first three types of certificates listed in table 1 of this document. Manufacturers are requested to self-certify that they are in compliance with all applicable requirements of the act, not only at the time that they submit their request to the appropriate center, but also at the time that they submit the certification to the foreign government.

The appropriate FDA centers will review product information submitted by firms in support of their certificate and any suspected case of fraud will be referred to FDA's Office of Criminal Investigations for followup. Making or submitting to FDA false statements on any documents may constitute violations of 18 U.S.C. 1001, with penalties including up to $250,000 in fines and up to 5 years imprisonment.

FDA estimates the burden of this collection of information as follows:

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Center	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Center for Biologics Evaluation and Research	2,114	1	2,114	1	2,114
Center for Drug Evaluation and Research	5,251	1	5,251	2	10,502
Center for Devices and Radiological Health	6,463	1	6,463	2	12,926
Center for Veterinary Medicine	855	1	855	1	855
Center for Food Safety and Applied Nutrition	1,794	5	8,970	2	17,940
Total					44,337

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7111 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Strengthening Communities Fund Program Evaluation.

OMB No.: New collection.

Description: This proposed information collection activity is to obtain evaluation information from Strengthening Communities Fund (SCF) grantees. Grantees include participants in two SCF grant programs contributing to the economic recovery as authorized in the American Recovery and Reinvestment Act of 2009 (ARPA). The SCF evaluation is an important opportunity to examine the outcomes

achieved by the Strengthening Communities Fund in meeting its objective of improving the capacity of grantees that include Nonprofit organizations and State, Local and Tribal Governments. The evaluation for each program will be designed to assess progress and measure increased organizational capacity of grantees is each of the two SCF programs. The purpose of this request will be to establish the approved baseline instruments for follow-up data collection.

Respondents: SCF Grantees (both the Nonprofit Capacity Building Program and the Government Capacity Building Program) made up of State, local, and Tribal governments, as well as nonprofit organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Nonprofit Capacity Building Program Performance Progress Report (PPR) ..	35	4	1	140
Government Capacity Building PPR	49	4	1	196

Estimated Total Annual Burden Hours: 336.

Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by April 15, 2010. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 17th Street NW., Washington, DC 20503, FAX (202) 395–6974.

Dated: March 22, 2010.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2010–6999 Filed 3–30–10; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request For Public Comment: 30-Day Proposed Information Collection: Indian Health Service Medical Staff Credentials and Privileges Files

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which requires 30 days for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (74 FR 63754) on December 4, 2009 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: 0917–0009, "Indian Health Service Medical Staff Credentials and Privileges Files."

Type of Information Collection Request: Extension, without revision, of currently approved information collection, 0917–0009, "Indian Health Service Medical Staff Credentials and Privileges Files" agreement.

Form Numbers(s): None.

Need and Use of Information Collection: This collection of information is used to evaluate individual health care providers applying for medical staff privileges at IHS health care facilities. The Department of Health and Human Services operates health care facilities that provide health care services to American Indians and Alaska Natives. To provide these services, the IHS employs (directly and under contract) several categories of health care providers including: Physicians (M.D. and D.O.), dentists, psychologists, optometrists, podiatrists, audiologists, physician assistants, certified registered nurse anesthetists, nurse practitioners, and certified nurse midwives. IHS policy specifically requires physicians and dentists to be members of the health care facility medical staff where they practice. Health care providers become medical staff members, depending on the local health care facility's capabilities and medical staff bylaws. There are three types of IHS medical staff applicants: (1) Health care providers applying for direct employment with IHS; (2) contractors who will not seek to become IHS employees; and (3) employed IHS health care providers who seek to transfer between IHS health care facilities.

National health care standards developed by the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and other accrediting organizations require health care facilities to review, evaluate and verify the credentials, training and experience of medical staff applicants prior to granting medical staff privileges. In order to meet these standards, IHS health care facilities require all medical staff applicants to provide information concerning their education, training, licensure, and work experience and any adverse disciplinary actions taken against them. This information is then verified with references supplied by the applicant and may include: Former employers, educational institutions, licensure and certification boards, the American Medical Association, the Federation of State Medical Boards, the National Practitioner Data Bank, and the applicants themselves.

In addition to the initial granting of medical staff membership and clinical privileges, JCAHO standards require that a review of the medical staff be conducted not less than every two years. This review evaluates the current competence of the medical staff and verifies whether they are maintaining the licensure or certification requirements of their specialty.

The medical staff credentials and privileges records are maintained at the health care facility where the health care provider is a medical staff member. The establishment of these records at IHS health care facilities is not optional; such records must be established and accredited by JCAHO. Prior to the establishment of this JCAHO requirement, the degree to which medical staff applications were

maintained at all health care facilities in the United States that are verified for completeness and accuracy varied greatly across the Nation.

The application process has been streamlined and is using information technology to make the application electronically available on the Internet.

Affected Public: Individuals and households.

Type of Respondents: Individuals.

The table below provides: Types of data collection instruments, Estimated number of respondents, Number of annual number of responses, Average burden per response, and Total annual burden hours.

Data collection instrument(s)	Estimated number of respondents	Responses per respondent	Average burden hour per response*	Total annual burden hours
Application to Medical Staff	570	1	1.00 (60 mins)	570
Reference Letter	1710	1	0.33 (20 mins)	570
Reappointment Request	190	1	1.00 (60 mins)	190
Ob-Gyn Privileges	20	1	1.00 (60 mins)	20
Internal Medicine	325	1	1.00 (60 mins)	325
Surgery Privileges	20	1	1.00 (60 mins)	20
Psychiatry Privileges	13	1	1.00 (60 mins)	13
Anesthesia Privileges	15	1	1.00 (60 mins)	15
Dental Privileges	150	1	0.33 (20 mins)	50
Optometry Privileges	21	1	0.33 (20 mins)	7
Psychology Privileges	30	1	0.17 (10 mins)	5
Audiology Privileges	7	1	0.08 (5 mins)	1
Podiatry Privileges	7	1	0.08 (5 mins)	1
Radiology Privileges	8	1	0.33 (20 mins)	3
Pathology Privileges	3	1	0.33 (20 mins)	1
Total	3,089			1,791

* For ease of understanding, burden hours are provided in actual minutes. There are no capital costs, operating costs and/or maintenance costs to respondents.

Request For Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate is logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, *Attention:* Desk Officer for IHS, New Executive Office Building, Room 10235, Washington, DC 20503.

Send Comments and Requests for Further Information: To request more information on the proposed collection or to obtain a copy of the data collection instrument(s) and/or instruction(s) contact: Mr. Hershel Gorham, Reports Clearance Officer, 801 Thompson Avenue, TMP, Suite 450, Rockville, MD 20852–1627; call non-toll free (301) 443–5932; send via facsimile to (301) 443–9879; or send your e-mail requests, comments, and return address to: *Hershel.Gorham@ihs.gov.*

Comment Due Date: Comments regarding this information collection are best assured of having full effect if received within 30 days of the date of this publication.

Dated: March 19, 2010.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2010–7253 Filed 3–30–10; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Common Formats for Patient Safety Data Collection and Event Reporting

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of Availability—Common Formats Version 1.1.

SUMMARY: The Patient Safety and Quality Improvement Act of 2005, 42 U.S.C. 299b–21 to b–26, (Patient Safety Act) provides for the formation of Patient Safety Organizations (PSOs), which collect, aggregate, and analyze confidential information regarding the quality and safety of healthcare delivery. The Patient Safety Act (at 42 U.S.C. 299b–23) authorizes the collection of this information in a standardized manner, as explained in the related Patient Safety and Quality Improvement Final Rule, 42 CFR part 3 (Patient Safety Rule), published in the **Federal Register** on November 21, 2008: 73 FR 70731–70814. As authorized by the Secretary of HHS, AHRQ coordinates the development of a set of common definitions and reporting formats (Common Formats) that allow healthcare providers to voluntarily collect and submit standardized information regarding patient safety events. The purpose of this notice is to announce the availability of the expanded and enhanced Common Formats Version 1.1—including updated event descriptions, reports, data elements, and technical specifications for software developers—and the process for their continued refinement.

DATES: Ongoing public input.

ADDRESSES: The Common Formats Version 1.1 can be accessed electronically at the following HHS Web site: *http://www.PSO.AHRQ.gov/index.html.*

FOR FURTHER INFORMATION CONTACT: Marcy Opstal, Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403–3697;

Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; E-mail: *PSO@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act and Patient Safety Rule establish a framework by which doctors, hospitals, and other healthcare providers may voluntarily report information regarding patient safety events and quality of care. Information that is assembled and developed by providers for reporting to PSOs and the information received and analyzed by PSOs—called "patient safety work product"—is privileged and confidential. Patient safety work product is used to identify events, patterns of care, and unsafe conditions that increase risks and hazards to patients. Definitions and other details about PSOs and patient safety work product are included in the Patient Safety Rule.

The Patient Safety Act and Patient Safety Rule require PSOs, to the extent practical and appropriate, to collect patient safety work product from providers in a standardized manner in order to permit valid comparisons of similar cases among similar providers. The collection of patient safety work product allows the aggregation of sufficient data to identify and address underlying causal factors of patient safety problems. Both the Patient Safety Act and Patient Safety Rule can be accessed electronically at *http://www.PSO.AHRQ.gov/regulations/regulations.htm.*

In order to facilitate standardized data collection, the Secretary of HHS authorized AHRQ to develop and maintain the Common Formats to improve the safety and quality of healthcare delivery. In August 2008, AHRQ issued the initial release of the formats, Version 0.1 Beta. The second release of the Common Formats, Version 1.0, was announced in the **Federal Register** on September 2, 2009: 74 FR 45457–45458.

Definition of Common Formats

The term "Common Formats" is used to describe clinical definitions and technical requirements developed for the uniform collection and reporting of patient safety data, including all supporting material. The Common Formats are not intended to replace any current mandatory reporting system, collaborative/voluntary reporting system, research-related reporting system, or other reporting/recording system. The scope of Common Formats applies to all patient safety concerns including:

- Incidents—patient safety events that reached the patient, whether or not there was harm,
- Near misses or close calls—patient safety events that did not reach the patient, and
- Unsafe conditions—circumstances that increase the probability of a patient safety event.

Common Formats Version 1.1 is currently limited to patient safety reporting for acute care hospitals and is designed to support the first stage in the improvement cycle. Version 1.1 includes two general types of formats, generic and event specific. The generic Common Formats pertain to all patient safety concerns. The three generic formats are: Healthcare Event Reporting Form, Patient Information Form, and Summary of Initial Report. The event-specific Common Formats pertain to frequently-occurring and/or serious patient safety events. The eight event-specific formats are: Blood or Blood Product, Device or Medical/surgical Supply, Fall, Healthcare-Associated Infection, Medication or Other Substance, Perinatal, Pressure Ulcer, and Surgery or Anesthesia.

The Common Formats Version 1.1 has a defined focus on patient safety reporting for acute care hospitals. It should be noted, however, that the privilege and confidentiality protections of the Patient Safety Act and Patient Safety Rule apply to patient safety work product developed under the aegis of a PSO with respect to healthcare in any setting. Future versions of the Common Formats are being developed for other settings such as: Skilled nursing facilities (SNFs), ambulatory surgery centers, and physician and practitioner offices.

AHRQ's Common Formats Version 1.1 includes:

- Descriptions of patient safety events and unsafe conditions to be reported (event descriptions),
- Specifications for patient safety aggregate reports and individual event summaries,
- Delineation of data elements to be collected for specific types of events,
- A user's guide and quick guide, and
- Technical specifications for electronic data collection and reporting.

Common Formats Development

In anticipation of the need for Common Formats, AHRQ began their development in 2005 by creating an inventory of functioning private and public sector patient safety reporting systems. This inventory provides an evidence base that informs construction of the Common Formats. The inventory now numbers 69 and includes many systems from the private sector, including prominent academic settings, hospital systems, and international reporting systems (*e.g.,* from the United Kingdom and the Commonwealth of Australia). In addition, virtually all major Federal patient safety reporting systems are included, such as those from the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Defense (DoD), and the Department of Veterans Affairs (VA).

Since February 2005, AHRQ has coordinated an interagency Federal Patient Safety Work Group (PSWG) to assist AHRQ with developing and maintaining the Common Formats. The PSWG includes major health agencies within the HHS CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, the Indian Health Service, the National Institutes of Health, the National Library of Medicine, the Office of the National Coordinator for Health Information Technology, the Office of Public Health and Science, the Substance Abuse and Mental Health Services Administration—as well as the DoD and the VA.

The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, framework, and definitions, contained in their draft International Classification for Patient Safety (ICPS).

Common Formats Version 1.1—Technical Specifications Enhancements

The technical specifications promote standardization by ensuring that data collected by PSOs and other entities are clinically and electronically comparable. The specifications also provide direction to software developers, so the Common Formats can be implemented electronically, and to PSOs, so the Common Formats can be submitted electronically to the PSO Privacy Protection Center (PPC) for data de-identification and transmission to the Network of Patient Safety Databases (NPSD).

The technical specifications consist of the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats Version 1.1;

• Clinical document architecture (CDA) implementation guide—provides instructions for developing a Health Level Seven (HL7) CDA Extensible Markup Language (XML) file to transmit the Common Formats patient safety data from the PSO to the PPC using the Common Formats;

• Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PPC;

• Common Formats flow charts—diagrams the valid paths to complete generic and event specific formats (a complete event report);

• Local specifications—provides specifications for processing, linking and reporting on events and details specifications for reports; and

• Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [*e.g.,* HL–7, International Standards Organization (ISO)].

Commenting on Common Formats Version 1.1

To allow for greater participation by the private sector in the subsequent development of the Common Formats, AHRQ engaged the National Quality Forum (NQF), a non-profit organization focused on healthcare quality, to solicit comments and advice to guide the further refinement of the Common Formats. The NQF began this process with feedback on AHRQ's 0.1 Beta release of the Common Formats. The NQF also convened an expert panel to review the comments received on Common Formats Version 1.0 and provide feedback to AHRQ. Based upon the expert panel's feedback, AHRQ, in conjunction with the PSWG, has further revised and refined the Common Formats that are now available as Version 1.1.

AHRQ is committed to continuing refinement of the Common Formats. The Agency is specifically interested in obtaining feedback from both the private and public sectors, particularly from those who use the Common Formats, to guide their improvement. Although AHRQ's Version 1.1 has been developed based on evidence, consensus of the PSWG, public comments and input, and feedback from the NQF expert panel, the formats do not fully reflect the refinement that comes from large-scale use and repeated revision. The process for updating and refining the formats will be an iterative one.

More information on the Common Formats Version 1.1, including the feedback process, can be obtained through AHRQ's PSO Web site: *http://www.PSO.AHRQ.gov/index.html.*

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–6781 Filed 3–30–10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

FY 2010 Special Diabetes Program for Indians Community-Directed Grant Program

Announcement Type: New/Competing Continuation.

Funding Opportunity Number: HHS–2010–IHS–SDPI–0004.

Catalog of Federal Domestic Assistance Number: 93.237

Key Dates:

Application Deadline: April 30, 2010.

Review Date: June 21–24, 2010.

Earliest Anticipated Start Date: July 15, 2010.

Other information: This announcement will be open throughout Fiscal Year (FY) 2010 based on existing budget cycles. Refer to application instructions for additional details. This current announcement targets grantees that currently operate under a budget cycle that begins on June 1.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting grant applications for the FY 2010 Special Diabetes Program for Indians (SDPI) Community-Directed grant program. This competitive grant announcement is open to all existing SDPI grantees that have an active grant in place and are in compliance with the previous terms and conditions of the grant. This program is authorized under H.R. 6331 "Medicare Improvement for Patients and Providers Act of 2008" (Section 303 of Pub. L. 110–275) and the Snyder Act, 25 U.S.C. 13. The program is described in the Catalog of Federal Domestic Assistance (CDFA) under 93.237.

Overview

The SDPI seeks to support diabetes treatment and prevention activities for American Indian/Alaska Native (AI/AN) communities. Grantees will implement programs based on identified diabetes-related community needs. Activities will be targeted to reduce the risk of diabetes in at-risk individuals, provide services that target those with new onset diabetes, provide high quality care to those with diagnosed diabetes, and/or reduce the complications of diabetes.

The purpose of the FY 2010 SDPI Community-Directed grant program is to support diabetes treatment and prevention programs that have a program plan which integrates at least one IHS Diabetes Best Practice and that have a program evaluation plan in place which includes tracking outcome measures.

This is not an application for continued funding as was previously available for Community-Directed grant programs.

Background

Diabetes Among American Indian/Alaska Native Communities

During the past 50 years, type 2 diabetes has become a major public health issue in many AI/AN communities, and it is increasingly recognized that AI/AN populations have a disproportionate burden of diabetes (Ghodes, 1995). In 2006, 16.1% of AI/ANs age 20 years or older had diagnosed diabetes (unpublished IHS Diabetes Program Statistics, 2006) compared to 7.8% for the non-Hispanic white population (CDC, 2007). In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population (Carter, 1996; Harris, 1995; Gilliland, 1997). Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

Under the Balanced Budget Act of 1997, Congress authorized the IHS to administer the SDPI grant program. SDPI grants are programmatically directed by the IHS Division of Diabetes Treatment and Prevention (DDTP).

Special Diabetes Program for Indians

The SDPI is a $150 million per year grant program. Over 330 programs have received SDPI Community-Directed grants annually since 1998. In addition, 66 demonstration projects have been funded annually since 2004 to address prevention of type 2 diabetes or cardiovascular disease risk reduction. A Congressional re-authorization in 2008 extended the SDPI through FY 2011.

II. Award Information

Type of Awards

Grants.

Estimated Funds Available

The total amount of funding identified for FY 2010 SDPI

Community-Directed grant program is $104.8 million. Funds available to each IHS Area and to urban Indian health programs have been determined through Tribal consultation. Within each Area, local Tribal consultation guided IHS decision-making on how much funding is available per eligible applicant. FY 2010 SDPI funding remains unchanged from FY 2009, per Tribal consultation. All awards issued under this announcement are subject to the availability of funds. In the absence of funding, the agency is under no obligation to make awards funded under this announcement.

Anticipated Number of Awards

Approximately 150 awards will be issued for Budget Cycle IV. Applications will be accepted from grantees whose current SDPI FY 2009 grants end on May 31, 2010. Additionally, applicants from Budget Cycles I, II or III that were deemed ineligible due to incomplete applications or that possessed delinquent OMB A–133 financial audits can resubmit applications under the timelines for Budget Cycle IV.

Project Period

The project period for grants made under this announcement is 24 months, subject to the availability of funds.

III. Eligibility Information

1. Eligible Applicants

Eligible applicants include the following:

- *Federally-recognized Tribes operating an Indian health program* operated pursuant to a contract, grant, cooperative agreement, or compact with the IHS pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), (Pub. L. 93–638).
- *Tribal organizations operating an Indian health program* operated pursuant to a contract, grant, cooperative agreement, or compact with the IHS pursuant to the ISDEAA, (Pub. L. 93–638).
- *Urban Indian health programs* that operate a Title V Urban Indian Health Program: This includes programs currently under a grant or contract with the IHS under Title V of the Indian Health Care Improvement Act, (Pub. L. 93–437).
- *Indian Health Service facilities* (refer to paragraph 3 below in this Section).

Current SDPI grantees are eligible to apply for competing continuation funding under this announcement and must demonstrate that they have complied with previous terms and conditions of the SDPI grant in order to receive funding under this announcement.

Non-profit Tribal organizations and national or regional health boards are not eligible, consistent with past Tribal consultation. Applicants that do not meet these eligibility requirements will have their applications returned without further consideration.

Under this announcement, only one SDPI Community-Directed diabetes grant will be awarded per entity. If a Tribe submits an application, their local IHS facility cannot apply; if the Tribe does not submit an application, the IHS facility can apply. Tribes that are awarded grant funds may sub-contract with local IHS facilities to provide specific clinical services. In this case, the Tribe would be the primary SDPI grantee and the Federal entity would have a sub-contract within the Tribe's SDPI grant.

Collaborative Arrangements

Tribes are encouraged to collaborate with any appropriate local entities including IHS facilities. If a Tribe seeks to provide specific clinical or support services, it may implement sub-contracts with these entities in order to transfer funds. The amount of SDPI funding that the Tribe receives remains the same. The Tribe, as the primary grantee, arranges with the entity to provide specified services that support the program's plan. The entity may request direct costs only.

When a Tribe sub-contracts with the local IHS facility, application requirements for collaborative arrangements include:

- A signed Memorandum of Agreement (MOA) must be submitted with the SDPI application. The MOA must include the scope of work assigned to the sub-contracting IHS facility.
- The IHS Area Director and the Tribal Chairperson must give signed approval of the MOA.
- The Tribe's application must include additional SF–424 and SF–424A forms that are completed by the IHS facility which includes a budget narrative and a face page that is signed by the Chief Executive Officer (CEO).

Applications With Sub-Grants

Programs that submit one application on behalf of multiple organizations (sub-grantees) must submit copies of selected application forms and documents for each of their sub-grantees. (*See* Section IV, Subsection 2 for specifics.) All sub-grantees must meet the eligibility requirements noted in Subsection 1 above.

2. Cost Sharing or Matching

The FY 2010 Special Diabetes Program for Indians (SDPI) Community-Directed grant program does not require matching funds or cost sharing.

3. Other Requirements

A. Program Coordinator

Provide information about the SDPI Program Coordinator on the "Key Contacts Form" which is included in the application package. The Program Coordinator must meet the following requirements:

- Have relevant health care education and/or experience.
- Have experience with program management and grants program management, including skills in program coordination, budgeting, reporting and supervision of staff.
- Have a working knowledge of diabetes.

B. Documentation of Support

Tribal Organizations

Existing SDPI grantees must submit a current, signed and dated Tribal resolution or Tribal letter of support from all Indian Tribe(s) served by the project. Applications from each Tribal organization must include specific resolutions or letters of support from all Tribes affected by the proposed project activities.

If the Tribal resolution or Tribal letter of support is not submitted with the application, it must be received in the Division of Grants Operations (DGO) by June 15, 2010. This date is prior to the objective review dates, June 21–24, 2010.

Title V Urban Indian Health Programs

Urban Indian health programs must submit a letter of support from the organization's board of directors. Urban Indian health programs are non-profit organizations and must also submit a copy of the 501(c)(3) Certificate. All letters of support must be included in the application or submitted to the DGO by June 15, 2010. This date is prior to the objective review dates, June 21–24, 2010.

IHS Hospitals or Clinics

IHS facilities must submit a letter of support from the CEO. The documentation must be received in the DGO by June 15, 2010. This date is prior to the objective review dates, June 21–24, 2010.

IV. Application and Submission Information

1. Obtaining Application Materials

The application package and instructions may be found at *www.Grants.gov.*

2. Content and Form of Application Submission

Mandatory documents for all applicants include:

- Application forms:
  - SF–424.
  - SF–424A.
  - SF–424B.
  - Key Contacts Form.
- Budget Narrative.
- Project Narrative.
- Tribal Resolution or Tribal Letter of Support (Tribal Organizations only).
- Letter of Support from Organization's Board of Directors (Title V Urban Indian Health Programs only).
- 501(c)(3) Certificate (Title V Urban Indian Health Programs only).
- CEO Letters of Support (IHS facilities only).
- 2008 and 2009 IHS Diabetes Care and Outcomes Audit Report.
- Biographical sketches for all Key Personnel.
- Disclosure of Lobbying Activities (SF–LLL) (if applicable).
- Documentation of OMB A–133 required Financial Audit for FY 2007 and FY 2008. Acceptable forms of documentation include:
  - E-mail confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or
  - Face sheets from audit reports. These can be found on the FAC Web site: *http://harvester.census.gov/fac/dissem/accessoptions.html?submit=Retrieve+Record.*

Mandatory Documents for Programs That Propose Sub-Grantees

The primary grantee for applications that propose sub-grantees must submit all of the mandatory documents listed above. In addition, they must submit the following documents for each sub-grantee:

- SF–424, SF–424A, SF–424B and Key Contacts Form.
- Project Narrative.
- Budget Narrative.
- 2008 and 2009 IHS Diabetes Care and Outcomes Audit Reports.

A separate budget is required for each sub-grantee, but the primary grantee's application must reflect the total budget for the entire cost of the project.

Mandatory Documents for Programs That Propose Sub-Contracts With Local IHS Facilities

Programs that propose sub-contracts with IHS facilities to provide clinical services must submit the documents noted below for the sub-contractor:

- MOA that is signed by the primary grantee, the sub-contractor, the IHS Area Director and the Tribal Chairperson.
- SF–424 and SF–424A forms completed by the IHS facility (in addition to the primary applicant's SF–424 forms).

A separate budget is required for the sub-contract, but the primary grantee's application must reflect the total budget for the entire cost of the project.

Public Policy Requirements: All Federal-wide public policies apply to IHS grants with the exception of the Discrimination Policy.

Requirements for Project and Budget Narratives

A. *Project Narrative:* This narrative should be a separate Word document that is no longer than 13–17 pages (see page limitations for each Part noted below) with consecutively numbered pages. Be sure to place all responses and required information in the correct section or they will not be considered or scored. If the narrative exceeds the page limit, only the first 13–17 pages will be reviewed. There are three parts to the narrative: Part A—Program Information; Part B—Program Planning and Evaluation; and Part C—Program Report. A sample project narrative and template are available in the application instructions. See below for additional details about what must be included in the narrative.

Part A: Program Information (no more than 4 pages)

Section 1: Community Needs Assessment

A1.1 Describe the burden of diabetes in your community. Include estimates of the number of people diagnosed with diabetes and the total number of people. Describe how you calculated these estimates.

A1.2 Briefly describe the top diabetes-related health issues in your community.

A1.3 Briefly describe the unique challenges your program experiences related to prevention and treatment of diabetes.

Section 2: Leadership Support

A2.1 Question: Has at least one organization administrator or Tribal leader agreed to be actively involved in your program's work? (Yes or No).

A2.2 Provide the name and role or position that this leader holds.

A2.3 Describe how this leader will be involved with your program.

Section 3: Personnel

Using the table format that is in the application instructions, provide the following information for each person who will be paid with SDPI funds:

A3.1 Name.

A3.2 Title.

A3.3 Brief description of tasks/activities.

A3.4 Is this person already on staff with your SDPI or diabetes program?

A3.5 What percent FTE of this person's salary will be paid using SDPI funds?

Section 4: Diabetes Audit Review

Obtain copies of your local IHS Diabetes Care and Outcomes Audit Reports for 2008 and 2009. Review and compare the results for these two years. Work with your local audit coordinator or Area Diabetes Consultant (ADC) if you need help.

A4.1 Provide a list of results for three to five items/elements (e.g., A1c, eye exam, education, etc.) that improved from 2008 to 2009.

A4.2 Provide a list of three to five items/elements that need to be improved.

A4.3 Describe how your program will address these three to five items/elements that need to be improved or describe how your program will work with your local health care facility to address these areas.

Section 5: Collaboration

A5.1 Describe existing partnerships and collaborations that your program has in place.

A5.2 Describe new partnerships and collaboration that your program is planning to implement.

Part B: Program Planning and Evaluation (no more than 3 pages, with 2 pages for each additional Best Practice)

Section 1: Overview

Each 2009 IHS Diabetes Best Practice includes two specific measures that are called "key measures." Programs may track additional measures based on local priorities. A list of all Best Practices is located in the application instructions. This list provides a short description of the contents and key measures for each Best Practice.

B1.1 List which IHS Diabetes Best Practice(s) your program will implement in order to address the needs that were identified in your community assessment.

Section 2: Program Planning

Provide the information requested below separately for each Best Practice that will be implemented:

B2.1 Target Population: What population will you target?

B2.2 Goal: Describe the goal that your program wants to achieve as a result of implementing the selected Best Practice.

B2.3 Objectives/Measures: List the objective(s) your program will work to accomplish, with at least one measure

identified for each objective. Be sure to include the two key measures for your selected Best Practice and use the Specific, Measurable, Action-oriented, Realistic and Time-bound (SMART) format (see application instructions for additional information). Also, indicate how frequently your program will review data for each measure. (Choose from the following options: weekly, twice a month, monthly, every other month, or quarterly).

B2.4 Activities: List the activities that your program will do to meet the selected Best Practice objectives. These could be events you will organize, services you will offer, materials you will develop and implement, or other activities.

Section 3: Evaluation

B3.1 Describe how your program will track activities for the selected Best Practice(s).

B3.2 Describe how your program will collect and track data on all measures (listed in Section 2 above) for the selected Best Practice(s).

B3.3 Describe how your program will collect stories about individual participants, community events, program staff, and other aspects of your program.

Part C: Program Report (no more than 4 pages)

Section 1: Major Accomplishments and Activities

C1.1 Describe three major accomplishments that your SDPI program achieved in the past 12 months.

C1.2 Describe three to five major accomplishments that your SDPI program has achieved since it began.

C1.3 Describe one story that exemplifies a major program accomplishment from the past year.

C1.4 Describe your SDPI program's primary activities during the past 12 months.

C1.5 Describe your SDPI program's primary activities since it began.

Section 2: Challenges

C2.1 Describe the two or three biggest challenges that your SDPI program encountered in the past 12 months.

C2.2 Describe how your SDPI program addressed these challenges.

C2.3 Indicate if you successfully addressed these challenges. (If so, why; if not, why not.)

Section 3: Dissemination

C3.1 Describe three to five major lessons that your SDPI program has learned since it began.

C3.2 Describe how your SDPI program has shared the lessons that you have learned with other diabetes programs.

C3.3 Describe materials or products your SDPI program has developed.

Section 4: Other Information

C4.1 Provide any additional information about your SDPI program.

B. Budget Narrative (no more than 4 pages)

The budget narrative should explain why each budget item on the SF–424A is necessary and relevant to the proposed project.

3. Submission Dates and Times

Applications are to be submitted electronically through Grants.gov by April 30, 2010 at 12 midnight Eastern Standard Time (EST). Any application received after the application deadline will not be accepted for processing, and it will be returned to the applicant(s) without further consideration for funding.

If technical challenges arise and the applicants need help with the electronic application process, contact Grants.gov Customer Support via e-mail to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Tammy Bagley, Senior Grants Policy Analyst, IHS Division of Grants Policy (DGP) *(tammy.bagley@ihs.gov)* at (301) 443–5204 to describe the difficulties being experienced. Be sure to contact Ms. Bagley at least ten days prior to the application deadline. Please do not contact the DGP until you have received a Grants.gov tracking number. In the event you are not able to obtain a tracking number, call the DGP as soon as possible.

If an applicant needs to submit a paper application instead of submitting electronically via Grants.gov, prior approval must be requested and obtained (see information under Subsection 6 " Electronic Submission Requirements" for additional information). The waiver must be documented in writing (e-mails are acceptable), before submitting a paper application. After a waiver is received, the application package must be downloaded by the applicant from Grants.gov. Once completed and printed, the original application and two copies must be sent to Denise E. Clark, Division of Grants Operations (DGO) (denise.clark@ihs.gov), 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852. Paper applications that are submitted without a waiver will be returned to the applicant without review or further consideration.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

A. Pre-award costs are allowable pending prior approval from the awarding agency. However, in accordance with 45 CFR Part 74 and 92, pre-award costs are incurred at the applicant'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 is less than anticipated.

B. The available funds are inclusive of direct and appropriate indirect costs (see Section VI, Subsection 3).

C. Only one grant will be awarded per applicant.

6. Electronic Submission Requirements

Use the *http://www.Grants.gov* Web site to submit an application electronically; select the "Apply for Grants" link on the homepage. Download a copy of the application package, complete it offline, and then upload and submit the application via the Grants.gov Web site. Electronic copies of the application may not be submitted as attachments to e-mail messages addressed to IHS employees or offices.

Applicants that receive a waiver to submit paper application documents must follow the rules and timelines that are noted below. The applicant must seek assistance at least ten 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 request timely assistance with technical issues will not be considered for a waiver to submit a paper application.

Please be aware of the following:

- Paper applications are not the preferred method for submitting applications.
- If you have problems electronically submitting your application on-line, contact Grants.gov Customer Support via e-mail to *support@grants.gov* or at (800) 518–4726. Customer Support is available to address questions 24 hours a day, 7 days a week (except on Federal holidays). If problems persist, contact Tammy Bagley, Senior Grants Policy Analyst, DGP, at (301) 443–5204.
- 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 to submit a paper application must be obtained.

• If it is determined that a waiver is needed, 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. If the waiver is approved, the application package must be downloaded by the applicant from Grants.gov. Once completed and printed, it should be sent directly to the DGO by the deadline date of April 30, 2010 (*see* Section IV, Subsection 3 for details).

• Upon entering the Grants.gov site, there is information that outlines the requirements to the applicant regarding electronic submission of an application through Grants.gov, as well as the hours of operation.

• Applicants are strongly encouraged 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.

• In order to use Grants.gov, the applicant must have a Dun and Bradstreet (DUNS) Number and register in the Central Contractor Registration (CCR). A minimum of ten working days should be allowed to complete CCR registration. *See* Subsection 8 below for more information.

• All documents must be submitted 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.

• The application must comply with any page limitation requirements described in the Funding Announcement.

• After you electronically submit your application, you will receive an automatic acknowledgment from Grants.gov that contains a Grants.gov tracking number. The DGO will download your application from Grants.gov and provide necessary copies to the DDTP. Neither the DGO nor the DDTP will notify applicants that the application has been received.

• You may access the electronic application package and instructions for this Funding Opportunity Announcement on http://www.Grants.gov.

• You may search for the application package on Grants.gov either with 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–2010–IHS–SDPI–0004.

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. Many organizations may already have a DUNS number. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number or to find out if your organization already has a DUNS number, access *http://fedgov.dnb.com/webform.*

Applicants must also be registered with the CCR. A DUNS number is required before an applicant can complete their CCR registration. Registration with the CCR is free of charge. Applicants may register online at *http://www.ccr.gov.* More detailed information regarding the DUNS, CCR, and Grants.gov processes can be found at: *http://www.Grants.gov.*

V. Application Review Information

1. Criteria

Criteria that will be used to evaluate the application are divided into three categories. They include:

• Project Narrative

The project narrative is divided into three parts: Part A—Program Information; Part B—Program Planning/Evaluation; and Part C—Project Report. Required information includes topics such as: Community needs assessment, leadership support, use of Diabetes Audit results, selected Best Practice(s), overall evaluation plan and project accomplishments. For each Best Practice that will be implemented, address: target population, goal, objectives/measures, review of key measures, and activities (*see* Section IV, Part B, Section 2).

• Budget Narrative

The budget narrative provides additional explanation to support the information provided on the SF–424A form. Budget categories to address include: Personnel, fringe benefits, travel, equipment and supplies, contractual/consultant and constructions/alterations/renovations. In addition to a line item budget, provide a brief justification of each budget item and how they support project objectives.

• Key Contacts Form

This form seeks to obtain contact information about only one person: the project's SDPI Program Coordinator.

Scoring of Applications

Points will be assigned in each category adding up to a total of 100. A minimum score of 60 points is required for funding. Points will be assigned as follows:

• *Project Narrative:* A total of 90 possible points are available for this information. It is divided into two parts: Program Information (20 possible points); Program Planning/Evaluation (60 possible points); and Program Report (10 possible points).

• *Budget Narrative:* A total of 10 possible points are available for this information.

2. Review and Selection Process

Each application will be prescreened by DGO staff for eligibility and completeness as outlined in this Funding Opportunity Announcement. Applications from entities that do not meet eligibility criteria or that are incomplete will not be reviewed. Applicants will be notified by the DGO that their application did not meet minimum requirements.

After being prescreened by the DGO, applications will be reviewed by an Objective Review Committee (ORC) and assigned a score. The ORC is an objective review group that will be convened by the DDTP in consultation with the DGP as required by Department of Health and Human Services (HHS) Grants Policy.

To obtain a minimum score for funding, applicants must address all program requirements and provide all required documentation. Applicants that receive less than a minimum score will be informed via e-mail of their application's deficiencies. (*See* Section 6 below for application revision guidance). A summary statement outlining the weaknesses of the application will be provided to these applicants. The summary statement will be sent to the Authorized Organizational Representative (AOR) that is identified on the face page of the application.

Review of Applications With Sub-Grants

When an application is submitted on behalf of multiple organizations (sub-grantees), the review score will be a combined score that is based on information provided by all of these organizations.

Programmatic Requirements

Funded applicants (grantees) must meet the following programmatic requirements:

A. Implement an IHS Diabetes Best Practice

Grantees must implement recommended services and activities from at least one 2009 IHS Diabetes Best Practice. They should implement recommendations based on program need, strengths, and resources. Program activities, services and key measures from the selected Best Practice(s) must be documented in the project narrative (*see* Section IV, Part B, Section 2).

B. Implement Program and Evaluation Plans

Grantees must follow the plans submitted with their application when implementing each selected Best Practice and their evaluation processes. A minimum evaluation requirement is to monitor the key measures over time. Programs may track additional measures based on local priorities.

C. Participate in Training and Peer-to-Peer Learning Sessions

Grantees must participate in SDPI training sessions and peer-to-peer learning activities. Training sessions will be primarily conference calls or combined WebEx/conference calls. Grantees will be expected to:

- Participate in interactive discussion during conference calls.
- Share activities, tools and results.
- Share problems encountered and how barriers are broken down.
- Share materials presented at conferences and meetings.
- Participate and share in other relevant activities.

Sessions, which will be led by DDTP, DGO, or their agents, will address clinical and other topics. Topics will include: program planning and evaluation, enhancing accountability through data management, and improvement of principles and processes. Grantees will integrate information and ideas in order to enhance effectiveness. Anticipated outcomes from participating in the learning sessions are improved communication and sharing among grantees, increased use of data for improvement, and enhanced accountability.

Application Revisions

If an application does not receive a minimum score for funding from the ORC, the applicant will be informed via a summary statement that will be sent to the AOR via e-mail. The applicant then has two opportunities to submit revisions to their application. Before application revisions can be submitted, the AOR must have received a summary statement from the previous review that outlines the weaknesses of the initial application.

A. Revision to Initial Application

Applicants will have five business days from the date that the summary statement is sent via e-mail to submit hard copies of their application revisions. Along with the revised application documents, applicants must prepare and submit an Introduction of not more than three pages that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to the criticism and issues raised in the summary statement.

The Introduction and revised application documents must be mailed directly to the DGO to the attention of Denise Clark, Lead Grants Management Specialist *(denise.clark@ihs.gov)* at: Division of Grants Operations, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852.

Technical assistance will be available to applicants as they prepare resubmission documentation.

An Ad Hoc Review Committee will be convened specifically to review the initial application revisions. If the revised application receives the minimum score for funding or above, the applicant will be informed via a Notice of Award (NoA). If the Review Committee determines that the application with revisions still does not receive a fundable score, the applicant will be informed of their application's deficiencies via a second summary statement that will be e-mailed to the AOR.

B. Second Application Revision

Applicants will have five business days from the date that the second summary statement is sent via e-mail to submit hard copies of their application revisions. Along with the revised application documents, applicants must prepare and submit an Introduction of not more than three pages that summarizes the substantial additions, deletions, and changes. The Introduction must also include responses to the criticism and issues raised in the summary statement.

The Introduction and revised application documents must, again, be mailed directly to the DGO to the attention of Denise Clark, Lead Grants Management Specialist *(denise.clark@ihs.gov)* at: Division of Grants Operations, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852.

A second Ad Hoc Review Committee will be convened to review the second application revisions. If the application with revisions receives the minimum score for funding or above, the applicant will be informed via a NoA.

If the Review Committee determines that the application with revisions still does not receive a fundable score, applicants will be informed in writing of their application's deficiencies.

Technical Assistance from Area Diabetes Consultants (ADCs) is available to all applicants in all cycles that did not/do not receive fundable scores. These applicants are encouraged to contact the ADC for their area to obtain assistance. Contact information for ADCs can be found on the Division of Diabetes Web site *http://www.diabetes.ihs.gov/index.cfm?module=peopleADCDirectory.*

7. Anticipated Announcement and Award Dates

Grantees that receive a fundable score will be notified of their approval for funding via the NoA.

VI. Award Administration Information

1. Award Notices

The NoA will be prepared by the DGO and sent via postal mail to each applicant that is approved for funding under this announcement. This document will be sent to the person who is listed on the SF–424 as the AOR. The NoA will be signed by the Grants Management Officer. The NoA is the authorizing document for which funds are dispersed to the approved entities. The NoA serves as the official notification of the grant award and reflects 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 disapproved based on the ORC score will receive a copy of the summary statement which identifies the weaknesses and strengths of the application submitted. The AOR serves as the business point of contact for all business aspects of the award.

The anticipated NoA date for all applicants that score well in the ORC review for Cycle IV is July 15, 2010.

2. Administrative Requirements

Grants are administered in accordance with the following regulations, policies, and Office of Management and Budget (OMB) cost principles:

A. The criteria as outlined in this Funding Opportunity Announcement.

B. Administrative Regulations for Grants:

- 45 CFR Part 92—Uniform Administrative Requirements for Grants

and Cooperative Agreements to State, Local and Tribal Governments.

• 45 CFR Part 74—Uniform Administrative Requirements for Awards and Subawards to Institutions of Higher Education, Hospitals, Other Non-Profit Organizations, and Commercial Organizations.

C. Grants Policy:

• HHS Grants Policy Statement, Revised 01/2007.

D. Cost Principles:

• OMB Circular A–87—State, Local, and Indian Tribal Governments (Title 2 Part 225).

• OMB Circular A–122—Non-Profit Organizations (Title 2 Part 230).

E. 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 obtain a current indirect cost rate agreement 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 covers the applicable grant activities under the current award's 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. The restrictions remain in place until the current rate is provided to the DGO.

Generally, indirect costs rates for IHS grantees are negotiated with the HHS Division of Cost Allocation *http://rates.psc.gov/* and the Department of the Interior (National Business Center) at *http://www.aqd.nbc.gov/indirect/indirect.asp.* If your organization has questions regarding the indirect cost policy, please contact the DGO at (301) 443–5204.

4. Reporting Requirements

The DDTP and the DGO have requirements for progress reports and financial reports based on the terms and conditions of this grant as noted below.

A. Progress Reports

Program progress reports are required semi-annually. These reports must include at a minimum: Reporting of Best Practice measures; and a brief comparison of actual accomplishments to the goals established for the budget period or provide sound justification for the lack of progress.

B. Financial Status Reports

Annual financial status reports are required until the end of the project period. Reports must be submitted annually no later than 30 days after the end of each specified reporting period. The final financial status report is due within 90 days after the end of the 24 month project period. Standard Form 269 (long form for those reporting program income; short form for all others) will be used for financial reporting.

Grantees are responsible and accountable for accurate reporting of the Progress Reports and Financial Status Reports (FSR). According to SF–269 instructions, the final SF–269 must be verified from the grantee records to support the information outlined in the FSR.

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.

C. FY 2007 and FY 2008 Single Audit Reports (OMB A–133)

Applicants who have an active SDPI grant are required to be up-to-date in the submission of required audit reports. These are the annual financial audit reports required by OMB A–133, audits of state, local governments, and non-profit organizations that are submitted. Documentation of (or proof of submission) of current FY 2007 and FY 2008 Financial Audit Reports is mandatory. Acceptable forms of documentation include: e-mail confirmation from FAC that audits were submitted; or face sheets from audit reports. Face sheets can be found on the FAC Web site: *http://harvester.census.gov/fac/dissem/accessoptions.html?submit=Retrieve+Records.*

Telecommunication for the hearing impaired is available at: TTY (301) 443–6394.

VII. Agency Contacts

• For Grants Budget Management, contact:

• Denise Clark, Lead Grants Management Specialist, DGO *(denise.clark@ihs.gov),* Division of Grants Operations, 801 Thompson Avenue, TMP, Suite 360, Rockville, MD 20852, (301) 443–5204.

• For Grants.gov electronic application process, contact:

• Tammy Bagley, Grants Policy, DGP *(tammy.bagley@ihs.gov),* (301) 443–5204, Grants Policy Web site:*http://www.ihs.gov/NonMedicalPrograms/gogp/index.cfm?module=gogp_funding.*

• For programmatic questions, contact:

• Bonnie Bowekaty, Program Assistant, DDTP *(bonnie.bowekaty@ihs.gov),* (505) 248–4182;

• Lorraine Valdez, Deputy Director, DDTP *(s.lorraine.valdez@ihs.gov),* (505) 248–4182;

• Area Diabetes Consultants Web site: *http://www.ihs.gov/MedicalPrograms/diabetes/index.cfm?module=peopleADCDirectory.*

Dated: March 12, 2010.

Yvette Roubideaux,

Director, Indian Health Service.

[FR Doc. 2010–7103 Filed 3–30–10; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Anti-Infective Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Anti-Infective Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 29, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Minh Doan, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery,

5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *minh.doan@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512530. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On April 29, 2010, the committee will discuss the efficacy and safety of new drug application (NDA) 21–242, artesunate rectal suppositories, submitted by the World Health Organization, for the proposed use as a single dose for the initial treatment of patients with acute malaria who cannot take medication by mouth and for whom injectable treatment is not available.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before April 15, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. to 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before April 7, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by April 8, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Minh Doan at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 25, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–7113 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice Of Amendment—OS ARRA Expansion of Research Capabilities To Study CE Complex Patients (R24) SEP Meeting

With this correction notice, the Agency for Healthcare Research and Quality (AHRQ) informs the public of an amendment made to the notice subject mentioned above published on March 18, 2010 Vol. 75, No. 52, Second paragraph of pages 13 135–13136.

The revised should read: "DATE: April 15–16, 2010 (Open on April 15 from 8 a.m. to 8:15 am. and closed for the remainder of the meeting)".

Dated: March 19, 2010.

Carolyn M. Clancy,

Director.

[FR Doc. 2010–6784 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–2312–N]

DEPARTMENT OF LABOR

Employee Benefits Security Administration

Medicaid and CHIP Programs; Meeting of the CHIP Working Group—April 26, 2010

AGENCIES: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (DHHS); Employee Benefits Security Administration (EBSA), Department of Labor (DOL).

ACTION: Notice.

SUMMARY: This notice announces the first meeting of the Medicaid, Children's Health Insurance Program ("CHIP"), and Employer-Sponsored Coverage Coordination Working Group (referred to as the "CHIP Working Group"). The CHIP Working Group will meet to address objectives specified under section 311(b)(1)(C) of the Children's Health Insurance Program Reauthorization Act of 2009. This meeting is open to the public.

DATES: *Meeting Date:* Monday, April 26, 2010 from 9 a.m. to 5 p.m., Eastern Standard Time (E.S.T.).

Deadline for Registration without Oral Presentation: April 21, 2010, 12 p.m., E.S.T.

Deadline for Registration of Oral Presentations: April 12, 2010 12 p.m., E.S.T.

Deadline for Submission of Oral Remarks and Written Comments: April 12, 2010 12 p.m., E.S.T.

Deadline for Requesting Special Accommodations: April 12, 2010 12 p.m., E.S.T.

ADDRESSES: *Meeting Location:* The meeting will be held at the Omni Shoreham, 2500 Calvert Street, NW. at Connecticut Avenue in Washington, DC 20008.

Submission of Testimony: Testimonies should be mailed to Stacey Green, Designated Federal Official (DFO), Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail stop C2–04–04, Baltimore, MD 21244–1850, or contact the DFO via e-mail at *stacey.green@cms.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Stacey Green, DFO, Centers for Medicare & Medicaid Services, DHHS at (410) 786–6102, or Amy Turner,

Employee Benefits Security Administration, DOL at (202) 693–8335. News media representatives must contact the CMS Press Office, (202) 690–6145. Please refer to the Internet at *http://www.cms.hhs.gov/FACA,* or *http://www.dol.gov/ebsa/CHIP.html* for additional information and updates on committee activities.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 10(a) of the Federal Advisory Committee Act (FACA), this notice announces the first meeting of the Medicaid, CHIP, and Employer-Sponsored Coverage Coordination Working Group ("CHIP Working Group"). The Secretary of Health and Human Services and the Secretary of Labor are required under section 311(b)(1)(C) of the Children's Health Insurance Program Reauthorization Act (CHIPRA) of 2009 (Pub. L. 111–3), enacted February 4, 2009, to jointly establish a CHIP Working Group. The membership of the group is based on nominations submitted in response to a **Federal Register** solicitation notice published on May 1, 2009 (74 FR 20323). The CHIP Working Group will meet two times to develop a model coverage coordination disclosure form for group health plan administrators to send to States upon request regarding benefits available under the plan. This notice will enable States to determine the availability and cost-effectiveness of providing premium assistance to individuals eligible for benefits under titles XIX or XXI of the Social Security Act (the Act) to enable them to enroll in group health plans. The CHIP Working Group will identify and report on the impediments to the effective coordination of coverage available to families that include employees of employers that maintain group health plans and members who are eligible for medical assistance under title XIX of the Act or child health assistance or other health benefits coverage under title XXI of the Act.

Not later than August 5, 2010, the CHIP Working Group must submit to the Secretary of Labor and the Secretary of Health and Human Services the model coverage coordination disclosure form and the report containing recommendations for appropriate measures for addressing the impediments to the effective coordination of coverage.

The CHIP Working Group consists of 22 individuals, including 2 Co-Chairs. Members of the CHIP Working Group are composed of representatives of the Department of Labor (DOL); the Department of Health and Human Services (DHHS); State directors of the Medicaid Program under title XIX of the Act; State directors of the State Children's Health Insurance Program under title XXI of the Act; employers, including owners of small businesses and their trade or industry representatives and certified human resource and payroll professionals; plan administrators and plan sponsors of group health plans as defined in section 607(1) of the Employee Retirement Income Security Act of 1974, as amended; health insurance issuers; and representatives of children and other beneficiaries of medical assistance under title XIX of the Act or child health assistance or other health benefits coverage under title XXI of the Act. Members serve for the duration of the committee.

The current members are:

- Department of Labor: Phyllis Borzi;
- Department of HHS: Victoria Wachino;
- State Representatives, including Medicaid and CHIP Directors: Mari Spaulding-Bynon, Rhonda Medows, Howard "Rocky" King, Ann Clemency Kohler; Janet Olszewski, Linda Sheppard, and Anita Smith;
- Employers, Plan Sponsors, and Plan Administrators: Emma Bennett-Williams, Barbara Caress, Roberta Casper Watson, Greta Cowart, Kaye Pestaina, and Mark Stember;
- Health Insurance Issuers: Terry Bayer, Ellyn Fuchsteiner, and Kevin Hayden; and
- Representatives of Children and Other Beneficiaries of Medical Assistance: Joan Alker, George Askew, Miguel Carranza, and Karen Pollitz.

II. Meeting Format and Agenda

The meeting will commence with welcoming remarks for the CHIP Working Group by Departmental representatives. In addition, the agenda will focus on the following:

- Opening statements from the Co-Chairs, as well as introductions and remarks by other CHIP Working Group members;
- Swearing in of members;
- An overview of FACA requirements;
- An overview by DOL and HHS staff of the deliverables that the CHIP Working Group is responsible for under CHIPRA:
  + A model coverage coordination disclosure form for plan administrators of group health plans.
  + A report containing recommendations for appropriate measures for addressing the impediments to the effective coordination of coverage between group health plans and title XIX and XXI State plans.
- An opportunity for public comment and testimony.

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual or organizational stakeholders that represent the focus area of the CHIP Working Group wishing to present a 5–minute oral testimony on agenda issues must register with the DFO by the date listed in the **DATES** section of this notice. Testimony is limited to agenda topics only. The number of oral testimonies may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to the DFO for distribution to CHIP Working Group members for review before the meeting by the date listed in the **DATES** section of this notice. Individual and organizational stakeholders not scheduled to speak may also submit written comments to the DFO for distribution by the date listed in the **DATES** section of this notice.

III. Meeting Registration and Security Information

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at the number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice.

Individuals requiring sign language interpretation or other special accommodations must contact the DFO via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

Authority: Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).

Dated: March 25, 2010.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: March 23, 2010.

Michael L. Davis,

Deputy Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

[FR Doc. 2010–7225 Filed 3–29–10; 8:45 am]

BILLING CODE 4120–01–P; 4510–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Antiviral Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Antiviral Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 2, 2010, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/ Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301–589–5200.

Contact Person: Paul Tran, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX: 301–827–6776, e-mail: *paul.tran@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512531. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On June 2, 2010, the committee will discuss biologics license application (BLA) 125283, motavizumab, MedImmune, LLC, proposing an indication for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 18, 2010. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 10, 2010. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 11, 2010.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Paul Tran at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 23, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010–7114 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Scientific Management Review Board.

The meeting will be open to the public, with attendance limited to space available. Registration is required since space is limited. Please visit the conference Web site for information on meeting logistics and to register for the meeting *http://www.circlesolutions.com/ncs/ncsac/index.cfm*. 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 Children's Study Advisory Committee.

Date: April 27, 2010.

Time: 9 a.m.to 12 p.m.

Agenda: The agenda will include an update on the current status of the Study, a legislative update, and a discussion pertaining to the National Children's Study Communications Plan.

Place: Fishers Lane Conference Center, 5635 Fishers Lane, Rockville, MD 20852.

Contact Person: Jessica E. DiBari, MHS, Executive Secretary, National Children's Study, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 3A01, Bethesda, MD 20892, (301) 451–2135.

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. For additional information about the Federal Advisory Committee meeting, please contact Circle Solutions at *ncs@circlesolutions.com*.

(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, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–7187 Filed 3–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Loan Repayment Program (L30's).

Date: April 28, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institute of Health, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Robert Blaine Moore, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7213, Bethesda, MD 20892. 301–594–8394. *mooreb@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Echocardiography Reading Center for Atherosclerosis Risk in Communities Study.

Date: April 29, 2010.

Time: 8 a.m. to 1 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: Tony L Creazzo, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924. 301–435–0725. *creazzot@mail.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, Cardiovascular Outcomes Research Center for the Atherosclerosis Risk in Communities Study.

Date: April 29, 2010.

Time: 1:30 p.m. to 4 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: Tony L Creazzo, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892–7924. 301–435–0725. *creazzot@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 25, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–7184 Filed 3–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance 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.

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 Heart, Lung, and Blood Advisory Council.

Date: May 26, 2010.

Open: 8 a.m. to 12 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Closed: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892.

Contact Person: Stephen C. Mockrin, Ph.D., Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7100, Bethesda, MD 20892. (301) 435–0260. *mockrins@nhlbi.nih.gov.*

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.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.nhlbi.nih.gov/meetings/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: March 25, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–7181 Filed 3–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, April 7, 2010, 8 a.m. to April 8, 2010, 5 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on March 17, 2010, 75 FR 12766.

The meeting will be held April 14, 2010 to April 15, 2010. The meeting time and location remain the same. The meeting is closed to the public.

Dated: March 24, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–7180 Filed 3–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Cancer Institute Special Emphasis Panel; Cancer Immunotherapy Trials Network.

Date: June 7, 2010.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Hilton, 620 Perry Parkway, Gaithersburg, MD 20877.

Contact Person: Kenneth L. Bielat, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 7147, Bethesda, MD 20892–8329, 301–496–7576, *bielatk@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 24, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–7178 Filed 3–30–10; 8:45 am]

BILLING CODE 4140–01–P

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. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke. The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Neurological Disorders and Stroke, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Neurological Disorders and Stroke.

Date: June 13–14, 2010.

Time: 7 a.m. to 6 p.m.

Agenda: To review and evaluate personal qualifications and performance, and competence of individual investigators.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Diplomat/Ambassador Room, Bethesda, MD 20814.

Contact Person: Alan P. Koretsky, PhD, Scientific Director, Division of Intramural Research, National Institute of Neurological Disorders & Stroke, NIH, 35 Convent Drive, Room 6A 908, Bethesda, MD 20892. 301–435–2232. *koretskya@ninds.nih.gov.*

(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 24, 2010.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–7088 Filed 3–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–259]

Proposed Substances To Be Evaluated for Set 24 Toxicological Profiles

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Request for comments on the proposed substances to be evaluated for Set 24 toxicological profiles.

SUMMARY: This notice announces the list of proposed substances that will be evaluated for Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) Set 24 toxicological profile development. ATSDR's Division of Toxicology and Environmental Medicine is soliciting public comments on the list of proposed substances to be evaluated for toxicological profile development. ATSDR also will consider the nomination of any additional, substances, not on this list, that may have public health implications.

DATES: Nominations must be submitted within 30 days of the publication of this notice.

ADDRESSES: Nominations may be submitted electronically. Refer to the section *Submission of Nominations* (following) for the specific address.

FOR FURTHER INFORMATION CONTACT: For further information, contact: Commander Jessilynn B. Taylor, Division of Toxicology and Environmental Medicine, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, F–62, Atlanta, GA, 30333; telephone: (770) 488–3313; or e-mail: *jbtaylor@cdc.gov.*

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act of 1986 (SARA) [42 U.S.C. 9601 *et seq.*] amended the CERCLA (or Superfund) [42 U.S.C. 9601 *et seq.*] by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (EPA) with regard to hazardous substances most commonly found at facilities on the CERCLA NPL. Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the Priority List of Hazardous Substances. This identifies 275 hazardous substances that ATSDR and EPA have determined pose the most significant potential threat to human health (*http://www.atsdr.cdc.gov/cercla/07list.html*). The availability of the revised list of the 275 priority substances was announced in the **Federal Register** on March 6, 2008 (73 FR 12178). For prior versions of the list of substances, see **Federal Register** notices dated April 17, 1987 (52 FR 12866); October 20, 1988 (53 FR 41280); October 26, 1989 (54 FR 43619); October 17, 1990 (55 FR 42067); October 17, 1991 (56 FR 52166); October 28, 1992 (57 FR 48801); February 28, 1994 (59 FR 9486); April 29, 1996 (61 FR 18744; November 17, 1997 (62 FR 61332); October 21, 1999 (64 FR 56792); October 25, 2001 (66 FR 54014); and November 7, 2003 (68 FR 63098), December 7, 2005 (70 FR 72840).

Proposed Substances To Be Evaluated for Set 24 Toxicological Profiles

Each year, ATSDR develops a list of substances to be considered for toxicological profile development. This list is compiled from ATSDR's Priority List of Hazardous Substances and from previously nominated substances of public health concern. The following list of 240 proposed substances will be considered for Set 24 Toxicological Profile development.

	Substances	CAS Nos.
1	METHANE	000074–82–8
2	BROMODICHLOROETHANE	000683–53–4
3	1,2,3–TRICHLOROBENZENE	000087–61–6
4	POLONIUM–210	013981–52–7
5	LEAD–210	014255–04–0
6	NEPTUNIUM–237	013994–20–2
7	S,S,S–TRIBUTYL PHOSPHOROTRITHIOATE	000078–48–8
8	BROMINE	007726–95–6
9	DICOLFOL	000115–32–2
10	PARATHIION	000056–38–2
11	TRICHLOROFLUOROETHANE	027154–33–2
12	TRIFLURALIN	000152–09–8
13	PENTACHLOROBENZENE	000608–93–5
14	TRICHLOROETHANE	025323–89–1
15	PALLADIUM	007440–05–3
16	DIBENZOFURAN	000132–64–9
17	2,4-DIMETHYLPHENOL	000105–67–9
18	TETRACHLOROETHANE	025322–20–7
19	BIS(2-METHOXYETHYL)PHTHALATE	034006–76–3
20	BUTYL BENZYL PHTHALATE	000085–68–7
21	1,2,4-TRICHLOROBENZENE	000120–82–1
22	NITRITE	014797–65–0
23	NITRATE	014797–55–8
24	POTASSIUM–40	013966–00–2
25	THORIUM–227	015623–47–9
26	PHORATE	000298–02–2
27	DIMETHOATE	000060–51–5
28	ACTINIUM–227	014952–40–0
29	STROBANE	008001–50–1
30	4–AMINOBIPHENYL	000092-67–1
31	ARSINE	007784–42–1
32	NALED	000300–76–5
33	ETHOPROP	013194–48–4
34	CARBOPHENOTHION	000786–19–6
35	2,4–D ACID	000094–75–7
36	DIURON	000330–54–1
37	BUTYLATE	002008–41–5
38	DIMETHYL FORMAMIDE	000068–12–2
39	DICHLOROBENZENE	025321–22–6
40	ETHYL ETHER	000060–29–7
41	DICHLOROETHANE	001300–21–6
42	PHOSPHINE	007803–51–2
43	TRICHLOROBENZENE	012002–48–1
44	PENTAERYTHRITOL TETRANITRATE	000078–11–5
45	BIS(2-ETHYLHEXYL)ADIPATE	000103–23–1
46	CARBAZOLE	000086–74–8
47	METHYL ISOBUTYL KETONE	000108–10–1
48	CARBARYL	000063–25–2
49	MERCURY	007439–97–6
50	METHYLMERCURY	022967–92–6
51	MERCURIC CHLORIDE	007487–94–7
52	POLYCHLORINATED BIPHENYLS	001336–36–3
53	AROCLOR 1254	011097–69–1
54	AROCLOR 1260	011096–82–5
55	AROCLOR 1248	012672–29–6
56	AROCLOR 1242	053469–21–9
57	AROCLOR	012767–79–2
58	AROCLOR 1221	011104–28–2
59	AROCLOR 1016	012674–11–2
60	AROCLOR 1232	011141–16–5
61	AROCLOR 1240	071328–89–7
62	TETRACHLOROBIPHENYL	026914–33–0
63	POLYCYCLIC AROMATIC HYDROCARBONS	130498–29–2
64	BENZO(A)PYRENE	000050–32–8
65	BENZO(B)FLUORANTHENE	000205–99–2
66	DIBENZO(A,H)ANTHRACENE	000053–70–3
67	BENZO(A)ANTHRACENE	000056–55–3
68	BENZO(K)FLUORANTHENE	000207–08–9

	Substances	CAS Nos.
69	BENZOFLUORANTHENE	056832–73–6
70	FLUORANTHENE	000206–44–0
71	CHRYSENE	000218–01–9
72	ACENAPHTHENE	000083–32–9
73	INDENO(1,2,3–CD)PYRENE	000193–39–5
74	BENZOPYRENE	073467–76–2
75	PHENANTHRENE	000085–01–8
76	PYRENE	000129–00–0
77	FLUORENE	000086–73–7
78	ANTHRACENE	000120–12–7
79	BENZO(A)FLUORANTHENE	000203–33–8
80	BENZO(GHI)PERYLENE	000191–24–2
81	ACENAPHTHYLENE	000208–96–8
82	BENZO(J)FLUORANTHENE	000205–82–3
83	BENZO(E)PYRENE	000192–97–2
84	BENZOPERYLENE	011057–45–7
85	BENZO(B)ANTHRACENE	000092–24–0
86	DIBENZ(A,J)ANTHRACENE	000224–41–9
87	BENZO(GHI)FLUORANTHENE	000203–12–3
88	1–METHYLPYRENE	002381–21–7
89	CHLOROFORM	000067–66–3
90	DDT, P,P′-	000050–29–3
91	DDE, P,P′-	000072–55–9
92	DDD, P,P′-	000072–54–8
93	DDT, O,P′-	000789–02–6
94	DDD, O,P′-	000053–19–0
95	DDE, O,P′-	003424–82–6
96	TRICHLOROETHYLENE	000079–01–6
97	DIELDRIN	000060–57–1
98	ALDRIN	000309–00–2
99	CHLORDANE	000057–74–9
100	CIS–CHLORDANE	005103–71–9
101	TRANS–CHLORDANE	005103–74–2
102	OXYCHLORDANE	027304–13–8
103	GAMMA–CHLORDENE	056641–38–4
104	CHLORDANE, TECHNICAL	012789–03–6
105	ALPHA–CHLORDENE	056534–02–2
106	NONACHLOR, TRANS-	039765–80–5
107	NONACHLOR, CIS-	005103–73–1
108	CHLORDENE	003734–48–3
109	HEXACHLOROBUTADIENE	000087–68–3
110	COAL TAR CREOSOTE	008001–58–9
111	COAL TARS	008007–45–2
112	DDD, P,P′-	000072–54–8
113	COAL TAR PITCH	065996–93–2
114	BENZIDINE	000092–87–5
115	TOXAPHENE	008001–35–2
116	TETRACHLOROETHYLENE	000127–18–4
117	1,2–DIBROMOETHANE	000106–93–4
118	DISULFOTON	000298–04–4
119	3,3′-DICHLOROBENZIDINE	000091–94–1
120	ENDRIN	000072–20–8
121	ENDRIN KETONE	053494–70–5
122	ENDRIN ALDEHYDE	007421–93–4
123	BERYLLIUM	007440–41–7
124	1,2–DIBROMO–3–CHLOROPROPANE	000096–12–8
125	DIBROMOCHLOROPROPANE	067708–83–2
126	PENTACHLOROPHENOL	000087–86–5
127	DI–N–BUTYL PHTHALATE	000084–74–2
128	ENDOSULFAN	000115–29–7
129	ENDOSULFAN SULFATE	001031–07–8
130	ENDOSULFAN, ALPHA	000959–98–8
131	ENDOSULFAN, BETA	033213–65–9
132	METHOXYCHLOR	000072–43–5
133	METHANE	000074–82–8
134	TOLUENE	000108–88–3
135	2–HEXANONE	000591–78–6
136	2,3,7,8–TETRACHLORODIBENZO–P–DIOXIN	001746–01–6
137	HEXACHLORODIBENZO–P–DIOXIN	034465–46–8
138	HEPTACHLORODIBENZO–P–DIOXIN	037871–00–4
139	TETRACHLORODIBENZO–P–DIOXIN	041903–57–5
140	PENTACHLORODIBENZO–P–DIOXIN	036088–22–9
141	1,2,3,4,6,7,8–HEPTACHLORODIBENZO–P–DIOXIN	035822–46–9
142	OCTACHLORODIBENZO–P–DIOXIN	003268–87–9

	Substances	CAS Nos.
143	1,2,3,6,7,8–HEXACHLORODIBENZO–P–DIOXIN	057653–85–7
144	1,2,3,4,7,8–HEXACHLORODIBENZO–P–DIOXIN	039227–28–6
145	1,2,3,7,8,9–HEXACHLORODIBENZO–P–DIOXIN	019408–74–3
146	1,2,3,7,8–PENTACHLORODIBENZO–P–DIOXIN	040321–76–4
147	DI(2–ETHYLHEXYL)PHTHALATE	000117–81–7
148	1,1–DICHLOROETHENE	000075–35–4
149	METHYLENE CHLORIDE	000075–09–2
150	BROMODICHLOROETHANE	000683–53–4
151	1,2–DICHLOROETHANE	000107–06–2
152	2,4,6–TRICHLOROPHENOL	000088–06–2
153	TETRACHLOROPHENOL	025167–83–3
154	2,4–DICHLOROPHENOL	000120–83–2
155	2,4,5–TRICHLOROPHENOL	000095–95–4
156	2–CHLOROPHENOL	000095–57–8
157	2,3,4,5–TETRACHLOROPHENOL	004901–51–3
158	2,3,5,6–TETRACHLOROPHENOL	000935–95–5
159	2,3,4,6–TETRACHLOROPHENOL	000058–90–2
160	4–CHLOROPHENOL	000106–48–9
161	CHLOROPHENOL	025167–80–0
162	2,4–DINITROPHENOL	000051–28–5
163	BIS(2–CHLOROETHYL) ETHER	000111–44–4
164	ASBESTOS	001332–21–4
165	CHRYSOTILE ASBESTOS	012001–29–5
166	AMOSITE ASBESTOS	012172–73–5
167	HEXACHLOROBENZENE	000118–74–1
168	2,4–DINITROTOLUENE	000121–14–2
169	DINITROTOLUENE	025321–14–6
170	2,6–DINITROTOLUENE	000606–20–2
171	RADIUM–226	013982–63–3
172	RADIUM	007440–14–4
173	RADIUM–228	015262–20–1
174	RADIUM–224	013233–32–4
175	ETHION	000563–12–2
176	THORIUM	007440–29–1
177	THORIUM–230	014269–63–7
178	THORIUM–228	014274–82–9
179	4,6–DINITRO–O–CRESOL	000534–52–1
180	CHLOROBENZENE	000108–90–7
181	N–NITROSODI–N–PROPYLAMINE	000621–64–7
182	1,2,3–TRICHLOROBENZENE	000087–61–6
183	POLONIUM–210	013981–52–7
184	CHLORPYRIFOS	002921–88–2
185	NEPTUNIUM–237	013994–20–2
186	CHLORDECONE	000143–50–0
187	MIREX	002385–85–5
188	S,S,S–TRIBUTYL PHOSPHOROTRITHIOATE	000078–48–8
189	BROMINE	007726–95–6
190	DICOFOL	000115–32–2
191	PARATHION	000056–38–2
192	SELENIUM	007782–49–2
193	TRICHLOROFLUOROETHANE	027154–33–2
194	TRIFLURALIN	001582–09–8
195	4,4'-METHYLENEBIS(2–CHLOROANILINE)	000101–14–4
196	PENTACHLOROBENZENE	000608–93–5
197	1,1–DICHLOROETHANE	000075–34–3
198	1,2,3,4,6,7,8,9–OCTACHLORODIBENZOFURAN	039001–02–0
199	HEPTACHLORODIBENZOFURAN	038998–75–3
200	2,3,4,7,8–PENTACHLORODIBENZOFURAN	057117–31–4
201	HEXACHLORODIBENZOFURAN	055684–94–1
202	PENTACHLORODIBENZOFURAN	030402–15–4
203	2,3,7,8–TETRACHLORODIBENZOFURAN	051207–31–9
204	DIBENZOFURANS, CHLORINATED	042934–53–2
205	1,2,3,4,6,7,8–HEPTACHLORODIBENZOFURAN	067562–39–4
206	1,2,3,7,8,9–HEXACHLORODIBENZOFURAN	072918–21–9
207	TETRACHLORODIBENZOFURAN	030402–14–3
208	1,2,3,6,7,8–HEXACHLORODIBENZOFURAN	057117–44–9
209	1,2,3,4,7,8–HEXACHLORODIBENZOFURAN	070648–26–9
210	2,3,4,6,7,8–HEXACHLORODIBENZOFURAN	060851–34–5
211	1,2,3,7,8–PENTACHLORODIBENZOFURAN	057117–41–6
212	1,2,3,4,7,8,9–HEPTACHLORODIBENZOFURAN	055673–89–7
213	1,1,2–TRICHLOROETHANE	000079–00–5
214	HEXACHLOROCYCLOPENTADIENE	000077–47–4
215	1,2–DIPHENYLHYDRAZINE	000122–66–7
216	1,2–DICHLOROETHENE, TRANS-	000156–60–5

	Substances	CAS Nos.
217	1,2–DICHLOROETHYLENE	000540–59–0
218	1,2–DICHLOROETHENE, CIS-	000156–59–2
219	CARBON DISULFIDE	000075–15–0
220	PALLADIUM	007440–05–3
221	CHLOROETHANE	000075–00–3
222	ACETONE	000067–64–1
223	DIBENZOFURAN	000132–64–9
224	2,4–DIMETHYLPHENOL	000105–67–9
225	CHLOROMETHANE	000074–87–3
226	BIS(2–METHOXYETHYL) PHTHALATE	034006–76–3
227	BUTYL BENZYL PHTHALATE	000085–68–7
228	N–NITROSODIMETHYLAMINE	000062–75–9
229	1,2,4–TRICHLOROBENZENE	000120–82–1
230	N–NITROSODIPHENYLAMINE	000086–30–6
231	2–BUTANONE	000078–93–3
232	FLUORINE	007782–41–4
233	HYDROGEN FLUORIDE	007664–39–3
234	FLUORIDE ION	016984–48–8
235	AMMONIA	007664–41–7
236	COPPER	065357–62–2
237	CHLORINE DIOXIDE	010049–04–4
238	PBBs	059536–65–1
239	PBDEs	001163–19–5
240	SYNTHETIC VITREOUS FIBERS	NONE

Submission of Nominations for the Evaluation Set 24 Proposed Substances: Today's notice also invites voluntary public nominations for substances not listed in this notice. Nominations are most useful if they include the nominator, including full name, title, affiliation, e-mail address, and telephone number.

ATSDR will evaluate all data and information associated with nominated substances and will determine the final list of substances to be chosen for toxicological profile development. Substances will be chosen according to ATSDR's specific guidelines for selection, found in the *Selection Criteria* announced in the **Federal Register** on May 7, 1993 (87 FR 27288).

Submission of Comments: Submit comments via e-mail at: *tpcandidatecomments@cdc.gov.* Please include "Set 24" in the subject line of the e-mail. Or, mail to: Commander Jessilynn B. Taylor, Division of Toxicology and Environmental Medicine, 1600 Clifton Road, MS F–62, Atlanta, GA 30333; e-mail: *jbtaylor@cdc.gov.*

Please ensure that your comments are submitted within the specified nomination period. Nominations received after the closing date will be marked as late and may be considered only if time and resources permit.

Dated: March 26, 2010.

Ken Rose,

Associate Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. 2010–7169 Filed 3–30–10; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0001]

Pharmaceutical Supply Chain; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled "2010 PDA/FDA Pharmaceutical Supply Chain Workshop—Enough Talk: Let's Find and Implement Solutions." The workshop, cosponsored with the Parenteral Drug Association (PDA), will focus on solutions to reduce the risk to product quality in the pharmaceutical supply chain.

Date and Time: The conference will be held on Monday, April 26, 2010, from 8 a.m. to 6 p.m.; Tuesday, April 27, 2010, from 7:15 a.m. to 5:45 p.m.; and Wednesday, April 28, 2010, from 7:15 a.m. to 1:15 p.m.

Location: The public workshop will be held at the Hyatt Regency Bethesda, 7400 Wisconsin Ave., 1 Bethesda Metro Center, Bethesda, MD 20814; Phone: 301–657–1234; FAX: 301–657–6453.

Contact: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East-West Hwy., Suite 200, Bethesda, MD 20814; Phone: 301–656–5900, ext. 149.

Accommodations: Attendees are responsible for their own accommodations. To make reservations at the Hyatt Regency Bethesda, at the reduced conference rate, contact the Hyatt Regency Bethesda (see *Location*), citing meeting code "PDA." Room Rates are: Single: $209, plus 13% state and local taxes and Double: $234, plus 13% state and local taxes. Reservations can be made on a space and rate availability basis.

Registration: You are encouraged to register at your earliest convenience. The PDA registration fees cover the cost of facilities, materials, and breaks. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted in to the conference will receive confirmation. Registration will close after applicable conference is filled. Onsite registration will be available on a space-available basis on the day of the public conference beginning at 7 a.m. on Monday, April 26, 2010.

The cost of registration is as follows:

PDA Members	$1850
PDA Nonmembers	$2099
PDA Member Government	$530
PDA Nonmember Government	$530
PDA Member Health Authority	$700
PDA Nonmember Health Authority	$800
PDA Member Academic	$700
PDA Nonmember Academic	$780

PDA Member Students	$280
PDA Nonmember Students	$310

If you need special accommodations due to a disability, please contact Wanda Neal, PDA (see *Contact*) at least 7 days in advance of the workshop.

Registration instructions: To register, please submit your name, affiliation, mailing address, phone, FAX number, and e-mail address, along with a check or money order payable to "PDA." Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East-West Hwy., Suite 200, Bethesda, MD 20814. To register via the Internet, go to See PDA Web site, *www.pda.org/supplychain2010* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**). The registrar will also accept payment by major credit cards (VISA/MasterCard only). For more information on the meeting, or for questions on registration, contact the PDA: Phone: 301–656–5900, FAX: 301–986–1093, or e-mail: *info@pda.org*.

SUPPLEMENTARY INFORMATION: A reliable supply of high quality, safe, and effective drug products and drug ingredients depends upon a series of controls across the entire supply chain from sourcing of incoming starting materials to distribution controls to marketing. Recent experiences in the market have highlighted the need for effective controls across the supply chain. There is a surge in global cooperation and efforts toward harmonization of good manufacturing practices (GMPs) and good distribution practices (GDPs) and controls pertaining to the supply chain among members of industry and regulatory agencies. Understanding and securing the entire ingredient manufacturing and distribution chain helps to ensure the quality and safety of medicines for patients.

Through a series of plenary sessions and working group breakout sessions, the workshop will provide participants the opportunity to:

- Hear from senior FDA personnel on the current regulatory environment.
- Share improvements in programs and technology.
- Identify any barriers to securing the entire ingredient manufacturing and distribution chain and associated actions to implement effective solutions.

Personnel with experience related to supply chain issues, including quality and technical functions, will find this level of information exchange with members of industry and regulatory agencies useful to their specific areas.

Dated: March 25, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–7151 Filed 3–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

United States Immigration and Customs Enforcement

Agency Information Collection Activities: Extension of an Existing Information Collection; Comment Request

ACTION: 30-Day notice of information collection for review; Form G–79A, Information Relating to Beneficiary of Private Bill; OMB Control No. 1653–0026.

The Department of Homeland Security, U.S. Immigration and Customs Enforcement (USICE), has submitted the following information collection request for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on January 19, 2010 Vol. 75 No. 11 2881, allowing for a 60 day public comment period. No comments were received on this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted for thirty days April 30, 2010. Written comments and suggestions from the public and affected agencies regarding items contained in this notice and especially with regard to the estimated public burden and associated response time should be directed to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to OMB Desk Officer, for U. S. Immigration and Customs Enforcement, Department of Homeland Security, and sent via electronic mail to *oira_submission@omb.eop.gov* or faxed to (202) 395–5806.

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 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 agencies 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 This Information Collection:

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Information Relating to Beneficiary of Private Bill.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form G–79A. U.S. Immigration and Customs Enforcement.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or Households. The information collected on the Form G–79A is necessary for U.S. Immigration and Customs Enforcement to provide reports to Congress on Private Bills when requested.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 100 responses at 60 minutes (1 hour) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 100 annual burden hours.

Requests for a copy of the proposed information collection instrument, with instructions; or inquiries for additional information should be requested via e-mail to: *forms.ice@dhs.gov* with "Form G–79A" in the subject line.

Dated: March 26, 2010.

Joseph M. Gerhart,

Chief, Records Management Branch, U.S. Immigration and Customs Enforcement, Department of Homeland Security.

[FR Doc. 2010–7186 Filed 3–30–10; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2010–0121]

Prince William Sound Regional Citizens' Advisory Council (PWSRCAC) Charter Renewal

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: The purpose of this notice is to inform the public that the Coast Guard has recertified the Prince William Sound Regional Citizens' Advisory Council (PWSRCAC) as an alternative voluntary advisory group for Prince William Sound, Alaska. This certification allows the PWSRCAC to monitor the activities of terminal facilities and crude oil tankers under the Prince William Sound Program established by statute.

DATES: This recertification is effective for the period from March 1, 2010 through February 28, 2011.

FOR FURTHER INFORMATION CONTACT: LCDR Ken Phillips, Seventeenth Coast Guard District (dpi), by telephone at (907) 463–2821, or by mail at P.O. Box 25517, Juneau, Alaska 99802.

SUPPLEMENTARY INFORMATION:

Background and Purpose

As part of the Oil Pollution Act of 1990, Congress passed the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), 33 U.S.C. 2732, to foster a long-term partnership among industry, government, and local communities in overseeing compliance with environmental concerns in the operation of crude oil terminals and oil tankers.

On October 18, 1991, the President delegated his authority under 33 U.S.C 2732(o) to the Secretary of Transportation in Executive Order 12777, section 8(g) (see 56 FR 54757; October 22, 1991) for purposes of certifying advisory councils, or groups, subject to the Act. On March 3, 1992, the Secretary redelegated that authority to the Commandant of the Coast Guard (see 57 FR 8582; March 11, 1992). The Commandant redelegated that authority to the Chief, Office of Marine Safety, Security and Environmental Protection (G–M) on March 19, 1992 (letter #5402).

On July 7, 1993, the USCG published a policy statement, 58 FR 36504, to clarify the factors that shall be considered in making the determination as to whether advisory councils, or groups, should be certified in accordance with the Act.

The Assistant Commandant for Marine Safety and Environmental Protection (G–M), redelegated recertification authority for advisory councils, or groups, to the Commander, Seventeenth Coast Guard District on February 26, 1999 (letter #16450).

On September 16, 2002, the Coast Guard published a policy statement, 67 FR 58440, which changed the recertification procedures such that applicants are required to provide the USCG with comprehensive information every three years (triennially). For each of the two years between the triennial application procedures, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification. Further, public comment is not solicited prior to recertification during streamlined years, only during the triennial comprehensive review.

The Alyeska Pipeline Service Company pays the PWSRCAC $2.9 million annually in the form of a long-term contract. In return for this funding, the PWSRCAC must annually show that it "fosters the goals and purposes" of OPA 90 and is "broadly representative of the communities and interests in the vicinity of the terminal facilities and Prince William Sound." The PWSRCAC is an independent, nonprofit organization founded in 1989. Though it receives Federal oversight like many independent, non-profit organizations, it is not a Federal agency. The PWSRCAC is a local organization that predates the passage of OPA 90. The existence of the PWSRCAC was specifically recognized in OPA 90 where it is defined as an "alternate voluntary advisory group."

Alyeska funds the PWSRCAC, and the Coast Guard makes sure the PWSRCRC operates in a fashion that is broadly consistent with OPA 90.

Recertification

By letter dated February 24, 2010, the Commander, Seventeenth Coast Guard District, certified that the PWSRCAC qualifies as an alternative voluntary advisory group under 33 U.S.C. 2732(o). This recertification terminates on February 28, 2011.

Dated: February 24, 2010.

C.C. Colvin,

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

[FR Doc. 2010–7157 Filed 3–30–10; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

National Communications System

[Docket No. NCS–2010–0001]

President's National Security Telecommunications Advisory Committee

AGENCY: National Communications System, DHS.

ACTION: Notice of open advisory committee meeting.

SUMMARY: The President's National Security Telecommunications Advisory Committee (NSTAC) will hold its annual meeting on May 6, 2010. The meeting will be open to the public.

DATES: May 6, 2010, from 2:30 p.m. until 5:30 p.m.

ADDRESSES: The meeting will take place at the U.S. Chamber of Commerce, 1615 H Street, NW., Washington, DC. If you desire meeting materials, please contact Ms. Sue Daage at (703) 235–4964 or by e-mail at *sue.daage@dhs.gov* by 5 p.m. April 29, 2010. If you desire to submit comments regarding the May 6, 2010, meeting, comments must be identified by Docket No. NCS–2010–0001 and may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: NSTAC1@dhs.gov.* Include docket number in the subject line of the message.
- *Mail:* Office of the Manager, National Communications System, Government Industry Planning and Management Branch, Department of Homeland Security, 245 Murray Lane, SW., Washington, DC 20598–0615.
- *Fax:* (866) 466–5370.

Instructions: All submissions received must include the words "Department of Homeland Security" and NCS–2010–0001, the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov*, including any personal information provided.

Docket: For access to the docket, background documents or comments received by the NSTAC, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Sue Daage, Government Industry Planning and Management Branch, at (703) 235–4964, e-mail: *sue.daage@dhs.gov*, or write to the Deputy Manager, National Communications System, Department of Homeland Security, 245 Murray Lane, SW., Washington, DC 20598–0615.

SUPPLEMENTARY INFORMATION: The NSTAC advises the President on issues and problems related to implementing national security and emergency preparedness telecommunications policy. Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Public Law 92–463 (1972), as amended appearing in 5 U.S.C. App. 2. At the upcoming meeting, the NSTAC Principals will receive Government stakeholder comments and updates on the progress of the Communications Resiliency Task Force and the Cybersecurity Collaboration Task Force.

Dated: March 24, 2010.

James Madon,

Director, National Communications System.

[FR Doc. 2010–7205 Filed 3–30–10; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5383–N–04]

Notice of Proposed Information Collection for Public Comment; Allocation of Operating Subsidies Under the Operating Fund Formula: Data Collection

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* June 1, 2010.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Leroy McKinney, Jr., Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Room 4178, Washington, DC 20410–5000; telephone 202.402.8048 (this is not a toll-free number), or e-mail Mr. McKinney at *Leroy.McKinneyJr@hud.gov* for a copy of the proposed forms, or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877–8339. (Other than the HUD USER information line and TTY numbers, telephone numbers are not toll-free.)

FOR FURTHER INFORMATION CONTACT: Dacia Rogers, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street, SW., Room 4116, Washington, DC 20410; telephone 202–402–3374 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Allocation of Operating Subsidies Under the Operating Fund Formula: Data Collection.

OMB Control Number: 2577–0029.

Description of the need for the information and proposed use: Section 9(f) of the United States Housing Act of 1937 establishes an Operating Fund for the purpose of making assistance available to public housing agencies (PHAs) which assistance is determined using a formula approach under the Operating Fund Program. PHAs compute their operating subsidy eligibility by completing the following HUD prescribed forms, as applicable, each fiscal year: Calculation of Utilities Expense Level (HUD–52722); Operating Fund Calculation of Operating Subsidy (HUD–52723); and Calculation of Subsidies for Operations: Non-Rental Housing (HUD–53087). HUD uses the information on these forms to determine the operating subsidy obligation and proration level for each PHA. The three forms listed in this collection are automated in the Subsidy and Grant Information System (SAGIS).

Agency form number: HUD–52722, HUD–52723, and HUD–53087.

Members of affected public: Public Housing Agencies.

Estimation of the total number of hours needed to prepare the information collection including number of respondents: 6,955 respondents annually with 1 response per respondent for forms HUD–52722 and HUD–52723 for a total of 13,919 responses; and 1 response per 9 respondents for form HUD–53087 for a total of 9 responses. Average time per response for each form is .75 hours and total annual burden hours are 10,439.

Status of the proposed information collection: Extension of currently approved collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 22, 2010.

Merrie Nichols-Dixon,

Acting Deputy Assistant Secretary for Policy, Programs, and Legislative Initiatives.

[FR Doc. 2010–7102 Filed 3–30–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5382–N–04]

Notice of Proposed Information Collection for Public Comment: Notice of Funding Availability for the Alaska Native/Native Hawaiian Institutions Assisting Communities (AN/NHIAC) Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comment Due Date:* June 1, 2010.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Reports Liaison Officer, Office of Policy Development and Research, Department of Housing and Urban Development, 451 7th Street, SW., Room 8228, Washington, DC 20410–6000.

FOR FURTHER INFORMATION CONTACT: Susan Brunson, 202–708–3061, ext. 3852 (this is not a toll-free number), for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department of Housing and Urban Development will submit the proposed extension of information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Notice of Funding Availability for the Alaska Native/Native Hawaiian Institutions Assisting Communities (AN/NHIAC) Program.

OMB Control Number: 2528–0206.

Description of the Need for the Information and Proposed Use: The information is being collected to select applicants for award in this statutorily created competitive grant program and too monitor performance of grantees to ensure they meet statutory and program goals and requirements.

Agency Form Numbers: SF–424, SF–424 Supplement, SF–LLL, HUD–424–CB, HUD–2730, HUD–2880, HUD–2993, HUD–2994–A, HUD–96011, and HUD–96010.

Members of the Affected Public: Alaska Native Institutions (ANI) and Native Hawaiian Institutions (NHI) of Higher Education that meet the statutory definition established in Title III, Part A, Section 317 of the Higher Education Act of 1965, as amended by the Higher Education Amendments of 1998 (Pub. L. 105–244; enacted October 7, 1998).

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: Information pursuant to grant award will be submitted once a year. The following chart details the respondent burden on an annual and semi-annual basis:

	Number of respondents	Total annual responses	Hours per response	Total hours
Applicants	20	20	40	800
Quarterly Reports	10	40	6	240
Final Reports	10	10	8	80
Recordkeeping	10	10	5	50
Total			59	1170

Status of the proposed information collection: Pending OMB approval.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 19, 2010.

Raphael W. Bostic,

Assistant Secretary for Policy Development and Research.

[FR Doc. 2010–7223 Filed 3–30–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5383–N–05]

Notice of Proposed Information Collection for Public Comment; Energy Conservation for PHA-Owned or Leased Projects—Audits, Utility Allowances

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of proposed information collection.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* June 1, 2010.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name/or OMB Control number and should be sent to: Leroy McKinney, Jr., Departmental Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Room 4178, Washington, DC 20410–5000; telephone 202–402–8048 (this is not a toll-free number), or e-mail Mr. McKinney at *Leroy.McKinneyJr@hud.gov* for a copy of the proposed forms, or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at 800–877–8339. (Other than the HUD USER information line and TTY numbers, telephone numbers are not toll-free.)

FOR FURTHER INFORMATION CONTACT: Dacia Rogers, Office of Policy, Programs and Legislative Initiatives, PIH, Department of Housing and Urban Development, 451 7th Street, SW., Room 4116, Washington, DC 20410; telephone 202–402–3374 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This Notice is soliciting comments from members of the public and affected agencies concerning the proposed collection of information to: (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; (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 collection techniques or other forms of information technology; e.g., permitting electronic submission of responses.

This notice also lists the following information:

Title of Proposal: Energy Conservation for PHA-owned or Leased Projects—Audits, Utility Allowances.

OMB Control Number: 2577–0062.

Description of the Need for the Information and Proposed Use: In support of national energy conservation goals, Public Housing Agencies (PHAs) establish allowances for PHA-furnished utilities and for resident-purchased utilities. PHAs document, and provide for resident inspection, the basis upon which allowances and schedules surcharges (and revisions thereof) are established. PHAs complete energy audits, benefit/cost analyses for individual vs. master metering. PHAs review tenant utility allowances.

Agency Form Numbers, if Applicable: Form HUD–50078.

Members of Affected Public: State, Local, or Tribal Government; Public Housing Agencies (PHAs).

Estimation of the Total Number of Hours Needed to Prepare the Information Collection Including Number of Respondents, Frequency of Response, and Hours of Response: 4,130 respondents; requiring annually of 4,130 responses; 79,330 total burden hours; average of 19.21 burden hours per respondent.

Status of the Proposed Information Collection: Revision of a currently approved collection.

Authority: Section 3506 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.

Dated: March 22, 2010.

Merrie Nichols-Dixon,

Acting Deputy Assistant Secretary for Policy, Programs, and Legislative Initiatives, PP.

[FR Doc. 2010–7101 Filed 3–30–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5408–N–01]

Notice of Intent To Prepare an Environmental Impact Statement for the Yesler Terrace Redevelopment Project

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: The Department of Housing and Urban Development (HUD) gives notice to the public, agencies, and Indian Tribes that the Seattle Housing Authority and the City of Seattle Human Services Department (Community Development Block Grant (CDBG) Administration Unit) intend to prepare an Environmental Impact Statement (EIS) for the Yesler Terrace Redevelopment Project, located in the City of Seattle, King County, WA. The project proponent is the Seattle Housing Authority. The City of Seattle Human Services Department and the Seattle Housing Authority, acting jointly as lead agencies, will prepare the EIS under the authority of the City of Seattle Human Services Department as the Responsible Entity for compliance with the National Environmental Policy Act (NEPA) in accordance with 42 U.S.C. 5304(g) and 42 U.S.C. 1437x and HUD regulations at 24 CFR 58.4, and under the Seattle Housing Authority's role as lead agency in accordance with the Washington State Environmental Policy Act (SEPA). The EIS will be a joint NEPA and SEPA document. The EIS will satisfy requirements of SEPA (RCW 43.21C) and the SEPA Rules (WAC 197–11) which require that all State and local government agencies consider the environmental consequences of projects over which they have discretionary authority before acting on those projects. The proposed action is subject to compliance with NEPA, because funds from the public housing programs under Title I of the United States Housing Act of 1937 (HOPE VI, Capital Funds, Demolition/Disposition) will used for this project (24 CFR 58.1(b)(6)(i)). This notice is given in accordance with the Council on Environmental Quality regulations at 40 CFR parts 1500–1508. All interested Federal, State, and local agencies, Indian Tribes, groups, and the public are invited to comment on the scope of the EIS. If you are an agency with jurisdiction by law over natural or other public resources affected by the project, the Seattle Housing Authority and the City of Seattle Human Services Department need to know what environmental information germane to your statutory responsibilities should be included in the EIS.

ADDRESSES: Comments relating to the scope of the EIS are requested and will be accepted by the contact persons listed below until May 17, 2010. Any person or agency interested in receiving a notice and wishing to make comment on the scope of the EIS should contact the persons listed below.

FOR FURTHER INFORMATION CONTACT: Stephanie Van Dyke, Development Director of the Seattle Housing Authority, *YTEISComments@seattlehousing.org,* P.O. Box 19028, Seattle, WA 98109–1028, (f) 206–615–3539 (SEPA) and Kristen Larson, Project Funding and Agreements Coordinator, City of Seattle Human Services Department, CDBG Administration Unit, *Kristen.Larson@seattle.gov,* P.O. Box 34215, Seattle, WA 98124–4215, (f) 206–621–5003 (NEPA).

For additional background information on the project proposal, please see the Seattle Housing Authority Web site: *http://www.seattlehousing.org/redevelopment/yesler-terrace/.*

Public Participation: A public EIS Scoping meeting/open house will be held to provide an additional opportunity for the public to learn more about the proposed actions and to provide verbal or written comment on the scope of the EIS. At the meeting, the public will be able to view graphics illustrating preliminary redevelopment concepts associated with the proposed actions and speak with staff of the Seattle Housing Authority, the City of Seattle and members of the consultant team providing technical analyses in support of the project. Written comments may be mailed, sent via fax or e-mailed to the Seattle Housing Authority contact listed above or submitted at the EIS Scoping Meeting.

The meeting/open house will be held at the Yesler Terrace Gym (835 Yesler Way, Seattle, WA 98122) on April 29, 2010. An open house will be held from 6–7 p.m. and public comments on the scope will be taken at 7 p.m. For accommodations and translation services in conjunction with the public meeting please contact Collette Frazier, (p) (206) 615–3556.

SUPPLEMENTARY INFORMATION:

Project Name and Description

The Seattle Housing Authority and the City of Seattle Human Services Department will consider a proposal for a phased redevelopment of the existing Yesler Terrace residential community to a mixed-use residential community on a 28-acre site on the southern slope of First Hill in Seattle, WA. The proposed project is generally bounded by Interstate 5 on the west, Alder Street and Fir Street on the north, 12th Avenue on the east, and Washington Street on the south.

The proposed project would include development of a mix of affordable and market-rate housing, office and retail uses, as well as parks and open space, enhanced landscaping, improved streets and a system of pedestrian and bike improvements. All existing residential structures on the site would be demolished under the Proposed Action; other structures on the site may also be demolished. The existing Yesler Terrace

community center would be retained. It is anticipated that the redevelopment of Yesler Terrace will take approximately 15 to 20 years to complete.

The proposed actions may involve the following: Comprehensive Plan Amendment, text amendment to the Land Use Code to allow a new zone for Yesler Terrace, street vacation, preliminary and final plat approval, adoption of a Planned Action Ordinance, Development Agreement approval, other construction and building permits and other Federal, State and local approvals for redevelopment of the Yesler Terrace community.

The EIS is also intended to fulfill SEPA requirements for a Planned Action environmental review for the portion of the site west of Boren Avenue, per RCW 43.21C.031, SMC 25.05.164 [*et seq.*], and SHA Resolution 4945. According to SEPA, a "Planned Action" is a designation for a project or elements of a project that shifts environmental review from the time a permit application is made to an earlier phase in the process, such as at the Comprehensive Plan amendment and/or rezone phase. The intent of this designation is to provide a more streamlined environmental process by using an existing EIS prepared at this earlier stage for SEPA compliance for long-term actions.

This is to be a combined document—an EIS under the State of Washington State Environmental Policy Act (RCW 43.21C. and WAC 197–11) and an EIS under NEPA (42 U.S.C. 4321) and implementing regulations of the Council on Environmental Quality (40 CFR parts 1500–1508) and HUD (24 CFR part 58).

Alternatives: Preliminary Yesler Terrace redevelopment concepts call for redevelopment over a range of: 3,000 to 5,000 residential units; 800,000 to 1.2 million square feet of office/institutional space; and 40,000 to 88,000 square feet of retail space. The EIS will analyze three redevelopment alternatives representing a range of densities and intensities of uses, a redevelopment alternative consistent with existing zoning, and a no-action alternative.

Probable Environmental Effects: The following subject areas will be analyzed in the combined EIS for probable environmental effects: Earth, Air Quality, Water, Plants and Animals, Energy, Environmental Health, Noise, Land Use, Housing, Aesthetics, Light and Glare, Recreation, Historic Resources, Cultural Resources, Transportation, Public Utilities, Public Services, Socioeconomics/Environmental Justice.

Lead Agencies

As a lead agency, the City of Seattle, through its Human Services Department, is the responsible entity (RE) for this project in accordance with 24 CFR part 58, "Environmental Review Procedures for Entities Assuming HUD Environmental Responsibilities." As a RE, the City of Seattle Human Services Department assumes the responsibility for environmental review, decision-making, and action that would otherwise apply to HUD under NEPA.

In addition, the Seattle Housing Authority is the State Environmental Policy Act (SEPA) lead agency responsible for preparing an Environmental Impact Statement (EIS).

Questions may be directed to the individuals named in this notice under the heading **FOR FURTHER INFORMATION CONTACT**.

Date Issued: March 9, 2010.

Mercedes Marquez,

Assistant Secretary for Community Planning and Development.

[FR Doc. 2010–7099 Filed 3–30–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5389–N–02]

Notice of FHA Debenture Call

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: This Notice announces a debenture recall of certain Federal Housing Administration (FHA) debentures, in accordance with authority provided in the National Housing Act.

FOR FURTHER INFORMATION CONTACT: Yong Sun, FHA Financial Reporting Division, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 5148, Washington, DC 20410, telephone (202) 402–4778. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: Pursuant to section 207(j) of the National Housing Act, 12 U.S.C. 1713(j), and in accordance with HUD's regulation at 24 CFR 207.259(e)(3), the Assistant Secretary for Housing—Federal Housing Commissioner, with the approval of the Secretary of the Treasury, announces the call of all FHA debentures, with a coupon rate of 5 percent or above, except for those debentures subject to "debenture lock agreements," that have been registered on the books of the Bureau of the Public Debt, Department of the Treasury, and are, therefore, "outstanding" as of March 31, 2010. The date of the call is July 1, 2010.

The debentures will be redeemed at par plus accrued interest. Interest will cease to accrue on the debentures as of the call date. At redemption, final interest on any called debentures will be paid along with the principal. Payment of final principal and interest due on July 1, 2010 will be made automatically to the registered holder.

During the period from the date of this notice to the call date, debentures that are subject to the call may not be used by the mortgagee for a special redemption purchase in payment of a mortgage insurance premium.

No transfer of debentures covered by the foregoing call will be made on the books maintained by the Treasury Department on or after June 14, 2010. This debenture call does not affect the right of the holder of a debenture to sell or assign the debenture on or after this date.

Dated: February 22, 2010.

David H. Stevens,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2010–7096 Filed 3–30–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5213–FA–02]

Announcement of Funding Awards for the HUD-Veterans Affairs Supportive Housing (HUD–VASH) Program for Fiscal Years (FY) 2008 and 2009

AGENCY: Office of Public and Indian Housing, HUD.

ACTION: Announcement of funding awards.

SUMMARY: In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989, this announcement notifies the public of funding decisions made by the Department for funding under the FY 2008 and FY 2009 HUD–VASH program. This announcement contains the consolidated names and addresses of those award recipients selected for funding under both the Consolidated Appropriations Act, 2008 (Pub. L. 110–161) and the Omnibus Appropriations Act, 2009 (Pub. L. 111–8).

FOR FURTHER INFORMATION CONTACT: Danielle Bastarache, Director, Housing Voucher Programs, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh

Street, SW., Room 4228, Washington, DC 20410, telephone number (202) 402–5264. For the hearing or speech impaired, this number may be accessed via TTY (text telephone) by calling the Federal Information Relay Service at 1 (800) 877–8339. (Other than the "800" TTY number, these telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Consolidated Appropriations Act, 2008 (Pub. L. 110–161) ("2008 Appropriations Act") made $75 million available for HUD–VASH, an initiative that combines HUD Housing Choice Voucher (HCV) rental assistance for homeless veterans with case management and clinical services provided by the Department of Veterans Affairs (VA) at its medical centers and in the community. The HCV program is authorized under section 8(o)(19) of the United States Housing Act of 1937. The Omnibus Appropriations Act, 2009 (Pub. L. 111–8) ("2009 Appropriations Act") made an additional $75 million available to HUD–VASH. Both the 2008 and 2009 Appropriations Acts require HUD to distribute assistance without competition, to public housing agencies (PHAs) that partner with eligible Veterans Affairs Medical Centers (VAMCs) or other entities as designated by the VA. As required by statute, selection was based on geographical need for such assistance as identified by the VA, public housing agency performance, and other factors as specified by the HUD in consultation with the VA. On May 6, 2008 (73 FR 25026), HUD published in the **Federal Register** a notice that set forth the policies and procedures for the administration of tenant-based Section 8 HCV rental assistance under the HUD–VASH program administered by local PHAs that have partnered with local VA medical centers. The **Federal Register** published a correction of the May 6, 2008 notice on May 19, 2008 (73 FR 28863).

As required by the FY 2008 and FY 2009 Appropriations Acts, the VA identified VAMCs to participate in the program taking into account the population of homeless veterans needing services in the area, the number of homeless veterans recently served by the homeless programs at each VAMC, geographic distribution, and the VA's case management resources. After considering location and administrative performance of PHAs in the jurisdiction of each VAMC, HUD invited PHAs to apply for HUD–VASH vouchers. In accordance with Section 102(a)(4)(C) of the Department of Housing and Urban Development Reform Act of 1989 (103 Stat. 1987, 42 U.S.C. 3545), today's **Federal Register** publication lists in Appendix A the names, addresses, number of vouchers and amounts of the 238 PHAs to which awards were made under the FY2008 and FY2009 HUD–VASH initiative to serve a total of 334 VA sites.

Dated: January 8, 2010.

Sandra B. Henriquez,

Assistant Secretary for Public and Indian Housing.

APPENDIX A

Recipient	Address	City	State	Zip code	Amount	Vouchers
2008 VASH Recipients						
Alaska Housing Finance Corp.	P.O. Box 101020	Anchorage	AK	99510	$233,066	35
Housing Authority of Birmingham District.	1826 3rd Avenue S.	Birmingham	AL	35233	669,539	105
Housing Authority of Tuscaloosa	P.O. Box 2281	Tuscaloosa	AL	35403	151,658	35
Housing Authority of Tuskegee	2901 Davison Street	Tuskegee Institute	AL	36083	111,594	35
Housing Authority of the City of North Little Rock.	P.O. Box 516	North Little Rock	AR	72115	508,750	105
Fayetteville Housing Authority	#1 North School Avenue.	Fayetteville	AR	72701	138,642	35
City of Phoenix	251 W. Washington Street.	Phoenix	AZ	85003	790,726	105
City of Tucson	P.O. Box 27210	Tucson	AZ	85726	402,041	70
State of Arizona	1110 W. Washington, Suite 310.	Phoenix	AZ	85007	188,118	35
San Francisco Housing Authority	440 Turk Street	San Francisco	CA	94102	1,518,754	105
City of Los Angeles Housing Authority	2600 Wilshire Blvd.	Los Angeles	CA	90057	7,537,622	840
City of Fresno Housing Authority	P.O. Box 11985	Fresno	CA	93776	199,886	35
County of San Bernardino Housing Authority.	715 E. Brier Dr.	San Bernardino	CA	92408	262,378	35
County of Santa Clara Housing Authority.	505 W. Julian Street	San Jose	CA	95110	901,505	70
City of Pittsburg Housing Authority	916 Cumberland Street.	Pittsburg	CA	94565	376,081	35
San Diego Housing Commission	1122 Broadway, Suite 300.	San Diego	CA	92101	1,018,798	105
City of Long Beach Housing Authority	521 East 4th Street	Long Beach	CA	90802	686,398	70
Colorado Department of Human Services.	4020 S. Newton St.	Denver	CO	80236	1,004,170	210
West Haven Housing Authority	15 Glade Street	West Haven	CT	06516	587,882	70
D.C. Housing Authority	1133 N. Capitol Street, NE.	Washington	DC	20002	1,689,341	140
Wilmington Housing Authority	400 Walnut Street	Wilmington	DE	19801	242,222	35
Housing Authority of Tampa	1529 W. Main Street	Tampa	FL	33607	897,007	105
Orlando Housing Authority	390 North Bumby Avenue.	Orlando	FL	32803	498,103	70
Housing Authority of West Palm Beach.	1715 Division Avenue	West Palm Beach	FL	33407	995,186	105
Housing Authority of Miami Beach	200 Alton Road	Miami Beach	FL	33139	763,447	105
Pinellas County Housing Authority	11479 Ulmerton Road	Largo	FL	33778	711,799	105

APPENDIX A—Continued

Recipient	Address	City	State	Zip code	Amount	Vouchers
Gainesville Housing Authority	Post Office Box 1468	Gainesville	FL	32602	408,610	70
Housing Authority of Alachua County	703 NE First Street	Gainesville	FL	32601	386,921	70
City of Pensacola Section 8	P.O. Box 12910	Pensacola	FL	32521	177,866	35
Housing Authority of Augusta	P.O. Box 3246	Augusta	GA	30914	196,081	35
Housing Authority Dekalb County	750 Commerce Drive, Suite 201.	Decatur	GA	30030	2,965,620	350
Georgia Department of Community Affairs.	60 Executive Parkway South, NE.	Atlanta	GA	30329	197,673	35
Guam Housing and Urban Renewal Authority.	117 Bien Venida Avenue.	Sinajana	GQ	96910	119,472	10
Hawaii Public Housing Authority	P.O. Box 17907	Honolulu	HI	96817	715,604	70
City of Des Moines Municipal Housing Agency.	100 East Euclid, Suite 101.	Des Moines	IA	50313	162,145	35
City of Iowa City	410 E. Washington Street.	Iowa City	IA	52240	160,520	35
Boise City Housing Authority	1276 River Street, Suite 300.	Boise	ID	83702	107,849	20
Chicago Housing Authority	626 W. Jackson Blvd.	Chicago	IL	60661	942,631	105
Housing Authority of Cook County	175 W. Jackson, Suite 350.	Chicago	IL	60604	650,471	70
City of N. Chicago Housing Authority	1440 Jackson Street	North Chicago	IL	60064	272,462	35
Fort Wayne Housing Authority	P.O. Box 13489	Fort Wayne	IN	46869	184,960	35
Indianapolis Housing Agency	1919 North Meridian Street.	Indianapolis	IN	46202	447,166	70
Topeka Housing Authority	2010 SE. California Avenue.	Topeka	KS	66607	135,790	35
Wichita Housing Authority	332 Riverview Street	Wichita	KS	67203	173,405	35
Housing Authority of the City of Leavenworth.	200 Shawnee Street	Leavenworth	KS	66048	482,038	105
Louisville Housing Authority	420 S. 8th Street	Louisville	KY	40203	418,748	70
Lexington Fayette Urban County Housing Authority.	300 West New Circle Road.	Lexington	KY	40505	172,168	35
Kenner Housing Authority	1013 31st Street	Kenner	LA	70065	1,148,414	140
Alexandria Housing Authority	P.O. Box 8219	Alexandria	LA	71306	166,349	35
Bossier Parish Police Jury	3022 Old Minden Road, Suite 206.	Bossier City	LA	71112	149,104	35
Boston Housing Authority	52 Chauncy Street	Boston	MA	02111	1,321,702	105
Northampton Housing Authority	49 Old South Street—Suite 1.	Northampton	MA	01060	487,402	70
Comm. Dev. Prog. Comm. of Ma., E.O.C.D.	100 Cambridge Street, Suite 300.	Boston	MA	02114	736,781	70
Cecil County Housing Agency	200 Chesapeake Blvd., Suite 1800.	Elkton	MD	21921	429,500	70
Baltimore Co. Housing Office	6401 York Road	Baltimore	MD	21212	741,623	105
Maine State Housing Authority	353 Water Street	Augusta	ME	04330	199,084	35
Saginaw Housing Commission	P.O. Box 3225	Saginaw	MI	48605	167,559	35
Battle Creek Housing Comm.	250 Champion Street	Battle Creek	MI	49017	125,357	35
Ann Arbor Housing Commission	727 Miller Avenue	Ann Arbor	MI	48103	554,467	70
Michigan State Housing Dev. Authority.	735 E. Michigan Avenue.	Lansing	MI	48912	598,538	105
Minneapolis Public Housing Authority	1001 Washington Avenue N.	Minneapolis	MN	55401	601,415	70
St. Louis Housing Authority	4100 Lindell Boulevard	Saint Louis	MO	63108	227,779	35
Housing Authority of Kansas City, Missouri.	301 E. Armour Blvd.—#200.	Kansas City	MO	64111	418,438	70
Columbia Housing Authority	201 Switzler Street	Columbia	MO	65203	166,585	35
Jackson Housing Authority	P.O. Box 11327	Jackson	MS	39283	205,036	35
MT Department of Commerce	P.O. Box 200545	Helena	MT	59620	141,683	35
Housing Authority of the City of Asheville.	P.O. Box 1898	Asheville	NC	28802	171,818	35
Housing Authority of the County of Wake.	P.O. Box 399	Zebulon	NC	27597	288,112	35
Housing Authority of Rowan County	310 Long Meadow Drive.	Salisbury	NC	28147	232,609	35
Fargo Housing And Redevelopment Authority.	P.O. Box 430	Fargo	ND	58107	131,153	35
Omaha Housing Authority	540 S. 27th Street	Omaha	NE	68105	206,732	35
Housing Authority of Lincoln	5700 R Street	Lincoln	NE	68505	144,816	35
Manchester Housing Authority	198 Hanover Street	Manchester	NH	03104	274,352	35
New Jersey Department of Community Affairs.	101 South Broad Street.	Trenton	NJ	08625	646,406	70

APPENDIX A—Continued

Recipient	Address	City	State	Zip code	Amount	Vouchers
Albuquerque Housing Authority	1840 University Boulevard SE.	Albuquerque	NM	87106	192,276	35
County of Clark Housing Authority	5390 E. Flamingo Road.	Las Vegas	NV	89122	842,688	105
Nevada Rural Housing Authority	3695 Desatoya Drive	Carson City	NV	89701	407,291	70
Housing Authority of Syracuse	516 Burt St	Syracuse	NY	13202	193,536	35
New York City Housing Authority	250 Broadway	New York	NY	10007	9,383,229	1015
Albany Housing Authority	200 South Pearl St	Albany	NY	12202	184,737	35
Housing Authority of Rochester	675 West Main St., Suite 100.	Rochester	NY	14611	159,655	35
Town of Amherst	1195 Main St	Buffalo	NY	14209	151,284	35
NYS Housing Trust Fund Corporation	25 Beaver St., 7th Floor.	New York	NY	10004	785,043	140
Columbus Metro. Housing Authority	880 East 11th Ave	Columbus	OH	43211	212,701	35
Cuyahoga MHA	1441 W. 25th Street	Cleveland	OH	44113	680,728	105
Cincinnati Metropolitan Housing Authority.	16 W. Central Parkway.	Cincinnati	OH	45202	430,189	70
Dayton Metropolitan Housing Authority.	400 Wayne Ave., P.O. Box 8750.	Dayton	OH	45401	183,683	35
Chillicothe Met. Housing Authority	178 W. 4th Street	Chillicothe	OH	45601	168,454	35
Oklahoma City Housing Authority	1700 NE. 4th Street	Oklahoma City	OK	73117	190,819	35
Muskogee Housing Authority	220 N. 40th Street	Muskogee	OK	74401	117,428	35
Housing Authority of Portland	135 SW. Ash Street	Portland	OR	97204	469,098	70
Housing Authority of Douglas County	902 West Stanton Street.	Roseburg	OR	97470	133,736	35
Housing Authority of Jackson County	2231 Table Rock Road.	Medford	OR	97501	173,809	35
Philadelphia Housing Authority	12 S. 23rd Street	Philadelphia	PA	19103	717,482	105
Allegheny County Housing Authority	625 Stanwix Street	Pittsburgh	PA	15222	379,302	70
Housing Authority of the County of Butler.	114 Woody Drive	Butler	PA	16001	184,750	35
Erie City Housing Authority	606 Holland Street	Erie	PA	16501	153,069	35
Hous. Authority of the Co. of Chester	30 W. Barnard St Street.	West Chester	PA	19382	887,783	105
Wilkes Barre Housing Authority	50 Lincoln Plaza, S. Wilkes Barre Blvd.	Wilkes Barre	PA	18702	159,667	35
Lebanon County Housing Authority	303 Chestnut Street	Lebanon	PA	17042	344,795	70
Providence H. A.	100 Broad Street	Providence	RI	02903	266,713	35
Puerto Rico Dept of Housing	P.O. Box 21365	San Juan	RQ	00928	111,365	20
Housing Authority of Charleston	550 Meeting Street	Charleston	SC	29403	360,872	70
Housing Authority of Columbia	1917 Harden Street	Columbia	SC	29204	383,116	70
Sioux Falls Housing & Redevelopment Commission.	630 S. Minnesota Avenue.	Sioux Falls	SD	57104	175,568	35
Pennington County Housing & Redevelopment Comm.	1805 W. Fulton Street, Ste. 101.	Rapid City	SD	57702	169,961	35
Meade County Housing & Redevelopment Commission.	1220 Cedar Street, Apartment 113.	Sturgis	SD	57785	138,508	35
Memphis Housing Authority	P.O. Box 3664	Memphis	TN	38103	626,081	105
Housing Authority of Johnson City	P.O. Box 59	Johnson City	TN	37605	286,440	70
Metropolitan Developmnt & Housing Agncy.	701 6th St	Nashville	TN	37202	385,342	70
Housing Authority of El Paso	5300 E. Paisano Dr	El Paso	TX	79905	192,759	35
Houston Housing Authority	2640 Fountain View	Houston	TX	77057	2,844,534	385
San Antonio Housing Authority	818 Flores St	San Antonio	TX	78295	423,830	70
Housing Authority of Dallas	3939 N. Hampton Road.	Dallas	TX	75212	784,312	105
Housing Authority of Waco	P.O. Box 978	Waco	TX	76703	539,078	105
Housing Authority of Salt Lake City	1776 S. West Temple	Salt Lake City	UT	84115	220,109	35
Richmond Redevelopment & Housing Authority.	P.O. Box 26887	Richmond	VA	23261	242,206	35
Roanoke Redevelopment & Housing Authority.	P.O. Box 6359	Roanoke	VA	24017	169,210	35
Hampton Redevelopement & Housing Authority.	P.O. Box 280	Hampton	VA	23669	993,283	140
Vermont State Housing Authority	1 Prospect Street	Montpelier	VT	05602	109,495	20
Seattle Housing Authority	120 Sixth Avenue North.	Seattle	WA	98109	406,511	52
King County Housing Authority	600 Andover Park West.	Seattle	WA	98188	431,621	53
Pierce County Housing Authority	P.O. Box 45410	Tacoma	WA	98445	225,901	35
Spokane Housing Authority	55 W. Mission Avenue	Spokane	WA	99201	165,635	35

APPENDIX A—Continued

Recipient	Address	City	State	Zip code	Amount	Vouchers
Housing Authority of the City of Walla Walla.	501 Cayuse Street	Walla Walla	WA	99362	278,670	70
Housing Authority of the City of Milwaukee.	P.O. Box 324	Milwaukee	WI	53201	384,241	70
Tomah Housing Authority	819 Superior Avenue	Tomah	WI	54660	53,596	35
Huntington Wv Housing Authority	P.O. Box 2183	Huntington	WV	25722	160,726	35
Martinsburg Housing Authority	703 S. Porter Avenue	Martinsburg	WV	25401	152,027	35
Clarksburg Housing Authority	433 Baltimore Avenue	Clarksburg	WV	26301	120,880	35
Housing Authority of the City of Cheyenne.	3304 Sheridan Street	Cheyenne	WY	82009	347,592	70
2009 VASH Recipients						
Alaska Housing Finance Corporation	P.O. Box 101020	Anchorage	AK	99510	209,277	35
Housing Authority of the City of Montgomery.	1020 Bell Street	Montgomery	AL	36104	185,507	35
Housing Authority of Huntsville	P.O. Box 486	Huntsville	AL	35804	172,523	35
Housing Authority of Bessemer	P.O. Box 1390	Bessemer	AL	35021	436,797	70
Housing Authority of the City of North Little Rock.	P.O. Box 516	North Little Rock	AR	72115	96,820	20
City of Phoenix	251 W. Washington Street, Floor 4.	Phoenix	AZ	85003	855,038	105
City of Tucson	P.O. Box 27210	Tucson	AZ	85726	417,221	70
City of Mesa	415 N. Pasadena	Mesa	AZ	85201	235,367	35
San Francisco Housing Authority	440 Turk Street	San Francisco	CA	94102	1,008,492	70
County of Los Angeles Housing Authority.	2 S. Coral Circle	Monterey Park	CA	91755	2,797,092	280
Oakland Housing Authority	1619 Harrison Street	Oakland	CA	94612	1,337,422	105
City of Los Angeles Housing Authority	2600 Wilshire Blvd	Los Angeles	CA	90057	996,056	105
City of Fresno Housing Authority	P.O. Box 11985	Fresno	CA	93776	209,174	35
County of Sacramento Housing Authority.	701 12th Street	Sacramento	CA	95814	578,793	70
Housing Authority of the County of Kern.	601–24th Street	Bakersfield	CA	93301	174,267	35
County of Santa Barbara Housing Authority.	P.O. Box 397	Lompoc	CA	93438	302,112	35
County of San Joaquin Housing Authority.	P.O. Box 447	Stockton	CA	95201	251,426	35
County of Riverside Housing Authority	5555 Arlington Avenue	Riverside	CA	92504	776,053	105
Tulare County Housing Authority	P.O. Box 791	Visalia	CA	93279	195,981	35
County of Monterey Housing Authority	123 Rico Street	Salinas	CA	93907	264,520	35
County of Butte Housing Authority	2039 Forest Ave., Suite # 10.	Chico	CA	95928	182,081	35
County of Marin Housing Authority	4020 Civic Center Drive.	San Rafael	CA	94903	418,286	35
County of Santa Clara Housing Authority.	505 W. Julian Street	San Jose	CA	95110	1,693,609	140
San Diego Housing Commission	1122 Broadway Suite 300.	San Diego	CA	92101	1,013,637	105
City of Long Beach Housing Authority	521 East 4th Street	Long Beach	CA	90802	1,049,687	105
Mendocino County	1076 N. State Street	Ukiah	CA	95482	213,295	35
City of Santa Rosa	P.O. Box 1806	Santa Rosa	CA	95402	296,429	35
County of Orange Housing Authority	1770 North Broadway	Santa Ana	CA	92706	745,382	70
County of San Diego	3989 Ruffin Road	San Diego	CA	92123	937,823	105
Housing Authority of the City and County of Denver.	Box 40305, Mile High Station.	Denver	CO	80204	1,181,620	140
Housing Authority of Pueblo	1414 N. Santa Fe Ave., 10th Floor.	Pueblo	CO	81003	185,153	35
Fort Collins Housing Authority	1715 W. Mountain Avenue.	Fort Collins	CO	80521	531,697	70
Grand Junction Housing Authority	1011 North Tenth Street.	Grand Junction	CO	81501	172,297	35
Hartford Housing Authority	180 Overlook Terrace	Hartford	CT	06106	283,080	35
Housing Authority of the City of New Haven.	P.O. Box 1912	New Haven	CT	06509	355,357	35
Waterbury Housing Authority	2 Lakewood Road	Waterbury	CT	06704	246,906	35
D.C. Housing Authority	1133 N. Capitol Street NE.	Washington	DC	20002	2,021,458	175
Housing Authority of Jacksonville	1300 Broad St. Street	Jacksonville	FL	32202	1,411,780	210
St. Petersburg Housing Authority	11479 Ulmerton Road	Largo	FL	33778	573,291	70
Housing Authority of Tampa	1529 W. Main Street	Tampa	FL	33607	309,330	35

APPENDIX A—Continued

Recipient	Address	City	State	Zip code	Amount	Vouchers
Orlando Housing Authority	390 North Bumby Avenue.	Orlando	FL	32803	729,331	105
Housing Authority of Daytona Beach	211 N. Ridgewood Ave., Suite 200.	Daytona Beach	FL	32114	219,714	35
Housing Authority of Sarasota	1300 6th Street	Sarasota	FL	34236	304,370	35
Housing Authority of West Palm Beach.	1715 Division Avenue	West Palm Beach	FL	33407	354,403	35
City of Lakeland Housing Authority	P.O. Box 1009	Lakeland	FL	33802	195,623	35
Housing Authority of Miami Beach	200 Alton Road	Miami Beach	FL	33139	531,154	70
Panama City Housing Authority	804 E. 15th Street	Panama City	FL	32405	197,832	35
Housing Authority of the City of Titusville.	524 S. Hopkins Avenue.	Titusville	FL	32796	414,515	70
Housing Authority of the City of Fort Meyers.	4224 Michigan Avenue	Fort Myers	FL	33916	340,112	70
Broward County Housing Authority	4780 N. State Road 7	Lauderdale Lakes	FL	33319	812,745	70
Housing Authority of Lee County	14170 Warner Circle	North Fort Myers	FL	33903	174,769	35
Housing Authority of Augusta	P.O. Box 3246	Augusta	GA	30914	208,557	35
Housing Authority of Dekalb County	750 Commerce Drive, Suite 201.	Decatur	GA	30030	1,127,269	140
Georgia Department of Community Affairs.	60 Executive Parkway South, NE.	Atlanta	GA	30329	609,645	105
Guam Housing and Urban Renewal Authority.	117 Bien Venida Avenue.	Sinajana	GQ	96910	124,142	10
Hawaii Public Housing Authority	P.O. Box 17907	Honolulu	HI	96817	363,545	35
City of Des Moines Municipal Housing Authority.	100 East Euclid, Suite 101.	Des Moines	IA	50313	159,910	35
Mason City Housing Authority	22 N. Georgia—#214	Mason City	IA	50401	110,305	35
Boise City Housing Authority	1276 River Street, Suite 300.	Boise	ID	83702	106,589	20
Chicago Housing Authority	626 W. Jackson Blvd	Chicago	IL	60661	984,977	105
City of Danville Housing Authority	P.O. Box 168	Danville	IL	61834	153,409	35
Rockford Housing Authority	223 S. Winnebago Street.	Rockford	IL	61102	179,432	35
Housing Authority of Cook County	175 W. Jackson, Suite 350.	Chicago	IL	60604	322,749	35
City of N. Chicago Housing Authority	1440 Jackson Street	North Chicago	IL	60064	285,313	35
City of Fort Wayne Housing Authority	P.O. Box 13489	Fort Wayne	IN	46869	184,692	35
Indianapolis Housing Agency	1919 North Meridian Street.	Indianapolis	IN	46202	220,611	35
Bloomington Housing Authority	1007 N. Summit Street	Bloomington	IN	47404	203,898	35
Marion Housing Authority	601 S. Adams Street	Marion	IN	46953	137,255	35
Topeka Housing Authority	2010 SE. California Avenue.	Topeka	KS	66607	129,976	35
Wichita Housing Authority	332 Riverview Street	Wichita	KS	67203	170,693	35
Louisville Housing Authority	420 S. 8th Street	Louisville	KY	40203	637,836	105
Lexington Fayette Urban County Housing Authority.	300 West New Circle Road.	Lexington	KY	40505	195,422	35
Newport Housing Authority	P.O. Box 72459	Newport	KY	41072	167,815	35
Lafayette (City) Housing Authority	115 Katie Drive	Lafayette	LA	70501	150,723	35
Kenner Housing Authority	1013 31st Street	Kenner	LA	70065	316,704	35
Bossier Parish Police Jury	3022 Old Minden Road, Suite 206.	Bossier City	LA	71112	164,155	35
Boston Housing Authority	52 Chauncy Street	Boston	MA	02111	1,315,498	105
Cambridge Housing Authority	675 Massachusetts Avenue.	Cambridge	MA	02139	476,676	35
New Bedford Housing Authority	134 South Second Street.	New Bedford	MA	02741	246,688	35
Worcester Housing Authority	40 Belmont Street	Worcester	MA	01605	243,505	35
Northampton Housing Authority	49 Old South Street—Suite 1.	Northampton	MA	01060	235,375	35
Braintree Housing Authority	25 Roosevelt Street	Braintree	MA	02184	376,236	35
Chelmsford Housing Authority	10 Wilson Street	Chelmsford	MA	01824	265,528	35
Community Development Program, Comm. of MA.	100 Cambridge Street, Suite 300.	Boston	MA	02114	339,396	35
Housing Authority Prince George's County.	9400 Peppercorn Place, Suite 200.	Largo	MD	20774	439,519	35
Baltimore County Housing office	6401 York Road	Baltimore	MD	21212	525,512	70
Portland Housing Authority	14 Baxter Boulevard	Portland	ME	04101	277,261	35
Battle Creek Housing Commission	250 Champion Street	Battle Creek	MI	49017	132,381	35
Lansing Housing Commission	310 Seymour Avenue	Lansing	MI	48933	202,216	35
Kent County Housing Commission	82 Ionia Avenue, NW. Suite 390.	Grand Rapids	MI	49503	247,387	35

APPENDIX A—Continued

Recipient	Address	City	State	Zip code	Amount	Vouchers
Michigan State Housing Development Authority.	735 E. Michigan Avenue.	Lansing	MI	48912	992,758	175
St. Paul Public Housing Authority	555 N. Wabasha Street Suite 400.	Saint Paul	MN	55102	270,759	35
Minneapolis Public Housing Authority	1001 Washington Avenue N.	Minneapolis	MN	55401	303,276	35
St. Cloud Hra	1225 W. Saint Germain.	Saint Cloud	MN	56301	173,399	35
St. Louis Housing Authority	4100 Lindell Boulevard	Saint Louis	MO	63108	215,553	35
Columbia Housing Authority	201 Switzler Street	Columbia	MO	65203	179,046	35
Joplin Housing Authority	1834 W. 24th Street	Joplin	MO	64804	112,366	35
Housing Authority of Biloxi	P.O. Box 447	Biloxi	MS	39533	230,230	35
Jackson Housing Authority	P.O. Box 11327	Jackson	MS	39283	207,936	35
Housing Authority of Billings	2415 1st Avenue N	Billings	MT	59101	156,954	35
Housing Authority of the City of Wilmington.	P.O. Box 899	Wilmington	NC	28402	82,712	15
Hou of the City of Charlotte	P.O. Box 36795	Charlotte	NC	28236	266,918	35
Housing Authority of the City of Asheville.	P.O. Box 1898	Asheville	NC	28802	166,359	35
Fayetteville Metropolitan Housing Authority.	P.O. Box 2349	Fayetteville	NC	28302	106,697	20
Greensboro Housing Authority	P.O. Box 21287	Greensboro	NC	27420	175,781	35
Housing Authority of Winston-Salem	500 West Fourth Street, Suite 300.	Winston-Salem	NC	27101	177,327	35
Housing Authority of the County of Wake.	P.O. Box 399	Zebulon	NC	27597	515,362	70
Housing Authority of the City of Greenville.	P.O. Box 1426	Greenville	NC	27835	140,175	35
Fargo Housing And Redevelopment Authority.	P.O. Box 430	Fargo	ND	58107	131,830	35
Omaha Housing Authority	540 S. 27th Street	Omaha	NE	68105	197,067	35
Manchester Housing Authority	198 Hanover Street	Manchester	NH	03104	271,561	35
Long Branch Housing Authority	P.O. Box 337	Long Branch	NJ	07740	379,682	35
Jersey City Housing Authority	400 U.S. Highway #1	Jersey City	NJ	07306	592,192	70
Camden Housing Authority	2021 Watson Street	Camden	NJ	08105	286,649	35
Paterson Housing Authority	60 Van Houten Street	Paterson	NJ	07505	378,658	35
New Brunswick Housing Authority	P.O. Box 110	New Brunswick	NJ	08903	347,757	35
New Jersey Department of Community Affairs.	101 South Broad Street.	Trenton	NJ	08625	637,224	70
Albuquerque Housing Authority	1840 University Boulevard SE.	Albuquerque	NM	87106	181,012	35
Las Cruces Housing Authority	926 S. San Pedro Street.	Las Cruces	NM	88001	161,013	35
Santa Fe County Housing Authority	52 Camino De Jacobo	Santa Fe	NM	87507	264,898	35
City of Reno Housing Authority	1525 E. 9th Street	Reno	NV	89512	218,419	35
County of Clark Housing Authority	5390 E. Flamingo Road.	Las Vegas	NV	89122	1,494,483	175
Housing Authority of Syracuse	516 Burt St	Syracuse	NY	13202	193,090	35
New York City Housing Authority	250 Broadway	New York	NY	10007	2,622,952	280
Albany Housing Authority	200 South Pearl St	Albany	NY	12202	372,050	70
Housing Authority of Rome	205 St. Peter's Ave	Rome	NY	13440	136,720	35
Housing Authority of Rochester	675 West Main St. Suite 100.	Rochester	NY	14611	162,283	35
Poughkeepsie Housing Authority	4 Howard Street	Poughkeepsie	NY	12601	222,791	35
Town of Amherst	1195 Main St	Buffalo	NY	14209	304,786	70
NYS Housing Trust Fund Corporation	25 Beaver St, 7th Floor.	New York	NY	10004	1,435,674	175
Columbus Metropolitan Housing Authority.	880 East 11th Ave	Columbus	OH	43211	205,551	35
Cuyahoga Metropolitan Housing Authority.	1441 W. 25th Street	Cleveland	OH	44113	467,896	70
Cincinnati Metropolitan Housing Authority.	16 W. Central Parkway.	Cincinnati	OH	45202	204,712	35
Lucas Metropolitan Housing Authority	P.O. Box 477	Toledo	OH	43697	184,318	35
Akron Metropolitan Housing Authority	100 W. Cedar Street	Akron	OH	44307	195,985	35
Athens Metropolitan Housing Authority	10 Hope Drive	Athens	OH	45701	155,823	35
Oklahoma City Housing Authority	1700 NE. 4th Street	Oklahoma City	OK	73117	184,939	35
Housing Authority of Portland	135 SW. Ash Street	Portland	OR	97204	240,639	35
Housing Authority & Community Services Agency of Lane County.	177 Day Island Road	Eugene	OR	97401	178,318	35
Housing Authority of Jackson County	2231 Table Rock Road.	Medford	OR	97501	354,333	70

APPENDIX A—Continued

Recipient	Address	City	State	Zip code	Amount	Vouchers
Linn-Benton Housing Authority	1250 SE. Queen Ave	Albany	OR	97322	181,818	35
Philadelphia Housing Authority	12 S. 23rd Street	Philadelphia	PA	19103	663,622	105
Allegheny County Housing Authority	625 Stanwix Street	Pittsburgh	PA	15222	187,995	35
Harrisburg Housing Authority	351 Chestnut Street	Harrisburg	PA	17101	229,013	35
Housing Authority of the County of Butler.	114 Woody Drive	Butler	PA	16001	76,344	15
Delaware County Housing Authority	1855 Constitution Avenue.	Woodlyn	PA	19094	274,485	35
Hous Authority of the County of Chester.	30 W. Barnard Street	West Chester	PA	19382	287,768	35
Wilkes Barre Housing Authority	50 Lincoln Plaza, S. Wilkes Barre Blvd.	Wilkes Barre	PA	18702	156,785	35
Lebanon County Housing Authority	303 Chestnut Street	Lebanon	PA	17042	99,544	20
Blair County Housing Authority	P.O. Box 167	Hollidaysburg	PA	16648	124,395	35
Providence Housing Authority	100 Broad Street	Providence	RI	02903	239,459	35
Puerto Rico Deparment of Housing	P.O. Box 21365	San Juan	RQ	00928	199,033	35
Housing Authority of Columbia	1917 Harden Street	Columbia	SC	29204	198,835	35
Housing Authority Greenville	P.O. Box 10047	Greenville	SC	29603	189,619	35
Housing Authority of Myrtle Beach	P.O. Box 2468	Myrtle Beach	SC	29578	189,891	35
Pennington County Housing & Redevelopment Comm.	1805 W. Fulton Street, Ste. 101.	Rapid City	SD	57702	170,767	35
Memphis Housing Authority	P.O. Box 3664	Memphis	TN	38103	121,432	20
Knoxville Community Devel. Corp	P.O. Box 3550	Knoxville	TN	37927	182,089	35
Chattanooga Housing Authority	P.O. Box 1486	Chattanooga	TN	37401	182,751	35
Metropolitan Development & Housing Agency.	701 6th St	Nashville	TN	37202	192,078	35
Housing Authority of Dickson	333 Martin Luther King Jr. Boulevard.	Dickson	TN	37055	161,769	35
Housing Authority of Oak Ridge	10 Van Hicks Lane	Oak Ridge	TN	37830	150,834	35
Austin Housing Authority	P.O. Box 6159	Austin	TX	78762	583,843	70
Housing Authority of El Paso	5300 E. Paisano Dr	El Paso	TX	79905	192,720	35
Fort Worth Housing Authority	1201 13th St	Fort Worth	TX	76101	647,941	105
Houston Housing Authority	2640 Fountain View	Houston	TX	77057	1,509,320	210
San Antonio Housing Authority	818 Flores St	San Antonio	TX	78295	470,815	70
Housing Authority of Dallas	3939 N. Hampton Road.	Dallas	TX	75212	821,591	105
Galveston Housing Authority	4700 Broadway Street	Galveston	TX	77551	225,015	35
Housing Authority of Abilene	P.O. Box 60	Abilene	TX	79604	297,186	70
Panhandle Community Services	P.O. Box 32150	Amarillo	TX	79120	157,385	35
Central Texas Council of Governments.	P.O. Box 729	Belton	TX	76513	163,501	35
Deep East Texas Council of Governments.	210 Premier Drive	Jasper	TX	75951	177,306	35
Housing Authority of Salt Lake City	1776 S. West Temple	Salt Lake City	UT	84115	435,308	70
Norfolk Redevelopment & Housing Authority.	P.O. Box 968	Norfolk	VA	23501	261,571	35
Fairfax County Redevelopment And Housing Authority.	3700 Pender Drive Suite 300.	Fairfax	VA	22030	426,409	35
City of Virginia Beach	Princess Anne Park Municipal Center—Building 18a.	Virginia Beach	VA	23456	270,541	35
Virginia Housing Development Authority.	P.O. Box 4545	Richmond	VA	23220	226,776	35
Vermont State Housing Authority	1 Prospect Street	Montpelier	VT	05602	195,007	35
Seattle Housing Authority	120 Sixth Avenue North.	Seattle	WA	98109	455,610	53
King County Housing Authority	600 Andover Park West.	Seattle	WA	98188	526,969	52
Housing Authority of the City of Bremerton.	P.O. Box 4460	Bremerton	WA	98312	222,766	35
Housing Authority of the City of Tacoma.	902 S. L Street	Tacoma	WA	98405	270,487	35
Housing Authority of the City of Vancouver.	2500 Main Street	Vancouver	WA	98660	406,718	70
Housing Authority of Snohomish County.	12625 4th Avenue W. Suite 200.	Everett	WA	98204	296,495	35
Housing Authority of the City of Yakima.	810 N. 6th Avenue	Yakima	WA	98902	161,987	35
Housing Authority of Thurston County	503 West Fourth Avenue.	Olympia	WA	98501	204,256	35
Pierce County Housing Authority	P.O. Box 45410	Tacoma	WA	98445	240,955	35
Spokane Housing Authority	55 W. Mission Avenue	Spokane	WA	99201	173,416	35

APPENDIX A—Continued

Recipient	Address	City	State	Zip code	Amount	Vouchers
Housing Authority of the City of Milwaukee.	P.O. Box 324	Milwaukee	WI	53201	193,382	35
Madison Community Development Authority.	P.O. Box 1785	Madison	WI	53701	224,674	35
Racine County Housing Authority	837 S. Main Street	Racine	WI	53403	177,360	35
Huntington WV Housing Authority	P.O. Box 2183	Huntington	WV	25722	165,746	35
Housing Authority of Raleigh County	P.O. Box 2618	Beckley	WV	25802	123,560	35

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BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5386–N–01]

Privacy Act of 1974; Notice of Modification of Existing Computer Matching Program Between the Department of Housing and Urban Development (HUD) and the Social Security Administration (SSA): Matching Tenant Data in Assisted Housing Programs

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice of modification of Existing Computer Matching Program.

SUMMARY: Pursuant to the Computer Matching and Privacy Protection Act of 1988, as amended, and the Office of Management and Budget's (OMB) Guidance on the statute (5 U.S.C. 552a, as amended), HUD is providing notice of its intent to modify an existing computer matching program with SSA to include the Disaster Housing Assistance Program (DHAP) as a covered HUD rental assistance program for the purpose of income verifications and computer matching.

DATES: *Effective Date:* The modification to the existing computer matching program and its matching activities may commence after the respective Data Integrity Boards (DIBs) of both agencies approve and sign the agreement modification, and after, the later of the following: (1) 30 days after HUD publishes notice of the modification in the **Federal Register**; (2) at least 40 days after HUD files a report of the modification with the Office of Management and Budge (OMB), and the Congressional committees, unless comments are received, which result in a contrary determination

Comments Due Date: April 30, 2010.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Rules Docket Clerk, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 10276, Washington, DC 20410–0500. Communications should refer to the above docket number and title. Comments sent by facsimile are not acceptable. A copy of each communication submitted will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address.

FOR FURTHER INFORMATION CONTACT: For Privacy Act inquires: Office of the Chief Information Officer, contact Donna Robinson-Staton, Departmental Privacy Act Officer, HUD, 451 Seventh Street, SW., Room 2256, Washington, DC 20410, telephone number (202) 402–8073. For program information: Office of Public and Indian Housing, contact Nicole Faison, Program Advisor for the Office of Public Housing and Voucher Programs, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 4214, Washington, DC 20410, telephone number (202) 402–4267; Office of Housing, contact Gail Williamson, Director of the Housing Assistance Policy Division, Department of Housing and Urban Development, 451 Seventh Street, SW., Room 6138, Washington, DC 20410, telephone number (202) 402–2473. (These are not toll free telephone numbers). A telecommunications device for hearing- and speech-impaired individuals (TTY) is available at (800) 877–8339 (Federal Information Relay Service).

SUPPLEMENTARY INFORMATION: This Notice supersedes a similar notice published in the **Federal Register** (FR) on March 11, 2009 at 74 FR 10605. On March 11, 2009, Section 239 of HUD's 2009 Appropriations Act modified Section 904 of the Stewart B. McKinney Act of 1988, as amended, to include the Disaster Housing Assistance Program (DHAP). Computer matching for participants of the Disaster Housing Assistance Program is expected to begin no sooner than April 2010. HUD will continue to obtain SSA data and make the results available to (1) program administrators such as public housing agencies (PHAs) and private owners and management agents (O/As) to enable them to verify the accuracy of income reported by the tenants (participants) of HUD rental assistance programs and (2) contract administrators (CAs) overseeing and monitoring O/A operations as well as independent public auditors (IPAs) that audit both PHAs and O/As. SSA data will also continue to be used to validate information provided by borrowers and co-borrowers applying for and obtaining insurance for Federal Housing Administration (FHA) mortgages. The HUD–SSA computer matching program will be modified to now include program participants of HUD's new Disaster Housing Assistance Program (DHAP).

Administrators of HUD rental assistance programs rely upon the accuracy of tenant-reported income to determine participant eligibility for and level of, rental assistance. The computer matching program will provide indicators of potential under-reported tenant income that will require additional verification to identify inappropriate (excess or insufficient) rental assistance, and perhaps administrative or legal actions. The matching program will be carried out to detect inappropriate (excessive or insufficient) rental assistance under sections 221(3), 221(d)(5), and 236 of the National Housing Act, the United States Housing Act of 1937, section 101 of the Housing and Community Development Act of 1965, section 202 of the Housing Act of 1959, section 811 of the Cranston-Gonzalez National Affordable Housing Act, the Native American Housing Assistance and Self-Determination Act of 1996, and the Quality Housing and Work Responsibility Act (QHWRA) of 1998. The program will also provide for verification of Social Security numbers (SSNs) for tenants participating in covered rental assistance programs, and borrowers and co-borrowers applying for mortgage insurance for FHA loans through HUD. This Notice provides an overview of computer matching for HUD's rental assistance programs. Specifically, the Notice describes HUD's program for computer matching of its tenant data to SSA's death data, Social

Security (SS) and Supplemental Security Income (SSI) benefits data.

The Computer Matching and Privacy Protection Act (CMPPA) of 1988, an amendment to the Privacy Act of 1974 (5 U.S.C. 552a), OMB's guidance on this statute entitled "Final Guidance Interpreting the Provisions of Public Law 100–503, the CMPPA of 1988" (OMB Guidance), and OMB Circular No. A–130 requires publication of notices of computer matching programs. Appendix I to OMB's Revision of Circular No. A–130, "Transmittal Memorandum No. 4, Management of Federal Information Resources," prescribes Federal agency responsibilities for maintaining records about individuals. In compliance with the CMPPA and Appendix I to OMB Circular No. A–130, copies of this notice are being provided to the Committee on Government Reform and Oversight of the House of Representatives, the Committee of Homeland Security and Governmental Affairs of the Senate, and OMB's Office of Information and Regulatory Affairs.

I. Authority

This matching program is being conducted pursuant to the Privacy Act of 1974 (5 U.S.C. 552a); 542(b) of the 1998 Appropriations Act (Pub. L. 105–65); section 904 of the Stewart B. McKinney Homeless Assistance Amendments Act of 1988, as amended (42 U.S.C. 3544); section 165 of the Housing and Community Development Act of 1987 (42 U.S.C. 3543); the National Housing Act (12 U.S.C. 1701–1750g); the United States Housing Act of 1937 (42 U.S.C. 1437–1437z); section 101 of the Housing and Community Development Act of 1965 (12 U.S.C. 1701s); the Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4101 *et seq.*); and the QHWRA Act of 1998 (42 U.S.C. 1437a(f)). The Housing and Community Development Act of 1987 authorizes HUD to require participants (and applicants) in HUD-administered programs involving loan and rental assistance to disclose to HUD their social security numbers (SSNs) as a condition of continuing (or initial) eligibility for participation in the programs. The QHWRA of 1998, section 508(d), 42 U.S.C. 1437a(f) authorizes the Secretary of HUD to require disclosure by the tenant to the PHA of income information received by the tenant from HUD as part of the income verification procedures of HUD. The QHWRA was amended by Public Law 106–74, which extended the disclosure requirements to participants in section 8, section 202, and section 811 assistance programs. The participants are required to disclose the HUD-provided income information to owners responsible for determining the participant's eligibility or level of benefits.

II. Covered Programs

This Notice of computer matching program applies to the following rental assistance programs:

A. Disaster Housing Assistance Program (DHAP)
B. Public Housing
C. Section 8 Housing Choice Voucher (HCV)
D. Project-Based Voucher
E. Section 8 Moderate Rehabilitation
F. Project-Based Section 8
  1. New Construction
  2. State Agency Financed
  3. Substantial Rehabilitation
  4. Section 202/8
  5. Rural Housing Services Section 515/8
  6. Loan Management Set-Aside (LMSA)
  7. Property Disposition Set-Aside (PDSA)
G. Section 101 Rent Supplement
H. Section 202/162 Project Assistance Contract (PAC)
I. Section 202 Project Rental Assistance Contract (PRAC)
J. Section 811 Project Rental Assistance Contract (PRAC)
K. Section 236
L. Section 236 Rental Assistance Program
M. Section 221(d)(3) Below Market Interest Rate (BMIR)

Note: This Notice does not apply to the Low Income Housing Tax Credit (LIHTC) or the Rural Housing Services Section 515 without Section 8 programs.

III. Objectives To Be Met by the Matching Program

HUD's primary objective in implementing the computer matching program is to verify the income of individuals participating in the rental assistance programs identified in section II above to determine the appropriate level of rental assistance, and to detect, deter, reduce and correct fraud and abuse in rental assistance programs. In meeting this objective, HUD also is carrying out its responsibility under 42 U.S.C. 1437f(K) to ensure that income data provided to POAs by household members is complete and accurate. HUD's various assisted housing programs, administered through POAs, require that applicants and participants meet certain income and other criteria to be eligible for rental assistance. In addition, tenants generally are required to report the amounts and sources of their income at least annually. However, under the QHWRA of 1998, PHAs must offer public housing tenants the option to pay a flat rent, or an income-based rent annually. Those tenants who select a flat rent will be required to recertify income at least every three years. In addition, the Changes to the Admissions and Occupancy Final Rule (March 29, 2000; 65 FR 16692) specified that household composition must be recertified annually for tenants who select a flat rent or income-based rent.

Other objectives of this computer matching program include: (1) Increasing the availability of rental assistance to individuals who meet the requirements of the rental assistance programs; (2) after removal of personal identifiers, conducting analyses of the Social Security death data and benefit information, and income reporting of program participants; and (3) measure improper payments due to under-reporting of income and/or overpayment of subsidy on behalf of deceased program participants (single member households).

IV. Program Description

In this computer matching program, tenant-provided information included in HUD's automated systems of records known as *Tenant Rental Assistance Certification System* (TRACS) (HUD/H–11) and the *Inventory Management System* (IMS), formerly known as the *Public and Indian Housing Information Center* (PIC) (HUD/PIH–4), will be compared to data from SSA databases. The notices for these systems were published at 62 FR 11909 and 73 FR 58256, respectively. HUD will disclose to SSA only tenant personal identifiers, i.e., full name, Social Security number, and date of birth. SSA will match the HUD-provided personal identifiers to personal identifiers included in their various systems of records identified in Section IV of this notice. SSA will validate HUD-provided personal identifiers and provide income data to HUD only for individuals with matched personal identifiers. SSA will also provide the date of death or indication of death for any program participant whose HUD-supplied personal identifiers are successfully matched against SSA databases. For any individual whose personal identifiers do not match the personal identifiers in the SSA database, SSA will provide HUD with an error message, which will describe the reason(s) for no match (*i.e.* incorrect date of birth or surname, or invalid Social Security number).

A. Income Verification

Any match (i.e., a "hit") will be further reviewed by HUD, the POAs, or the HUD Office of Inspector General (OIG) to determine whether the income reported by tenants to the program administrator is correct and complies with HUD and program administrator requirements. Specifically, current or prior SS and SSI benefit information and other data will be sought directly from tenants. For public housing and Section 8 tenant-based HCV programs, tenants will be required to provide PHAs with original SSA benefit verification letters dated within the last 60 days for comparison to computer matching results for accuracy. For multifamily housing programs, tenants must provide O/As with SSA benefit verification letters dated within the last 120 days. For SS and SSI benefit information for prior years, the tenant may be required to provide POAs with an original benefit history document from SSA if there is a dispute regarding historical income information obtained through the computer matching program.

B. Administrative or Legal Actions

Regarding all the matching described in this notice, POAs will take appropriate action in consultation with tenants to: (1) Resolve income disparities between tenant-reported and SSA-reported data; and (2) Use correct income amounts in determining rental assistance.

POAs must compute the rent in full compliance with all applicable statutes, regulations and administrator policies. POAs must ensure that they use the correct income and correctly compute the rent. In order to protect any individual whose records are used in this matching program, POAs may not suspend, terminate, reduce, or make a final denial of any rental assistance to any tenant, or take other adverse action against the tenant as a result of information produced by this matching program until: (a) The tenant has received notice from the POA of its findings and has been informed of the opportunity to contest such findings; (b) The POA has independently verified the information; and (c) either the notice period provided in applicable regulations of the program, or 30 days, whichever is later, has expired. "Independently verified" in item (b) means the specific information relating to the tenant that is used as a basis for an adverse action has been investigated and confirmed by the POA. (5 U.S.C. 552a) As such, POAs must resolve income discrepancies in consultation with tenants. Additionally, serious violations, which POAs, HUD Program staff, or the HUD OIG verify, should be referred for full investigation and appropriate civil and/or criminal proceedings.

With respect to SSA-provided error messages regarding HUD-provided tenant, and matched borrower or co-borrower personal identifiers, the POA and FHA administrator/agent will confirm its file and system documentation to confirm accuracy of data elements, and make any necessary corrections. If there is no error in the documentation, the POAs and FHA administrators/agents will notify the individual of the error and request that the individual contact the SSA to correct any SSA data errors. POAs and FHA administrators/agents cannot correct such errors.

V. Records To Be Matched

SSA will conduct the matching of tenant SSNs and additional identifiers (surnames and dates of birth) to tenant data that HUD supplies from its systems of records known as the *Tenant Rental Assistance Certification System* (TRACS) (HUD/H–11) and the *Inventory Management System (IMS),* formerly the *Public and Indian Housing Information Center* (PIC) (HUD/PIH–4). Program administrators utilize the form HUD–50058 module within the IMS system and the form HUD–50059 module within the TRACS to provide HUD with the tenant data.

SSA will match the tenant records included in HUD/H–11 and HUD/PIH–4 to their systems of records known as SSA's *Master Files of Social Security Number Holders, and SSN Applications* (60–0058), *Master Beneficiary Record* (60–0090), and *Supplemental Security Income Record* (60–103). The notice for these systems was published at 71 FR 1795 on January 11, 2006. HUD will place the resulting matched data into its *Enterprise Income Verification (EIV) system* (HUD/PIH–5). The notice for this system was initially published at 70 FR 41780 on July 20, 2005, and amended on September 1, 2009 (74 FR 45235) to reflect changes in the following categories (sections): Categories of Individuals Covered by the System, Categories of Records in the System, Purposes of the System, and Routine Uses of Records Maintained in the System, Including Categories of Users and Purposes of Such Users. The tenant records (one record for each family member) include these data elements: full name, SSN, and date of birth.

HUD data will also be matched to the *SSA's Master Files of Social Security Number Holders, and SSN Applications* (60–0058) for the purpose of validating SSNs of borrowers and co-borrowers of FHA mortgages and participants of HUD rental assistance programs to identify noncompliance with program eligibility requirements. The Computerized Homes Underwriting Management System (HUD/H–5), published at 57 FR 62142 on December 29, 1997 is the HUD FHA system of records used to match data transferred from SSA's Master Files of Social Security Number Holder and SSN Applications (60–0058) to the HUD mainframe. Mortgagees enter SSN data and review the returning verification/failure data through the FHA Connection. HUD will compare tenant SSNs provided by POAs to reveal duplicate SSNs and potential duplicate rental assistance.

VI. Period of the Match

The computer matching program will be conducted according to the computer matching agreement between HUD and the SSA. The computer matching agreement for the planned matches will terminate either when the purpose of the computer matching program is accomplished, or 18 months from the date the original agreement was signed, whichever comes first. The agreement may be extended for one 12-month period, with the mutual agreement of all involved parties, if the following conditions are met:

(1) Within three months of the expiration date, all Data Integrity Boards review the agreement, find that the program will be conducted without change, and find a continued favorable examination of benefit/cost results; and (2) All parties certify that the program has been conducted in compliance with the agreement.

The agreement may be terminated, prior to accomplishment of the computer matching purpose or 18 months from the date the agreement is signed (whichever comes first), by the mutual agreement of all involved parties within 30 days of written notice.

Dated: March 25, 2010.

Jerry E. Williams,

Chief Information Officer.

[FR Doc. 2010–7220 Filed 3–30–10; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Renewal of Agency Information Collection for Tribal Energy Resource Agreements; Comment Request

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission to the Office of Management and Budget.

SUMMARY: As required by the Paperwork Reduction Act, the Office of Indian Energy and Economic Development (IEED), in the Office of the Assistant Secretary—Indian Affairs, is submitting the information collection titled "Tribal Energy Resource Agreements (TERAs)" to the Office of Management and Budget (OMB) for renewal. The information collection is currently authorized by OMB Control Number 1076–0167, which expires March 31, 2010. The information collection requires Indian tribes interested in entering into a TERA or who already have a TERA to provide certain information, including information as part of the application for, and implementation, reassumption, and rescission of the TERA.

DATES: Interested persons are invited to submit comments on or before April 30, 2010.

ADDRESSES: You may submit comments on the information collection to the Desk Officer for Department of the Interior at the Office of Management and Budget, by facsimile to (202) 395–5806 or you may send an e-mail to: *OIRA_DOCKET@omb.eop.gov.* Please send a copy of your comments to Darryl Francois, Department of the Interior, Office of Indian Energy and Economic Development, Room 20—South Interior Building, 1951 Constitution Avenue, NW., Washington, DC 20245, fax (202) 208–4564; *e-mail: Darryl.Francois@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Darryl Francois, Department of the Interior, Office of Indian Energy and Economic Development, Room 20—South Interior Building, 1951 Constitution Avenue, NW., Washington, DC 20245, fax (202) 208–4564; *e-mail: Darryl.Francois@bia.gov,* telephone (202) 219–0740.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Energy Policy Act of 2005 (Pub. L. 109–58) authorizes the Secretary to approve individual TERAs. The intent of these agreements is to promote tribal oversight and management of energy and mineral resource development on tribal lands and further the goal of Indian self-determination. A TERA offers a tribe an alternative for developing energy-related business agreements and awarding leases and granting rights-of-way for energy facilities without having to obtain further approval from the Secretary.

This information collection conducted under TERA regulations at 25 CFR part 224 will allow IEED to determine the capacity of tribes to manage the development of energy resources on tribal lands. Information collected:

- Enables IEED to engage in a consultation process with tribes that is designed to foster optimal pre-planning of development proposals and speed up the review and approval process for TERA agreements;
- Provides wide public notice and opportunity for review of TERA agreements by the public, industry, and government agencies;
- Ensures that the public has an avenue for review of the performance of tribes in implementing a TERA;
- Creates a process for preventing damage to sensitive resources as well as ensuring that the public has fully communicated with the tribe in the petition process;
- Ensures that a tribe is fully aware of any attempt by the Department of the Interior to resume management authority over energy resources on tribal lands; and
- Ensures that the tribal government fully endorses any relinquishment of a TERA.

II. Request for Comments

IEED requests that you send your comments on this collection to the location listed in the **ADDRESSES** section. Your comments should address: (a) The necessity of the information collection for the proper performance of the agencies, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents, such as through the use of automated collection techniques or other forms of information technology.

Please note that an agency may not sponsor or conduct, and an individual need not respond to, a collection of information unless it has a valid OMB Control Number. Response to the information collection is required to obtain a benefit.

It is our policy to make all comments available to the public for review at the following location, during the hours of 9 a.m.–5 p.m., Eastern Daylight Savings Time, Monday through Friday except for legal holidays: Department of the Interior, Office of Indian Energy and Economic Development, Room 20—South Interior Building, 1951 Constitution Avenue, NW., Washington, DC 20245. Before including your address, phone number, e-mail address or other personally identifiable information, be advised that your entire comment—including your personally identifiable information—may be made public at any time. While you may request that we withhold your personally identifiable information, we cannot guarantee that we will be able to do so.

OMB has up to 60 days to make a decision on the submission for renewal, but may make the decision after 30 days. Therefore, to receive the best consideration of your comments, you should submit them closer to 30 days than 60 days.

III. Data

OMB Control Number: 1076–0167.

Title: Tribal Energy Resource Agreements, 25 CFR Part 224.

Brief Description of Collection: Submission of this information is required for Indian tribes to apply for, implement, reassume, or rescind a TERA that has been entered into in accordance with the Energy Policy Act of 2005 and 25 CFR part 224. This collection also requires the tribe to notify the public of certain actions. Response is required to obtain a benefit.

Type of Review: Extension without change of a currently approved collection.

Respondents: Indian tribes.

Number of Respondents: 14 (4 applicant tribes and 10 tribes with a TERA).

Frequency of Response: On occasion.

Total Number of Responses: 34.

Estimated Time per Response: Ranges from 32 hours to 1,080 hours.

Estimated Total Annual Burden: 10,752 hours.

Estimated Nonhour Cost Burden: $48,200.

Alvin Foster,

Acting Chief Information Officer—Indian Affairs.

[FR Doc. 2010–7172 Filed 3–30–10; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Renewal of Agency Information Collection for Navajo Partitioned Lands Grazing Permits; Request for Comments

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of submission to the Office of Management and Budget.

SUMMARY: As required by the Paperwork Reduction Act, the Bureau of Indian Affairs (BIA) is submitting the information collection, titled "Navajo Partitioned Lands Grazing Permits, 25 CFR 161" to the Office of Management and Budget (OMB) for renewal. The information collection is currently authorized by OMB Control Number 1076–0162, which expires March 31, 2010. The information collection requires the Navajo Nation, members of the Navajo Nation, and tribal organizations authorized by the Navajo Nation to submit certain information in order to obtain, modify, or assign a grazing permit.

DATES: Interested persons are invited to submit comments on or before April 30, 2010.

ADDRESSES: You may submit comments on the information collection to the Desk Officer for Department of the Interior at the Office of Management and Budget, by facsimile to (202) 395–5806 or you may send an e-mail to: *OIRA_DOCKET@omb.eop.gov.* Please send a copy of your comments to David Edington, Office of Trust Services, Bureau of Indian Affairs, Department of the Interior, 1849 C Street, NW., Mail Stop 4655, Washington, DC 20240, *facsimile:* (202) 219–0006, or e-mail *David.Edington@bia.gov.*

FOR FURTHER INFORMATION CONTACT: You may request further information or obtain copies of the information collection request submission from David Edington, *telephone:* (202) 513–0886.

SUPPLEMENTARY INFORMATION:

I. Abstract

The BIA is seeking renewal of the approval for the information collection conducted under 25 CFR part 161, implementing the Navajo-Hopi Settlement Act of 1974, 24 U.S.C. 640d–6402–31, as amended by the Navajo-Hopi Indian Relocation Amendments Acts of 1980, 94 Stat. 929, and the Federal court decisions of *Healing* v. *Jones,* 174 F. Supp.211 (D. Ariz. 1959) (Healing I), *Healing* v. *Jones,* 210 F. Suppl 126 (D. Ariz. 1962), aff'd 363 U.S. 758 (1963) (Healing II), *Hopi Tribe* v. *Watt,* 530 F. Supp. 1217 (D. Ariz. 1982), and *Hopi Tribe* v. *Watt,* 719 F.2d 314 (9th Cir. 1983).

This information collection allows BIA to receive the information necessary to determine whether an applicant to obtain, modify, or assign a grazing permit on Navajo-partitioned lands is eligible and complies with all applicable grazing requirements. No third party notification or public disclosure burden is associated with this collection.

II. Request for Comments

The BIA requests that you send your comments on this collection to the locations listed in the **ADDRESSES** section. Your comments should address: (a) The necessity of the information collection for the proper performance of the agencies, including whether the information will have practical utility; (b) the accuracy of the agencies' estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents, such as through the use of automated collection techniques or other forms of information technology.

Please note that an agency may not sponsor or conduct, and an individual need not respond to, a collection of information unless it has a valid OMB Control Number.

It is our policy to make all comments available to the public for review at the location listed in the **ADDRESSES** section during the hours of 9 a.m.–5 p.m., Eastern Time, Monday through Friday except for legal holidays. Before including your address, phone number, e-mail address or other personally identifiable information, be advised that your entire comment—including your personally identifiable information—may be made public at any time. While you may request that we withhold your personally identifiable information, we cannot guarantee that we will be able to do so.

OMB has up to 60 days to make a decision on the submission for renewal, but may make the decision after 30 days. Therefore, to receive the best consideration of your comments, you should submit them closer to 30 days than 60 days.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on February 24, 2010 (75 FR 8731). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity.

III. Data

OMB Control Number: 1076–0162.

Title: Navajo Partitioned Lands Grazing Permits, 25 CFR 161.

Brief Description of Collection: Submission of this information is required for Navajo Nation representatives, members, and authorized tribal organizations to obtain, modify or assign a grazing permit on Navajo partitioned lands. Response is required to obtain a benefit.

Type of Review: Extension without change of a currently approved collection.

Respondents: Tribes, tribal organizations, and individual Indians.

Number of Respondents: 700.

Total Number of Responses: 3,120.

Estimated Time per Response: Varies, from 15 minutes to 1 hour.

Estimated Total Annual Burden: 1,188 hours.

Alvin Foster,

Acting Chief Information Officer—Indian Affairs.

[FR Doc. 2010–7174 Filed 3–30–10; 8:45 am]

BILLING CODE 4310–4J–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: Museum of Cultural and Natural History, Central Michigan University, Mt. Pleasant, MI

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 Museum of Cultural and Natural History, Central Michigan University, Mt. Pleasant, MI. The human remains and associated funerary objects were removed from Arenac, Isabella, and Saginaw Counties, MI.

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 Museum of Cultural and Natural History professional staff and physical anthropologists from Western Michigan University, Kalamazoo, MI, and the University of Western Ontario, Canada, and in consultation with representatives of the Little Traverse Bay Bands of

Odawa Indians, Michigan, and the Saginaw Chippewa Indian Tribe of Michigan.

In 1970, human remains representing a minimum of two individuals were removed from Point Lookout, 20AC18, in Arenac County, MI. Students from Central Michigan University and amateur archeologists excavated the site and the material was immediately turned over to the Museum of Cultural and Natural History. No known individuals were identified. The 11 associated funerary objects are 2 (reconstructed) ceramic vessels, 1 piece of worked bone, 1 small sheet of copper, 1 bag of ochre sand, 1 stone object, 1 bag of ceramic sherds, 1 group of copper beads and bead fragments, 1 stone tool, 1 bone needle, and 1 tooth from an unknown animal.

Archeological evidence dates the material from the Early Late Woodland Era, and the determination is supported by publications of the State Archaeologist's Office of Michigan. The human remains were identified as being of Native American ancestry based on archeological dating and osteological examination.

In 1970–1971, human remains representing a minimum of 18 individuals were removed from Indian Mound Park, 20IB1, in Isabella County, MI. Faculty and students from Central Michigan University excavated the site and the material was immediately turned over to the Museum of Cultural and Natural History. No known individuals were identified. The five associated funerary objects are one celt, one projectile point, and three ceramic sherds.

Archeological evidence dates the material from the Early Late Woodland Era, and the determination is supported by publications of the State Archaeologist's Office of Michigan. The human remains were identified as being of Native American ancestry based on archeological dating and osteological examination.

From 1968 to 1970, and in 1972, human remains representing a minimum 124 individuals were removed from the Frazier-Tyra site, 20SA9, in Saginaw County, MI. Amateur archeologists excavated the site from 1968 to 1970, and turned over the material to the Anthropology Department of Central Michigan University, which transferred it to the Museum of Cultural and Natural History in the early 1990s. Students from Central Michigan University excavated the site again in 1972, and immediately turned over the materials they found to the Museum of Cultural and Natural History. No known individuals were identified. The 372 associated funerary objects are 285 ceramic sherds, 76 pieces of lithic debitage, 4 scrapers, 1 piece of copper, 1 abrading stone, 1 projectile point, 1 piece of conch, 1 bag of ochre, 1 pipe and 1 pipe fragment.

Archeological evidence dates the material from the Early Late Woodland Era, and the determination is supported by publications of the State Archaeologist's Office of Michigan. The human remains were identified as being of Native American ancestry based on archeological dating and osteological examination.

The area of Arenac, Isabella, and Saginaw Counties in mid-Michigan has a long established history of Native American occupation before European encroachment in the early 17th century. The Anishnaabek, which is comprised of the Odawa/Ottawa, Ojibwe/Chippewa and Potawatomi, have long called this area home. Officials of the Museum of Cultural and Natural History have reasonably determined that the individuals described above from Arenac, Isabella, and Saginaw Counties are Native American, however, officials of the Museum of Cultural and Natural History have determined that the evidence is insufficient to determine cultural affiliation with any present-day Indian tribe.

Officials of the Museum of Cultural and Natural History have determined that, pursuant to 25 U.S.C. 3001 (9–10), the human remains described above represent the physical remains of 144 individuals of Native American ancestry. Officials of the Museum of Cultural and Natural History also have determined that, pursuant to 25 U.S.C. 3001 (3)(A), the 388 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 Museum of Cultural and Natural History have determined that, pursuant to 25 U.S.C. 3001 (2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and associated funerary objects and any present-day Indian tribe.

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 February 2009, the Museum of Cultural and Natural History requested that the Review Committee recommend disposition of the 144 culturally unidentifiable human remains and associated funerary objects to the Little Traverse Bay Bands of Odawa Indians, Michigan, and the Saginaw Tribe of Chippewa Indians of Michigan, as the aboriginal occupants of the lands encompassing the present-day Arenac, Isabella, and Saginaw Counties, MI. The Review Committee considered the proposal at its May 23 - 24, 2009 meeting and recommended disposition of the human remains and associated funerary objects to the Little Traverse Bay Bands of Odawa Indians, Michigan, and the Saginaw Tribe of Chippewa Indians of Michigan. A September 16, 2009, letter on behalf of the Secretary of Interior from the Designated Federal Official transmitted the authorization for the museum to effect disposition of the culturally unidentifiable human remains and associated funerary objects to the two Indian tribes listed above contingent on the publication of a Notice of Inventory Completion in the **Federal Register**. This notice fulfills that requirement.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with the human remains and associated funerary objects should contact Dr. Pamela Gates, NAGPRA Representative, Museum of Cultural and Natural History, 103 Rowe Hall, Central Michigan University, Mt. Pleasant, MI 48859, telephone (989) 774–3341, before April 30, 2010. Disposition of the human remains and associated funerary objects to the Little Traverse Bay Bands of Odawa Indians, Michigan, and the Saginaw Tribe of Chippewa Indians of Michigan may proceed after that date if no additional claimants come forward.

The Museum of Cultural and Natural History is responsible for notifying the Little Traverse Bay Bands of Odawa Indians, Michigan, and the Saginaw Tribe of Chippewa Indians of Michigan that this notice has been published.

Dated: March 2, 2010

Sherry Hutt,

Manager, National NAGPRA Program.

[FR Doc. 2010–7254 Filed 3–30–10; 8:45 am]

BILLING CODE 4312–50–S

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decrees Under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

Notice is hereby given that on March 1, 2010, a proposed Consent Decree in the case of *United States and the Coeur d'Alene Tribe* v. *Sidney Resources Corp.,* civ. no. 10–00112–BLW, was lodged concurrently with the filing of a

complaint in the United States District Court for the District of Idaho.

The United States and the Coeur d'Alene Tribe ("Tribe") filed a complaint against Sidney Resources Corp. ("Sidney") alleging that Sidney is liable pursuant to Section 107(a) of CERCLA for response costs and natural resources damages in connection with Operable Unit Three of the Bunker Hill Mining and Metallurgical Complex Superfund Site in northern Idaho. The U.S. Environmental Protection Agency has incurred response costs and the U.S. Department of the Interior, U.S. Department of Agriculture and the Tribe are trustees of injured natural resources for the Site. The proposed Consent Decree is based on a financial analysis that Sidney has no ability to pay. Sidney does not currently own property within the Site. The Decree requires Sidney to assign its interests in insurance policies to a trust, for the benefit of EPA and the natural resource trustees. The Decree grants Sidney a covenant not to sue for response costs and natural resource damages in connection with the Site.

For thirty (30) days after the date of this publication, the Department of Justice will receive comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and either e-mailed to *pubcomment-ees.enrd@usdoj.gov* or mailed to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. In either case, the comments should refer to *United States and the Coeur d'Alene Tribe* v. *Sidney Resources Corp.,* D.J. Ref. No. 90–11–3–128/8.

During the comment period, the Consent Decree may be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the Consent Decree may also be obtained by mail from the Consent Decree Library, P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611, or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $14.25 (25 cents per page reproduction cost) payable to the United States Treasury or, if by e-mail or fax, forward a check in that amount to the Consent Decree Library at the stated address.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2010–7118 Filed 3–30–10; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Material Modification to Consent Decree Under the Clean Water Act

Pursuant to Department of Justice policy, notice is hereby given that, on March 26, 2010, a proposed First Material Modification to Consent Decree ("First Decree Modification") in *United States and the State of Indiana* v. *City of Anderson, Indiana,* Civil Action No. IP 02–1103 C M/S (S.D. Ind.) was lodged with the United States District Court for the Southern District of Indiana. The original Consent Decree in this matter, entered on September 18, 2002, addressed alleged violations of the Clean Water Act, 33 U.S.C. 1251–1387, and corresponding state law by the City of Anderson ("Anderson"). Among other things, the 2002 Consent Decree required Anderson to develop and implement a Long Term Control Plan to control Combined Sewer Overflows from its combined sewer system. Since entry of the 2002 Consent Decree, Anderson has been developing a Long Term Control Plan in consultation with the U.S. Environmental Protection Agency and the Indiana Department of Environmental Management. The control plan alternative that Anderson selected under that proposed Long Term Control Plan would require an array of sewer system and wastewater treatment plant improvement projects, at an estimated cost of more than $160 million. The First Decree Modification would require Anderson to adhere to a new three-phase Long Term Control Plan implementation schedule: (1) Phase I would be completed by no later than December 31, 2014; (2) Phase II would be completed by no later than December 31, 2019; and (3) Phase III would be completed by no later than December 31, 2029.

The Department of Justice will receive comments relating to the First Decree Modification for a period of thirty (30) days from the date of this publication. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and mailed either electronically to *pubcomment-ees.enrd@usdoj.gov* or in hard copy to P.O. Box 7611, U.S. Department of Justice, Washington, DC 20044–7611. Comments should refer to *United States and the State of Indiana* v. *City of Anderson, Indiana,* Civil Action No. IP 02–1103 C M/S (S.D. Ind.) and D.J. Ref. No. 90–5–2–1–07043/2.

The First Decree Modification may be examined at: (1) The offices of the United States Attorney, 10 West Market Street, Suite 2100, Indianapolis, Indiana; and (2) the offices of the U.S. Environmental Protection Agency, 77 West Jackson Boulevard, 14th Floor, Chicago, Illinois. During the public comment period, the First Decree Modification may also be examined on the following Department of Justice Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* A copy of the First Decree Modification may also be obtained by mail from the Department of Justice Consent Decree Library, P.O. Box 7611, Washington, DC 20044–7611 or by faxing or e-mailing a request to Tonia Fleetwood (*tonia.fleetwood@usdoj.gov*), fax no. (202) 514–0097, phone confirmation number (202) 514–1547. In requesting a copy from the Consent Decree Library, please enclose a check in the amount of $2.75 (11 pages at 25 cents per page reproduction cost) payable to the U.S. Treasury.

Maureen M. Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2010–7208 Filed 3–30–10; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Coordinating Council on Juvenile Justice and Delinquency Prevention

[OJP (OJJDP) Docket No. 1514]

Meeting of the Coordinating Council on Juvenile Justice and Delinquency Prevention

AGENCY: Coordinating Council on Juvenile Justice and Delinquency Prevention.

ACTION: Notice of meeting.

SUMMARY: The Coordinating Council on Juvenile Justice and Delinquency Prevention (Council) announces its April 2010 meeting.

DATES: Friday, April 16, 2010 from 11 a.m. to 12:30 p.m.

ADDRESSES: The meeting will take place in the third floor main conference room at the U.S. Department of Justice, Office of Justice Programs, 810 7th St. NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Visit the Web site for the Coordinating Council at *http://www.juvenilecouncil.gov* or contact Robin Delany-Shabazz, Designated Federal Official, by telephone at 202–307–9963 [**Note:** this is not a toll-free telephone number], or by e-mail at *Robin.Delany-Shabazz@usdoj.gov.* The meeting is open to the public.

SUPPLEMENTARY INFORMATION: The Coordinating Council on Juvenile Justice and Delinquency Prevention, established pursuant to Section 3(2)A of the Federal Advisory Committee Act (5 U.S.C. App. 2) will meet to carry out its advisory functions under Section 206 of the Juvenile Justice and Delinquency Prevention Act of 2002, 42 U.S.C. 5601, *et seq.* Documents such as meeting announcements, agendas, minutes, and reports will be available on the Council's Web page, *http://www.JuvenileCouncil.gov.,* where you may also obtain information on the meeting.

Although designated agency representatives may attend, the Council membership is composed of the Attorney General (Chair), the Administrator of the Office of Juvenile Justice and Delinquency Prevention (Vice Chair), the Secretary of Health and Human Services (HHS), the Secretary of Labor, the Secretary of Education, the Secretary of Housing and Urban Development, the Director of the Office of National Drug Control Policy, the Chief Executive Officer of the Corporation for National and Community Service, and the Assistant Secretary of Homeland Security for U.S. Immigration and Customs Enforcement. Up to nine additional members are appointed by the Speaker of the House of Representatives, the Senate Majority Leader, and the President of the United States. Other federal agencies take part in Council activities including the Departments of Agriculture, Defense, the Interior, and the Substance Abuse and Mental Health Services Administration of HHS.

Meeting Agenda

The agenda for this meeting will include: (a) Reports from the Council's Operations Committee and Issue Team; (b) presentations on juvenile information systems work and children's exposure to violence and c) update on and discussion of reconstruction of the Juvenile Justice system in New Orleans.

Registration

For security purposes, members of the public who wish to attend the meeting must pre-register online at *http://www.juvenilecouncil.gov* no later than Monday, April 12, 2010. Should problems arise with web registration, call Daryel Dunston at 240–221–4343 or send a request to register for the April 16, 2010 Council meeting to Mr. Dunston. Include name, title, organization or other affiliation, full address and phone, fax and e-mail information and send to his attention either by fax to 301–945–4295, or by e-mail to *ddunston@edjassociates.com.* [**Note:** these are not toll-free telephone numbers.] Additional identification documents may be required. Space is limited.

Note: Photo identification will be required for admission to the meeting.

Written Comments: Interested parties may submit written comments and questions by Monday, April 12, 2010, to Robin Delany-Shabazz, Designated Federal Official for the Coordinating Council on Juvenile Justice and Delinquency Prevention, at *Robin.Delany-Shabazz@usdoj.gov.* The Coordinating Council on Juvenile Justice and Delinquency Prevention expects that the public statements presented will not repeat previously submitted statements.

Jeff Slowikowski,

Acting Deputy Administrator.

[FR Doc. 2010–7175 Filed 3–30–10; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Cooperative Research Group on Integrated Investigations of Faulting in Carbonate Strata

Notice is hereby given that, on February 25, 2010, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Southwest Research Institute ("SwRI"): Cooperative Research Group on Integrated Investigations of Faulting in Carbonate Strata has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership, nature and objective. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, ConocoPhillips Co., Houston, TX; and Shell International Exploration & Production, Inc., Houston, TX have withdrawn as parties to this venture. The changes in its nature and objectives are: The period of performance has been extended to December 31, 2011.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and the participants intend to file additional written notifications disclosing all changes in membership.

On September 10, 2007, Cooperative Research Group on Integrated Investigation of Faulting in Carbonate Strata filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on November 7, 2007 (72 FR 62870).

Patricia A. Prink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 2010–7004 Filed 3–30–10; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Joint Venture Agreement Between Cambridge Major Laboratories, Inc. and Konarka Technologies, Inc., in Furtherance of NIST Cooperative Agreement (Proposal Number 00–00–7749)

Notice is hereby given that, on February 18, 2010, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* ("the Act"), Joint Venture Agreement Between Cambridge Major Laboratories, Inc. and Konarka Technologies, Inc., in Furtherance of NIST Cooperative Agreement (Proposal Number 00–00–7749) ("Cambridge and Konarka 00–00–7749") has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing (1) the identities of the parties to the venture and (2) the nature and objectives of the venture. The notifications were filed for the purpose of invoking the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances.

Pursuant to Section 6(b) of the Act, the identities of the parties to the venture are: Konarka Technologies, Inc., Lowell, MA; and Cambridge Major Laboratories, Inc., Germantown, WI. The general area of Cambridge and Konarka 00–00–7749's planned activity is to

develop commercializable organic photovoltaic modules that are transparent to any pre-selected region of the visible spectrum. This unique feature enables the application of these colored, transparent, power producing modules in windows for commercial and residential building and greenhouses.

Patricia A. Brink,

Deputy Director of Operations, Antitrust Division.

[FR Doc. 2010–7003 Filed 3–30–10; 8:45 am]

BILLING CODE 4410–11–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Notice of Affirmative Decisions on Petitions for Modification Granted in Whole or in Part

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice of affirmative decisions on petitions for modification granted in whole or in part.

SUMMARY: The Mine Safety and Health Administration (MSHA) enforces mine operator compliance with mandatory safety and health standards that protect miners and improve safety and health conditions in U.S. mines. This **Federal Register** Notice (FR Notice) notifies the public that it has investigated and issued a final decision on certain mine operator petitions to modify a safety standard.

ADDRESSES: Copies of the final decisions are posted on MSHA's Web Site at *http://www.msha.gov/indexes/petition.htm*. The public may inspect the petitions and final decisions during normal business hours in MSHA's Office of Standards, Regulations and Variances, 1100 Wilson Boulevard, Room 2349, Arlington, Virginia 22209. All visitors must first stop at the receptionist desk on the 21st Floor to sign-in.

FOR FURTHER INFORMATION CONTACT: Roslyn B. Fontaine, Acting Deputy Director, Office of Standards, Regulations and Variances at 202–693–9475 (Voice), *fontaine.roslyn@dol.gov* (E-mail), or 202–693–9441 (Telefax), or Barbara Barron at 202–693–9447 (Voice), *barron.barbara@dol.gov* (E-mail), or 202–693–9441 (Telefax). [These are not toll-free numbers].

SUPPLEMENTARY INFORMATION:

I. Introduction

Under section 101 of the Federal Mine Safety and Health Act of 1977, a mine operator may petition and the Secretary of Labor (Secretary) may modify the application of a mandatory safety standard to that mine if the Secretary determines that: (1) An alternative method exists that will guarantee no less protection for the miners affected than that provided by the standard; or (2) that the application of the standard will result in a diminution of safety to the affected miners.

MSHA bases the final decision on the petitioner's statements, any comments and information submitted by interested persons, and a field investigation of the conditions at the mine. In some instances, MSHA may approve a petition for modification on the condition that the mine operator complies with other requirements noted in the decision.

II. Granted Petitions for Modification

On the basis of the findings of MSHA's investigation, and as designee of the Secretary, MSHA has granted or partially granted the following petitions for modification:

• *Docket Number:* M–2008–047–C
FR Notice: 73 FR 69680 (November 19, 2008).
Petitioner: Knight Hawk Coal, LLC, 7290 County Line Road, Cutler, Illinois 62238.
Mine: Prairie Eagle Underground Mine, MSHA I.D. No. 11–03147, located in Perry County, Illinois.
Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

• *Docket Number:* M–2009–008–C
FR Notice: 73 FR 23745 (May 20, 2009).
Petitioner: Excel Mining, LLC, Box 4126, State Highway 194 West, Pikeville, Kentucky 41501.
Mine: Mine No. 3, MSHA I.D. No. 15–08079, located in Pike County, Kentucky.
Regulation Affected: 30 CFR 75.503 (18.35) (Permissible electric face equipment; maintenance).

• *Docket Number:* M–2009–012–C
FR Notice: 74 FR 23746 (May 20, 2009).
Petitioner: Wolf Run Mining Company, 1 Edmiston Way, Buckhannon, West Virginia 26201.
Mine: Imperial Mine, MSHA I.D. No. 46–09115, located in Upshur County, West Virginia.
Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

• *Docket Number:* M–2009–013–C
FR Notice: 74 FR 27185 (June 8, 2009).
Petitioner: Wolf Run Mining Company, Rt. 3, Box 146, Philippi, West Virginia 26416.
Mine: Sentinel Mine, MSHA I.D. No. 46–04168, located in Barbour County, West Virginia.
Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

• *Docket Number:* M–2009–003–M
FR Notice: 74 FR 27186 (June 8, 2009).
Petitioner: Resolution Copper Mining, LLC, 102 Magma Heights, P.O. Box 1944, Superior, Arizona 85273.
Mine: Resolution Copper Mine, MSHA I.D. No. 02–00152, located in Pinal County, Arizona.
Regulation Affected: 30 CFR 57.15031 (Location of self-rescue devices).

Dated: March 26, 2010.

Patricia W. Silvey,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 2010–7196 Filed 3–30–10; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Employment and Training Administration

Employment and Training Administration Program Year (PY) 2010 Workforce Investment Act (WIA) Allotments; PY 2010 Wagner-Peyser Act Final Allotments and PY 2010 Workforce Information Grants

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This Notice announces allotments for PY 2010 for WIA Title I Youth, Adults and Dislocated Worker Activities programs; final allotments for Employment Service (ES) activities under the Wagner-Peyser Act for PY 2010 and Workforce Information Grants allotments for PY 2010. Allotments for the Work Opportunity Tax Credits will be announced separately.

The WIA allotments for States and the State final allotments for the Wagner-Peyser Act are based on formulas defined in their respective statutes. The WIA allotments for the outlying areas are based on a formula determined by the Secretary. As required by WIA section 182(d), on February 17, 2000, a Notice of the discretionary formula for allocating PY 2000 funds for the outlying areas (American Samoa, Guam, Marshall Islands, Micronesia, Northern Marianas, Palau, and the Virgin Islands) was published in the **Federal Register** at 65 FR 8236 (February 17, 2000). The rationale for the formula and methodology was fully explained in the February 17, 2000, **Federal Register** Notice. The formula for PY 2010 is the same as used for PY 2000 and is described in the section on Youth Activities program allotments.

Comments are invited on the formula used to allot funds to the outlying areas.

DATES: Comments on the formula used to allot funds to the outlying areas must be received by April 30, 2010.

ADDRESSES: Submit written comments to the Employment and Training Administration, Office of Financial and Administrative Management, 200 Constitution Ave., NW., Room N–4702, Washington, DC 20210, Attention: Mr. Kenneth Leung, (202) 693–3471 (phone), (202) 693–2859 (fax), e-mail: *Leung.Kenneth@dol.gov.*

FOR FURTHER INFORMATION CONTACT: WIA Youth Activities allotments—Evan Rosenberg at (202) 693–3593 or LaSharn Youngblood at (202) 693–3606; WIA Adult and Dislocated Worker Activities and ES final allotments—Mike Qualter at (202) 693–3014; Workforce Information Grant allotments—Anthony Dais at (202) 693–2784.

SUPPLEMENTARY INFORMATION: The Department of Labor (DOL or Department) is announcing WIA allotments for PY 2010 for Youth Activities, Adults and Dislocated Worker Activities, and Wagner-Peyser Act PY 2010 final allotments. This notice provides information on the amount of funds available during PY 2010 to States with an approved WIA Title I and Wagner-Peyser Act Strategic Plan for PY 2010, and information regarding allotments to the outlying areas.

The allotments are based on the funds appropriated in the Consolidated Appropriations Act, 2010, Public Law 111–117, December 16, 2009. Included below are tables listing the PY 2010 allotments for programs under WIA Title I Youth Activities (Table I), Adult and Dislocated Workers Employment and Training Activities (Tables II and III, respectively), and the PY 2010 Wagner-Peyser Act final allotments (Table IV). Also attached is the PY 2010 Workforce Information Grant table (Table V).

Youth Activities Allotments. PY 2010 Youth Activities funds under WIA total $924,069,000. Table I includes a breakdown of the Youth Activities program allotments for PY 2010 and provides a comparison of these allotments to PY 2009 Youth Activities allotments for all States, outlying areas, Puerto Rico and the District of Columbia. Before determining the amount available for States, the total funding available for the outlying areas was reserved at 0.25 percent of the full amount appropriated for Youth Activities. On December 17, 2003, the President signed Public Law 108–188, the *Compact of Free Association Amendments Act of 2003,* which provides for consolidation of all funding, including WIA Title I, for the Marshall Islands and Micronesia into supplemental funding grants in the Department of Education (48 U.S.C. 1921 d (f)(1)(B)(iii)).

The Department of Education's appropriations now include funding for these supplemental grants; therefore, WIA Title I funds are no longer being provided for these two areas. The Compact, as amended by Section 309 of Division D of Public Law 111–117, the Consolidated Appropriations Act, 2010 (in the Department of Education's General Provisions), extends the availability of programs previously available to Palau through September 2010, including WIA Title I funding provisions.

The methodology for distributing funds to all outlying areas is not specified by WIA, but is at the Secretary's discretion. The methodology used is the same as used since PY 2000, i.e., funds are distributed among the remaining areas by formula based on relative share of number of unemployed, a 90 percent hold-harmless of the prior year share, a $75,000 minimum, and a 130 percent stop-gain of the prior year share. As in PY 2009, data for the relative share calculation in the PY 2010 formula were from 2000 Census data for all outlying areas, obtained from the Bureau of the Census (Bureau) and are based on 2000 Census surveys for those areas conducted either by the Bureau or the outlying areas under the guidance of the Bureau. The total amount available for Native Americans is 1.5 percent of the total amount for Youth Activities, in accordance with WIA section 127. After determining the amount for the outlying areas and Native Americans, the amount available for allotment to the States for PY 2010 is $907,897,792. This total amount was below the required $1 billion threshold specified in section 127(b)(1)(C)(iv)(IV); therefore, as in PY 2009, the WIA additional minimum provisions were not applied, and, instead, as required by WIA, the Job Training Partnership Act (JTPA) section 202(a)(3) (as amended by section 701 of the Job Training Reform Amendments of 1992) minimums of 90 percent hold-harmless of the prior year allotment percentage and 0.25 percent State minimum floor were used. Also, as required by WIA, the provision applying a 130 percent stop-gain of the prior year allotment percentage was used. The three formula factors required in WIA use the following data for the PY 2010 allotments:

(1) Number of unemployed for Areas of Substantial Unemployment (ASUs), averages for the 12-month period, July 2008 through June 2009;

(2) Number of excess unemployed individuals or the ASU excess (depending on which is higher), averages for the same 12-month period used for ASU unemployed data; and

(3) Number of economically disadvantaged youth (age 16 to 21, excluding college students and military), from special 2000 Census calculations.

As done beginning with the PY 2006 allotments, the ASU data for the PY 2010 allotments was identified by the States using special 2000 Census data based on households, obtained under Employment and Training Administration contract with the Census Bureau and provided to States by the Bureau of Labor Statistics.

Adult Employment and Training Activities Allotments. The total Adult Employment and Training Activities appropriation is $861,540,000. Table II shows the PY 2010 Adult Employment and Training Activities allotments and comparison to PY 2009 allotments by State. Like the Youth Activities program, the total available for the outlying areas was reserved at 0.25 percent of the full amount appropriated for Adult Activities. As discussed in the Youth Activities paragraph, beginning in PY 2005, WIA funding for the Marshall Islands and Micronesia is no longer provided; instead, funding is provided in the Department of Education's appropriation. The Adult Activities funds for grants to the remaining outlying areas, for which the distribution methodology is at the Secretary's discretion, were distributed among the areas by the same principles, formula and data as used for outlying areas for Youth Activities. After determining the amount for the outlying areas, the amount available for allotments to the States is $859,386,150. Like the Youth Activities program, the WIA minimum provisions were not applied for the PY 2010 allotments because the total amount available for the States was below the $960 million threshold required for Adult Activities in section 132(b)(1)(B)(iv)(IV). Instead, as required by WIA, the minimum allotments were calculated using the JTPA section 202(a)(3) (as amended by section 701 of the Job Training Reform Amendments of 1992) minimums of 90 percent hold-harmless of the prior year allotment percentage and 0.25 percent State minimum floor. Also, like the Youth Activities program, a provision applying a 130 percent stop-gain of the prior year allotment percentage was used. The three formula factors use the same data as used for the PY 2010

Youth Activities formula, except that data from the 2000 Census for the number of economically disadvantaged adults (age 22 to 72, excluding college students and military) were used.

Dislocated Worker Employment and Training Activities Allotments. The total Dislocated Worker appropriation is $1,413,000,000. The total appropriation includes formula funds for the States, while the National Reserve is used for National Emergency Grants, technical assistance and training, demonstration projects, and the outlying areas' Dislocated Worker allotments. Table III shows the PY 2010 Dislocated Worker Activities fund allotments by State. Like the Youth and Adult Activities programs, the total available for the outlying areas was reserved at 0.25 percent of the full amount appropriated for Dislocated Worker Activities. WIA funding for the Marshall Islands and Micronesia is no longer provided, as discussed above. The Dislocated Worker Activities funds for grants to outlying areas, for which the distribution methodology is at the Secretary's discretion, were distributed among the remaining areas by the same pro rata share as the areas received for the PY 2010 WIA Adult Activities program, the same methodology used in PY 2009. For the State distribution of formula funds, the three formula factors required in WIA use the following data for the PY 2010 allotments:

(1) Number of unemployed, averages for the 12-month period, October 2008 through September 2009;

(2) Number of excess unemployed, averages for the 12-month period, October 2008 through September 2009; and

(3) Number of long-term unemployed, averages for the 12-month period, October 2008 through September 2009.

Since the Dislocated Worker Activities formula has no floor amount or hold-harmless provisions, funding changes for States directly reflect the impact of changes in the number of unemployed.

Discontinuance of Additional Funding from WIA Section 173(e) for Adult/Dislocated Worker Activities for Eligible States. Section 173(e) of WIA facilitated the transition from the JTPA to the WIA Adult formula by providing funding from the National Reserve to States meeting certain criteria. However, the WIA formula has been in effect for a decade and the transition is complete. Therefore, in accordance with language in the Department of Labor Appropriations Act, 2010, no PY 2010 funds will be obligated to carry out Section 173(e) of the WIA.

Wagner-Peyser Act Employment Service Final Allotments. The appropriated level for PY 2010 for ES grants totals $703,576,000. After determining the funding for outlying areas, allotments to States were calculated using the formula set forth at section 6 of the Wagner-Peyser Act (29 U.S.C. 49e). PY 2010 formula allotments were based on each state's share of calendar year 2009 monthly averages of the civilian labor force (CLF) and unemployment. The Secretary of Labor is required to set aside up to three percent of the total available funds to assure that each State will have sufficient resources to maintain statewide employment service activities, as required under section 6(b)(4) of the Wagner-Peyser Act. In accordance with this provision, the three percent set-aside funds are included in the total allotment. The set-aside funds were distributed in two steps to States that have lost in relative share of resources from the previous year. In Step 1, States that have a CLF below one million and are also below the median CLF density were maintained at 100 percent of their relative share of prior year resources. All remaining set-aside funds were distributed on a pro-rata basis in Step 2 to all other States losing in relative share from the prior year but not meeting the size and density criteria for Step 1. The distribution of Employment Service funds (Table IV) includes $701,860,926 for States, as well as $1,715,074 for outlying areas.

Under section 7 of the Wagner-Peyser Act, 10 percent of the total sums allotted to each State shall be reserved for use by the Governor to provide performance incentives for ES offices, services for groups with special needs, and for the extra costs of exemplary models for delivering job services.

Workforce Information Grants Allotments. Total PY 2010 funding for Workforce Information Grants allotments to States is $32,000,000. The allotment figures for each State are listed in Table V. Funds are distributed by administrative formula, with a reserve of $176,800 for Guam and the Virgin Islands. The remaining funds are distributed to the States with 40 percent distributed equally to all States and 60 percent distributed based on each State's share of CLF for the 12 months ending September 2009.

Signed at Washington, DC on this 22nd day of March 2010.

Jane Oates,

Assistant Secretary, Employment and Training Administration.

TABLE I—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WIA YOUTH ACTIVITIES STATE ALLOTMENTS; COMPARISON OF PY 2010 VS PY 2009

State	PY 2009	PY 2010	Difference	% Difference
Total	$924,069,000	$924,069,000	$0	0.00
Alabama	9,059,768	11,777,698	2,717,930	30.00
Alaska	3,061,576	2,755,418	(306,158)	−10.00
Arizona	13,869,309	15,982,731	2,113,422	15.24
Arkansas	9,385,022	8,446,520	(938,502)	−10.00
California	145,161,310	136,875,948	(8,285,362)	−5.71
Colorado	9,236,777	11,132,070	1,895,293	20.52
Connecticut	8,583,204	8,869,254	286,050	3.33
Delaware	2,269,744	2,269,744	0	0.00
District of Columbia	3,087,869	2,779,082	(308,787)	−10.00
Florida	33,348,363	43,352,872	10,004,509	30.00
Georgia	24,394,229	28,251,785	3,857,556	15.81
Hawaii	2,269,744	2,690,193	420,449	18.52
Idaho	2,269,744	2,950,667	680,923	30.00
Illinois	48,384,035	43,545,632	(4,838,403)	−10.00
Indiana	18,417,265	19,697,136	1,279,871	6.95
Iowa	4,023,109	4,750,212	727,103	18.07
Kansas	5,539,524	5,930,458	390,934	7.06

TABLE I—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WIA YOUTH ACTIVITIES STATE ALLOTMENTS; COMPARISON OF PY 2010 VS PY 2009—Continued

State	PY 2009	PY 2010	Difference	% Difference
Kentucky	13,775,333	14,303,105	527,772	3.83
Louisiana	15,566,262	14,009,636	(1,556,626)	−10.00
Maine	3,339,802	3,476,520	136,718	4.09
Maryland	9,011,703	11,311,383	2,299,680	25.52
Massachusetts	19,319,917	17,387,925	(1,931,992)	−10.00
Michigan	57,520,566	51,768,509	(5,752,057)	−10.00
Minnesota	13,837,056	14,264,509	427,453	3.09
Mississippi	14,535,436	13,081,892	(1,453,544)	−10.00
Missouri	19,757,091	17,781,382	(1,975,709)	−10.00
Montana	2,269,744	2,344,418	74,674	3.29
Nebraska	2,290,428	2,518,508	228,080	9.96
Nevada	5,888,382	7,654,897	1,766,515	30.00
New Hampshire	2,269,744	2,269,744	0	0.00
New Jersey	16,205,512	20,938,294	4,732,782	29.20
New Mexico	4,850,334	4,365,301	(485,033)	−10.00
New York	55,635,768	51,835,670	(3,800,098)	−6.83
North Carolina	19,500,888	25,351,154	5,850,266	30.00
North Dakota	2,269,744	2,269,744	0	0.00
Ohio	43,682,103	39,313,893	(4,368,210)	−10.00
Oklahoma	6,773,423	6,970,582	197,159	2.91
Oregon	11,720,493	13,707,810	1,987,317	16.96
Pennsylvania	31,617,301	31,871,328	254,027	0.80
Puerto Rico	33,024,567	29,722,110	(3,302,457)	−10.00
Rhode Island	4,364,513	4,531,698	167,185	3.83
South Carolina	19,222,108	17,299,897	(1,922,211)	−10.00
South Dakota	2,269,744	2,269,744	0	0.00
Tennessee	19,522,993	18,716,506	(806,487)	−4.13
Texas	63,783,091	57,404,782	(6,378,309)	−10.00
Utah	3,941,414	3,547,273	(394,141)	−10.00
Vermont	2,269,744	2,269,744	0	0.00
Virginia	10,098,341	13,127,843	3,029,502	30.00
Washington	18,236,698	17,997,280	(239,418)	−1.31
West Virginia	4,156,224	3,924,261	(231,963)	−5.58
Wisconsin	10,740,989	13,963,286	3,222,297	30.00
Wyoming	2,269,744	2,269,744	0	0.00
State Total	907,897,792	907,897,792	0	0.00
American Samoa	131,813	131,813	0	0.00
Guam	1,072,924	1,072,924	0	0.00
Northern Marianas	397,035	397,035	0	0.00
Palau	75,000	75,000	0	0.00
Virgin Islands	633,401	633,401	0	0.00
Outlying Areas Total	2,310,173	2,310,173	0	0.00
Native Americans	13,861,035	13,861,035	0	0.00

TABLE II—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WIA ADULT ACTIVITIES STATE ALLOTMENTS; COMPARISON OF PY 2010 VS PY 2009

State	PY 2009	PY 2010	Difference	% Difference
Total	$861,540,000	$861,540,000	$0	0.00
Alabama	8,881,745	11,546,269	2,664,524	30.00
Alaska	2,923,068	2,630,761	(292,307)	−10.00
Arizona	13,256,136	15,227,363	1,971,227	14.87
Arkansas	8,829,357	7,946,421	(882,936)	−10.00
California	139,444,084	131,676,574	(7,767,510)	−5.57
Colorado	8,341,034	10,028,610	1,687,576	20.23
Connecticut	7,632,284	7,899,746	267,462	3.50
Delaware	2,148,465	2,148,465	0	0.00
District of Columbia	2,685,463	2,416,917	(268,546)	−10.00
Florida	33,848,953	44,003,639	10,154,686	30.00
Georgia	22,833,446	26,468,737	3,635,291	15.92
Hawaii	2,148,465	2,786,714	638,249	29.71
Idaho	2,148,465	2,793,005	644,540	30.00
Illinois	44,888,169	40,399,352	(4,488,817)	−10.00
Indiana	16,349,181	17,396,927	1,047,746	6.41

TABLE II—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WIA ADULT ACTIVITIES STATE ALLOTMENTS; COMPARISON OF PY 2010 VS PY 2009—Continued

State	PY 2009	PY 2010	Difference	% Difference
Iowa	2,706,167	3,329,069	622,902	23.02
Kansas	4,703,065	4,907,309	204,244	4.34
Kentucky	14,258,220	14,765,556	507,336	3.56
Louisiana	15,147,944	13,633,150	(1,514,794)	−10.00
Maine	3,146,947	3,276,134	129,187	4.11
Maryland	8,545,357	10,691,615	2,146,258	25.12
Massachusetts	17,533,066	15,779,759	(1,753,307)	−10.00
Michigan	53,707,324	48,336,592	(5,370,732)	−10.00
Minnesota	12,099,930	12,498,015	398,085	3.29
Mississippi	13,528,436	12,175,592	(1,352,844)	−10.00
Missouri	18,243,831	16,419,448	(1,824,383)	−10.00
Montana	2,148,465	2,281,343	132,878	6.18
Nebraska	2,148,465	2,148,465	0	0.00
Nevada	5,904,037	7,675,248	1,771,211	30.00
New Hampshire	2,148,465	2,148,465	0	0.00
New Jersey	16,336,946	20,803,661	4,466,715	27.34
New Mexico	4,629,318	4,166,386	(462,932)	−10.00
New York	54,853,314	51,297,403	(3,555,911)	−6.48
North Carolina	17,991,679	23,389,183	5,397,504	30.00
North Dakota	2,148,465	2,148,465	0	0.00
Ohio	40,703,627	36,633,264	(4,070,363)	−10.00
Oklahoma	6,353,066	6,516,603	163,537	2.57
Oregon	11,013,161	12,848,682	1,835,521	16.67
Pennsylvania	28,797,617	29,034,229	236,612	0.82
Puerto Rico	35,033,711	31,530,340	(3,503,371)	−10.00
Rhode Island	3,666,405	3,919,536	253,131	6.90
South Carolina	18,131,016	16,317,914	(1,813,102)	−10.00
South Dakota	2,148,465	2,148,465	0	0.00
Tennessee	18,859,653	18,105,616	(754,037)	−4.00
Texas	59,776,554	53,798,899	(5,977,655)	−10.00
Utah	3,129,661	2,816,695	(312,966)	−10.00
Vermont	2,148,465	2,148,465	0	0.00
Virginia	9,098,617	11,828,202	2,729,585	30.00
Washington	16,872,727	16,563,114	(309,613)	−1.83
West Virginia	4,194,765	4,058,158	(136,607)	−3.26
Wisconsin	9,022,419	11,729,145	2,706,726	30.00
Wyoming	2,148,465	2,148,465	0	0.00
State Total	859,386,150	859,386,150	0	0.00
American Samoa	122,595	122,595	0	0.00
Guam	997,885	997,885	0	0.00
Northern Marianas	369,268	369,268	0	0.00
Palau	75,000	75,000	0	0.00
Virgin Islands	589,102	589,102	0	0.00
Outlying Areas Total	2,153,850	2,153,850	0	0.00

TABLE III—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WIA DISLOCATED WORKER ACTIVITIES STATE ALLOTMENTS; COMPARISON OF PY 2010 VS PY 2009

State	PY 2009	PY 2010	Difference	% Difference
Total	$1,466,891,000	$1,413,000,000	($53,891,000)	−3.67
Alabama	12,621,558	17,669,335	5,047,777	39.99
Alaska	3,392,665	2,187,095	(1,205,570)	−35.53
Arizona	16,648,405	22,788,184	6,139,779	36.88
Arkansas	7,192,470	6,867,051	(325,419)	−4.52
California	212,284,647	192,413,016	(19,871,631)	−9.36
Colorado	13,837,694	14,509,305	671,611	4.85
Connecticut	14,238,672	11,850,579	(2,388,093)	−16.77
Delaware	1,950,897	2,778,921	828,024	42.44
District of Columbia	3,628,361	2,990,511	(637,850)	−17.58
Florida	77,059,075	83,019,633	5,960,558	7.74
Georgia	41,902,519	40,912,792	(989,727)	−2.36
Hawaii	2,067,480	3,268,124	1,200,644	58.07
Idaho	2,709,982	4,536,856	1,826,874	67.41
Illinois	65,561,923	54,673,396	(10,888,527)	−16.61
Indiana	25,076,767	27,257,656	2,180,889	8.70

TABLE III—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WIA DISLOCATED WORKER ACTIVITIES STATE ALLOTMENTS; COMPARISON OF PY 2010 VS PY 2009—Continued

State	PY 2009	PY 2010	Difference	% Difference
Iowa	4,999,095	5,888,367	889,272	17.79
Kansas	4,978,239	6,855,442	1,877,203	37.71
Kentucky	17,901,696	18,089,024	187,328	1.05
Louisiana	8,857,065	9,812,674	955,609	10.79
Maine	4,373,817	4,578,544	204,727	4.68
Maryland	10,767,103	15,543,289	4,776,186	44.36
Massachusetts	20,303,163	22,706,846	2,403,683	11.84
Michigan	75,050,239	64,544,036	(10,506,203)	−14.00
Minnesota	20,054,286	18,020,939	(2,033,347)	−10.14
Mississippi	13,594,096	9,867,047	(3,727,049)	−27.42
Missouri	24,710,779	22,223,344	(2,487,435)	−10.07
Montana	1,679,893	2,174,950	495,057	29.47
Nebraska	2,478,758	2,428,300	(50,458)	−2.04
Nevada	13,691,153	14,124,712	433,559	3.17
New Hampshire	2,393,494	3,181,956	788,462	32.94
New Jersey	31,288,216	33,365,324	2,077,108	6.64
New Mexico	2,832,500	4,093,214	1,260,714	44.51
New York	63,490,356	65,534,311	2,043,955	3.22
North Carolina	42,493,181	44,039,515	1,546,334	3.64
North Dakota	876,713	690,086	(186,627)	−21.29
Ohio	55,974,110	51,610,221	(4,363,889)	−7.80
Oklahoma	5,762,276	6,905,534	1,143,258	19.84
Oregon	16,418,257	20,167,658	3,749,401	22.84
Pennsylvania	40,639,918	39,561,993	(1,077,925)	−2.65
Puerto Rico	28,244,122	17,054,847	(11,189,275)	−39.62
Rhode Island	7,601,362	6,227,600	(1,373,762)	−18.07
South Carolina	23,633,802	23,089,893	(543,909)	−2.30
South Dakota	912,475	1,000,388	87,913	9.63
Tennessee	27,141,982	26,930,077	(211,905)	−0.78
Texas	51,436,825	61,378,563	9,941,738	19.33
Utah	3,383,375	4,625,970	1,242,595	36.73
Vermont	1,673,255	1,787,950	114,695	6.85
Virginia	13,503,287	18,472,220	4,968,933	36.80
Washington	21,181,897	24,271,171	3,089,274	14.58
West Virginia	3,424,387	4,551,211	1,126,824	32.91
Wisconsin	15,363,236	19,934,322	4,571,086	29.75
Wyoming	558,477	786,008	227,531	40.74
State Total	1,183,840,000	1,183,840,000	0	0.00
American Samoa	208,735	201,066	(7,669)	−3.67
Guam	1,699,037	1,636,618	(62,419)	−3.67
Northern Marianas	628,730	605,632	(23,098)	−3.67
Palau	127,698	123,006	(4,692)	−3.67
Virgin Islands	1,003,028	966,178	(36,850)	−3.67
Outlying Areas Total	3,667,228	3,532,500	(134,728)	−3.67
National Reserve	279,383,772	225,627,500	(53,756,272)	−19.24

TABLE IV—U. S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; EMPLOYMENT SERVICE (WAGNER-PEYSER); PY 2010 FINAL VS PY 2009 FINAL ALLOTMENTS

State	Final PY 2009	Final PY 2010	Difference	% Difference
Total	$703,576,000	$703,576,000	$0	0.00
Alabama	9,048,957	9,042,125	(6,832)	−0.08
Alaska	7,648,207	7,648,207	0	0.00
Arizona	12,477,755	12,822,660	344,905	2.76
Arkansas	5,880,640	5,773,513	(107,127)	−1.82
California	83,452,931	84,038,299	585,368	0.70
Colorado	11,037,674	10,944,825	(92,849)	−0.84
Connecticut	7,905,625	7,843,690	(61,935)	−0.78
Delaware	1,965,210	1,965,210	0	0.00
District of Columbia	2,536,120	2,479,777	(56,343)	−2.22
Florida	39,347,985	40,350,319	1,002,334	2.55
Georgia	20,807,886	20,714,232	(93,654)	−0.45
Hawaii	2,534,022	2,525,177	(8,845)	−0.35

TABLE IV—U. S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; EMPLOYMENT SERVICE (WAGNER-PEYSER); PY 2010 FINAL VS PY 2009 FINAL ALLOTMENTS—Continued

State	Final PY 2009	Final PY 2010	Difference	% Difference
Idaho	6,372,318	6,372,318	0	0.00
Illinois	29,435,140	29,258,315	(176,825)	−0.60
Indiana	13,961,618	13,903,821	(57,797)	−0.41
Iowa	6,620,728	6,548,144	(72,584)	−1.10
Kansas	6,106,309	6,048,497	(57,812)	−0.95
Kentucky	9,142,999	9,125,242	(17,757)	−0.19
Louisiana	9,223,752	9,018,836	(204,916)	−2.22
Maine	3,789,556	3,789,556	0	0.00
Maryland	11,883,400	11,800,235	(83,165)	−0.70
Massachusetts	14,326,399	14,269,289	(57,110)	−0.40
Michigan	24,621,640	24,475,871	(145,769)	−0.59
Minnesota	12,250,556	12,164,816	(85,740)	−0.70
Mississippi	6,427,984	6,285,179	(142,805)	−2.22
Missouri	13,146,226	13,030,412	(115,814)	−0.88
Montana	5,207,490	5,207,490	0	0.00
Nebraska	6,258,380	6,258,380	0	0.00
Nevada	6,167,234	6,370,598	203,364	3.30
New Hampshire	2,873,239	2,859,890	(13,349)	−0.46
New Jersey	18,943,556	18,931,877	(11,679)	−0.06
New Mexico	5,843,720	5,843,720	0	0.00
New York	40,607,026	40,405,589	(201,437)	−0.50
North Carolina	19,706,162	20,093,605	387,443	1.97
North Dakota	5,302,783	5,302,783	0	0.00
Ohio	26,681,937	26,537,471	(144,466)	−0.54
Oklahoma	6,951,895	6,902,154	(49,741)	−0.72
Oregon	8,702,863	8,902,979	200,116	2.30
Pennsylvania	26,826,020	26,651,245	(174,775)	−0.65
Puerto Rico	8,253,932	8,070,562	(183,370)	−2.22
Rhode Island	2,661,374	2,652,902	(8,472)	−0.32
South Carolina	9,957,757	9,953,286	(4,471)	−0.04
South Dakota	4,900,991	4,900,991	0	0.00
Tennessee	13,173,347	13,154,566	(18,781)	−0.14
Texas	48,305,269	48,080,415	(224,854)	−0.47
Utah	7,638,164	7,468,473	(169,691)	−2.22
Vermont	2,295,903	2,295,903	0	0.00
Virginia	15,659,584	15,795,653	136,069	0.87
Washington	14,623,623	14,688,343	64,720	0.44
West Virginia	5,609,667	5,609,667	0	0.00
Wisconsin	12,954,947	12,881,393	(73,554)	−0.57
Wyoming	3,802,426	3,802,426	0	0.00
State Total	701,860,926	701,860,926	0	0.00
Guam	329,219	329,219	0	0.00
Virgin Islands	1,385,855	1,385,855	0	0.00
Outlying Areas Total	1,715,074	1,715,074	0	0.00

TABLE V—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WORKFORCE INFORMATION GRANTS TO STATES; PY 2010 VS PY 2009 ALLOTMENTS

State	PY 2009	PY 2010	Difference	% Difference
Total	$32,000,000	$32,000,000	$0	0.00
Alabama	513,199	505,992	(7,207)	−1.40
Alaska	288,558	288,781	223	0.08
Arizona	626,020	631,779	5,759	0.92
Arkansas	413,813	412,277	(1,536)	−0.37
California	2,507,217	2,515,778	8,561	0.34
Colorado	583,382	577,959	(5,423)	−0.93
Connecticut	476,002	475,973	(29)	−0.01
Delaware	299,219	298,498	(721)	−0.24
District of Columbia	285,208	285,170	(38)	−0.01
Florida	1,388,142	1,377,429	(10,713)	−0.77
Georgia	842,605	832,325	(10,280)	−1.22
Hawaii	325,132	324,368	(764)	−0.23
Idaho	338,097	337,134	(963)	−0.28
Illinois	1,070,081	1,056,837	(13,244)	−1.24

TABLE V—U.S. DEPARTMENT OF LABOR; EMPLOYMENT AND TRAINING ADMINISTRATION; WORKFORCE INFORMATION GRANTS TO STATES; PY 2010 VS PY 2009 ALLOTMENTS—Continued

State	PY 2009	PY 2010	Difference	% Difference
Indiana	642,235	637,859	(4,376)	−0.68
Iowa	451,190	450,390	(800)	−0.18
Kansas	427,610	430,687	3,077	0.72
Kentucky	495,574	498,273	2,699	0.54
Louisiana	494,844	499,711	4,867	0.98
Maine	332,053	331,210	(843)	−0.25
Maryland	612,613	608,631	(3,982)	−0.65
Massachusetts	662,375	665,387	3,012	0.45
Michigan	855,176	840,933	(14,243)	−1.67
Minnesota	606,203	606,706	503	0.08
Mississippi	407,221	404,978	(2,243)	−0.55
Missouri	615,454	613,786	(1,668)	−0.27
Montana	306,660	306,340	(320)	−0.10
Nebraska	366,425	365,970	(455)	−0.12
Nevada	414,616	416,502	1,886	0.45
New Hampshire	335,737	335,493	(244)	−0.07
New Jersey	796,139	800,638	4,499	0.57
New Mexico	361,891	362,201	310	0.09
New York	1,420,420	1,439,096	18,676	1.31
North Carolina	805,049	803,030	(2,019)	−0.25
North Dakota	290,398	289,915	(483)	−0.17
Ohio	982,778	974,547	(8,231)	−0.84
Oklahoma	459,625	461,686	2,061	0.45
Oregon	484,917	487,891	2,974	0.61
Pennsylvania	1,027,599	1,032,188	4,589	0.45
Puerto Rico	412,752	408,794	(3,958)	−0.96
Rhode Island	315,475	314,349	(1,126)	−0.36
South Carolina	508,829	512,460	3,631	0.71
South Dakota	299,586	299,507	(79)	−0.03
Tennessee	621,026	616,563	(4,463)	−0.72
Texas	1,680,566	1,704,900	24,334	1.45
Utah	415,279	414,068	(1,211)	−0.29
Vermont	288,282	288,734	452	0.16
Virginia	748,577	753,436	4,859	0.65
Washington	671,927	679,171	7,244	1.08
West Virginia	344,271	342,209	(2,062)	−0.60
Wisconsin	624,534	624,061	(473)	−0.08
Wyoming	280,619	280,600	(19)	−0.01
State Total	31,823,200	31,823,200	0	0.00
Guam	92,899	92,899	0	0.00
Virgin Islands	83,901	83,901	0	0.00
Outlying Areas Total	176,800	176,800	0	0.00

[FR Doc. 2010–6696 Filed 3–30–10; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Petitions for Modification

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice of petitions for modification of existing mandatory safety standards.

SUMMARY: Section 101(c) of the Federal Mine Safety and Health Act of 1977 and 30 CFR Part 44 govern the application, processing, and disposition of petitions for modification. This notice is a summary of petitions for modification filed by the parties listed below to modify the application of existing mandatory safety standards published in Title 30 of the Code of Federal Regulations.

DATES: All comments on the petitions must be received by the Office of Standards, Regulations and Variances on or before April 30, 2010.

ADDRESSES: You may submit your comments, identified by "docket number" on the subject line, by any of the following methods:

1. *Electronic Mail: Standards-Petitions@dol.gov.*
2. *Facsimile:* 1–202–693–9441.
3. *Regular Mail:* MSHA, Office of Standards, Regulations and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, Attention: Patricia W. Silvey, Director, Office of Standards, Regulations and Variances.
4. *Hand-Delivery or Courier:* MSHA, Office of Standards, Regulations and Variances, 1100 Wilson Boulevard, Room 2350, Arlington, Virginia 22209–3939, Attention: Patricia W. Silvey, Director, Office of Standards, Regulations and Variances.

MSHA will consider only comments postmarked by the U.S. Postal Service or proof of delivery from another delivery service such as UPS or Federal Express on or before the deadline for comments. Individuals who submit comments by hand-delivery are required to check in at the receptionist desk on the 21st floor.

Individuals may inspect copies of the petitions and comments during normal

business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: Barbara Barron, Office of Standards, Regulations and Variances at 202–693–9447 (Voice), *barron.barbara@dol.gov* (E-mail), or 202–693–9441 (Telefax). [These are not toll-free numbers].

SUPPLEMENTARY INFORMATION:

I. Background

Section 101(c) of the Federal Mine Safety and Health Act of 1977 (Mine Act) allows the mine operator or representative of miners to file a petition to modify the application of any mandatory safety standard to a coal or other mine if the Secretary determines that: (1) An alternative method of achieving the result of such standard exists which will at all times guarantee no less than the same measure of protection afforded the miners of such mine by such standard; or (2) that the application of such standard to such mine will result in a diminution of safety to the miners in such mine. In addition, the regulations at 30 CFR 44.10 and 44.11 establish the requirements and procedures for filing petitions for modification.

II. Petitions for Modification

Docket Number: M–2010–011–C.

Petitioner: Alex Energy, Jerry Fork Road, Drennen, West Virginia 26667.

Mine: Jerry Fork Eagle Mine, MSHA I. D. No. 46–08787, located in Nicholas County, West Virginia.

Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

Modification Request: The petitioner requests a modification of the existing standard to eliminate the use of blow-off dust covers for the spray nozzles of a deluge-type water spray system. As an alternative to using the blow-off dust covers, the petitioner proposes the following terms and conditions: (1) A person trained in the testing procedures specific to the deluge-type water spray fire suppression systems utilized at each belt drive will once each week: (a) Conduct a visual examination of each of the deluge-type water spray fire suppression systems; (b) conduct functional test of the deluge-type water spray fire suppression systems by actuating the system and watching its performance; and (c) record the results of the examination and functional test in a book maintained on the surface for that purpose. The record will be made available to the authorized representative of the Secretary and retained at the mine for one year; (2) any malfunction or clogged nozzle detected as a result of the weekly examination or functional test will be corrected immediately; and (3) the procedure used to perform the functional test will be posted at or near each belt drive that utilizes a deluge-type water spray fire suppression system. The petitioner asserts that the proposed alternative method will provide a measure of protection equal to or greater than that of the standard.

Docket Number: M–2010–012–C.

Petitioner: White Buck Coal Company, P.O. Box 180, Leivasy, West Virginia 26676.

Mine: Grassy Creek Mine, MSHA I.D. No. 46–08365 and Hominy Creek Mine, MSHA I.D. No. 46–09266, located in Nicholas County, West Virginia; and Pocahontas Mine, MSHA I.D. No. 46–09154, located in Greenbrier County, West Virginia.

Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

Modification Request: The petitioner requests a modification of the existing standard to eliminate the use of blow-off dust covers for the spray nozzles of a deluge-type water spray system. As an alternative to using the blow-off dust covers, the petitioner proposes the following terms and conditions: (1) A person trained in the testing procedures specific to the deluge-type water spray fire suppression systems utilized at each belt drive will once each week: (a) Conduct a visual examination of each of the deluge-type water spray fire suppression systems; (b) conduct functional test of the deluge-type water spray fire suppression systems by actuating the system and watching its performance; and (c) record the results of the examination and functional test in a book maintained on the surface for that purpose. The record will be made available to the authorized representative of the Secretary and retained at the mine for one year; (2) any malfunction or clogged nozzle detected as a result of the weekly examination or functional test will be corrected immediately; and (3) the procedure used to perform the functional test will be posted at or near each belt drive that utilizes a deluge-type water spray fire suppression system. The petitioner asserts that the proposed alternative method will provide a measure of protection equal to or greater than that of the standard.

Docket Number: M–2010–013–C.

Petitioner: RoxCoal, Inc., 1576 Stoystown Road, P.O. Box 149, Friedens, Pennsylvania 15541.

Mine: Quecreek No. 1 Mine, MSHA I. D. No. 36–08746, and Roytown Deep Mine, MSHA I.D. No. 36–09260, located in Somerset County, Pennsylvania.

Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

Modification Request: The petitioner requests a modification of the existing standard to permit an alternate method of compliance with the blow-off dust cover requirement at deluge-type water spray systems. In lieu of using blow-off dust covers, the petitioner proposes to: (1) Once every 7 days, a person trained in the testing procedures specific to the water deluge-type fire suppression systems utilized at each belt drive will: (a) Conduct a visual examination of each water deluge-type fire suppression system; (b) conduct a functional test of the water deluge-type fire suppression systems by actuating the system; and (c) any malfunction or clogged nozzle detected as a result of the examination and functional test will be recorded in a book maintained on the surface for that purpose. The record will be made available to the authorized representative of the Secretary and retained at the mine for one year; (2) any malfunction or clogged nozzle detected as a result of the weekly examination or functional test will be corrected immediately; (3) the written procedure used to perform the functional test will be provided to each individual trained in the testing procedure for reference; and (4) conducting weekly functional tests of the water deluge-type fire suppression systems as the proposed alternative method will provide for a level of safety equal to or greater than the statute in place. The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded the miners by such standard with no diminution of safety to the miners.

Docket Number: M–2010–014–C.

Petitioner: Sunrise Coal, LLC, 1183, East Canvasback Drive, Terre Haute, Indiana 47802.

Mine: Carlisle Mine, MSHA I.D. No. 12–02349, located in Sullivan County, Indiana.

Regulation Affected: 30 CFR 75.1101–1(b) (Deluge-type water spray systems).

Modification Request: The petitioner requests a modification of the existing standard to permit weekly examinations and functional testing of the deluge-type water fire suppression systems in lieu of providing blow-off dust covers. The petitioner states that: (1) Conducting a weekly examination and functional test of the deluge water fire suppression systems will provide an improvement in safety and insure that the spray nozzles do not become plugged; and (2) replacing the dust caps creates an unnecessary hazard by exposing miners

to the risk of a slip/fall type accident. The petitioner asserts that this petition upon approval will be mandated throughout the Carlisle Mine and will provide no less than the same measure of protection afforded by the standard.

Docket Number: M–2010–015–C.

Petitioner: Sunrise Coal, LLC, 1183 East Canvasback Drive, Terre Haute, Indiana 47802.

Mine: Carlisle Mine, MSHA I.D. No. 12–02349, located in Sullivan County, Indiana.

Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

Modification Request: The petitioner requests a modification of the existing standard to permit mine through or near (whenever the safety barrier diameter is reduced to a distance less than the District Manager would approve pursuant to 75.1700) plugged oil and gas wells penetrating the Indian V coal seam. The petitioner has listed in this petition a complete list of procedures to be utilized when plugging oil and gas wells. Persons may review these procedures at the MSHA address listed in this notice. The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded to the miners under 30 CFR 75.1700.

Docket Number: M–2010–016–C.

Petitioner: Lone Mountain Processing, Inc., Drawer C, St. Charles, Virginia 24282.

Mine: Huff Creek No. 1 Mine, MSHA I.D. No. 15–17234, Darby Fork No. 1 Mine, MSHA I.D. No. 15–02263, Clover Fork No. 1 Mine, MSHA I.D. No. 15–18647, all located in Harlan County, Kentucky.

Regulation Affected: 30 CFR 75.208 (Warning devices).

Modification: The petitioner requests a modification of the existing standard to permit a readily visible warning to be posted, or a physical barrier to be installed on the second row of permanent roof support outby unsupported roof to impede travel beyond permanent support, except during the installation of roof supports. The petitioner asserts that the proposed alternative method will at all times guarantee no less than the same measure of protection afforded by the appropriate portion of 30 CFR 75.208.

Dated: March 26, 2010.

Patricia W. Silvey,

Director.

[FR Doc. 2010–7197 Filed 3–30–10; 8:45 am]

BILLING CODE 4510–43–P

LEGAL SERVICES CORPORATION

Sunshine Act Meetings of the Board of Directors and Five Committees of the Board

Notice

DATE AND TIME: The Legal Services Corporation Board of Directors will meet on April 7, 2010 at 12 p.m., Eastern Time.

LOCATION: Legal Services Corporation, 3333 K Street, NW., Washington, DC 20007, 3rd Floor Conference Center.

PUBLIC OBSERVATION: For all meetings and portions thereof open to public observation, members of the public who are unable to attend but wish to listen to the proceedings may do so by following the telephone call-in directions given below. You are asked to keep your telephone muted to eliminate background noises. From time to time the Chairman may solicit comments from the public.

Call-in Directions for Open Session(s)

- Call toll-free number: 1–(866) 451–4981;
- When prompted, enter the following numeric pass code: 5907707348;
- When connected to the call, please "MUTE" your telephone immediately.

STATUS OF MEETING: Open.

MATTERS TO BE CONSIDERED:

Board of Directors

Agenda

Open Session

1. Approval of agenda;
2. Consider and act on nominations for the Chairman of the Board of Directors;
3. Consider and act on nominations for the Vice Chairman of the Board of Directors;
4. Consider and act on delegation to Chairman of authority to make Committee assignments;
5. Public comment;
6. Consider and act on other business;
7. Consider and act on motion to adjourn meeting.

CONTACT PERSON FOR INFORMATION: Katherine Ward, Executive Assistant to the Vice President & General Counsel, at (202) 295–1500. Questions may be sent by electronic mail to *FR_NOTICE_QUESTIONS@lsc.gov.*

SPECIAL NEEDS: Upon request, meeting notices will be made available in alternate formats to accommodate visual and hearing impairments. Individuals who have a disability and need an accommodation to attend the meeting may notify Katherine Ward, at (202) 295–1500 or *FR_NOTICE_QUESTIONS@lsc.gov.*

Dated: March 29, 2010.

Patricia D. Batie,

Corporate Secretary.

[FR Doc. 2010–7388 Filed 3–29–10; 4:15 pm]

BILLING CODE 7050–01–P

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

Work Reserved for Performance by Federal Government Employees

AGENCY: Office of Management and Budget, Office of Federal Procurement Policy.

ACTION: Notice of proposed policy letter.

SUMMARY: The Office of Federal Procurement Policy (OFPP) in the Office of Management and Budget (OMB) is issuing a proposed policy letter to provide guidance to Executive Departments and agencies on circumstances when work must be reserved for performance by Federal government employees. The Presidential Memorandum on Government Contracting, issued on March 4, 2009, directs OMB to clarify when governmental outsourcing of services is, and is not, appropriate, consistent with section 321 of the National Defense Authorization Act (NDAA) for FY 2009. Section 321 requires OMB to (i) create a single definition for the term "inherently governmental function" that addresses any deficiencies in the existing definitions and reasonably applies to all agencies; (ii) establish criteria to be used by agencies to identify "critical" functions and positions that should only be performed by federal employees; and (iii) provide guidance to improve internal agency management of functions that are inherently governmental or critical. The Presidential Memorandum is available at *http://www.whitehouse.gov/the_press_office/.*

Memorandum-for-the-Heads-of-Executive-Departments-and-Agencies-Subject-Government/.

Section 321 may be found at *http://thomas.loc.gov/cgi-bin/query/F?c110:5:./temp/~c110wWVqGQ:* e178256.

Comment Date: OFPP invites interested parties from both the public and private sectors to provide comments to be considered in the formulation of the final policy letter. Interested parties should submit comments in writing to

the address below on or before June 1, 2010.

ADDRESSES: Comments may be submitted by any of the following methods:

- *E-mail: OFPPWorkReserved@omb.eop.gov.*
- *Facsimile:* 202–395–5105.
- *Mail:* Office of Federal Procurement Policy, ATTN: Mathew Blum, New Executive Office Building, Room 9013, 724 17th Street, NW., Washington, DC 20503.

Instructions: Please submit comments only and cite "Proposed OFPP Policy Letter" in all correspondence. All comments received will be posted, without change, to *http://www.whitehouse.gov/omb/procurement/workreserved/work_comments.html,* without redaction, so commenters should not include information that they do not wish to be posted (for example because they consider it personal or business-confidential).

FOR FURTHER INFORMATION CONTACT: Mathew Blum, OFPP, (202) 395–4953 or *mblum@omb.eop.gov.*

SUPPLEMENTARY INFORMATION:

A. Overview

OFPP is issuing a proposed policy letter to provide guidance addressing when work must be reserved for performance by federal employees. The policy letter is intended to implement direction in the President's March 4, 2009, *Memorandum on Government Contracting* that requires OMB to "clarify when governmental outsourcing for services is and is not appropriate, consistent with section 321 of Public Law 110–417 (31 U.S.C. 501 note)." The proposed policy letter would:

- *Clarify what functions are inherently governmental and must always be performed by federal employees.* A single definition of "inherently governmental function" built around the well-established statutory definition in the Federal Activities Inventory Reform Act (FAIR Act), Public Law 105–270, would replace existing definitions in regulation and policy. The FAIR Act defines an activity as inherently governmental when it is so intimately related to the public interest as to mandate performance by Federal employees. Examples and tests would be provided to help agencies identify inherently governmental functions.
- *Help agencies identify when other functions (or portions of functions) need to be performed by Federal employees.* Existing guidance addressing functions closely associated with inherently governmental functions would be strengthened to ensure that performance of such functions does not expand to include performance of inherently governmental functions or otherwise interfere with federal employees' ability to carry out their inherently governmental responsibilities. In addition, consistent with section 321, a new category, "critical function," would be defined to help agencies identify and build sufficient internal capacity to effectively perform and maintain control over functions that are core to the agency's mission and operations.
- *Outline a series of agency management responsibilities to strengthen accountability for the effective implementation of these policies.* Agencies would be required to take specific actions, before and after contract award, to prevent contractor performance of inherently governmental functions and overreliance on contractors in "closely associated" and critical functions. Agencies would also be required to develop agency-level procedures, provide training, and designate senior officials to be responsible for implementation of these policies.

After public comment is considered and the policy letter is finalized, appropriate changes will be made to the Federal Acquisition Regulation (FAR).

B. Background

The Presidential Memorandum on Government Contracting requires the Director of OMB to develop guidance addressing when governmental outsourcing of services is, and is not, appropriate. The Memorandum states that the line between inherently governmental activities that should not be outsourced and commercial activities that may be subject to private-sector performance has become blurred, which may have led to the performance of inherently governmental functions by contractors and, more generally, an overreliance on contractors by the government. It directs OMB to clarify when outsourcing is, and is not, appropriate, consistent with section 321 of the NDAA for FY 2009.

Section 321 directed OMB to: (1) Create a single, consistent definition for the term "inherently governmental function" that addresses any deficiencies in the existing definitions and reasonably applies to all agencies; (2) develop criteria for identifying critical functions with respect to the agency's missions and structure; (3) develop criteria for determining positions dedicated to critical functions which should be reserved for federal employees to ensure the department or agency maintains control of its mission and operations; (4) provide criteria for identifying agency personnel with responsibility for (a) maintaining sufficient organic expertise and technical capability within the agency, and (b) issuing guidance for internal activities associated with determining when work is to be reserved for performance by Federal employees; and (5) solicit the views of the public regarding these matters.

OMB's OFPP reviewed current laws, regulations, policies, and reports addressing the definition of inherently governmental functions and the reservation of work for government employees. The review was conducted with the assistance of an interagency team that included representatives from the Chief Acquisition Officers Council and the Chief Human Capital Officers Council. As part of this effort, OFPP reviewed the definition of inherently governmental functions in the Federal Activities Inventory Reform Act (FAIR Act), Public Law 105–270, section 2383 of title 10 (which cites to definitions in the Federal Acquisition Regulation (FAR)), the FAR, OMB Circular A–76, OFPP Policy Letter 92–1, *Inherently Governmental Functions* (which was rescinded and superseded by OMB Circular A–76 in 2003) and reports by the Government Accountability Office (GAO). OFPP also reviewed the analyses in a recent report by the Congressional Research Service, *Inherently Governmental Functions and Department of Defense Operations: Background, Issues, and Options for Congress* (June 2009) and relevant findings and recommendations set forth in the *Report of the Acquisition Advisory Panel* (January 2007), available at *https://www.acquisition.gov/comp/aap/documents/Chapter6.pdf.* The Panel concluded, among other things, that "[t]here is a need to assure that the increase in contractor involvement in agency activities does not undermine the integrity of the government's decision-making processes." See the Panel's Report at 392.

To supplement this review, OMB held a public meeting and solicited comments from the public last spring and summer to inform the development of guidance. Comments were specifically sought regarding the definition of inherently governmental functions and criteria for identifying critical functions. See 74 FR 25775 (May 29, 2009) for a copy of the notice. OMB received 11 comments addressing these issues. For a copy of public comments, go to *http://www.whitehouse.gov/omb/assets/procurement_govcontracting/public_comments.pdf.* For a transcript

of the public meeting, go to *http://www.whitehouse.gov/omb/assets/procurement_gov_contracting/transcript_public_meeting.pdf*.

Respondents generally favored the definition of "inherently governmental function" found in the FAIR Act. Some concern was raised regarding changes made to the definition by OMB Circular A–76 when the Circular was revised in 2003.

Some respondents recommended that the criteria OMB develops to identify critical functions and positions reserved for federal employees be tied to mission performance. Some cautioned that these criteria should also guard against the contracting out of a function if such action poses too great a risk of creating a single point of mission failure. However, at least one commenter expressed the view that, as long as the overall function is managed by a federal employee, not every position performing a critical function needs to be performed by federal employees in order to protect the government's interest and prevent mission failure. Another commenter stated that tasks closely associated with governmental decision-making should not be contracted out unless the government can effectively guard against or otherwise mitigate conflicts of interest.

Based on this review and consideration of the public comments, OFPP has: (1) Developed a proposed policy letter and (2) formulated a list of tailored questions to elicit feedback on specific issues that will help inform its deliberations in shaping final guidance.

C. Proposed Policy Letter

1. Summary

OFPP has developed a proposed policy letter to improve the rules addressing the proper roles of the public and private sectors in performing work for the government. The policy letter is designed to address a number of weaknesses with existing rules that are affecting the efficiency and effectiveness of government performance. These weaknesses are summarized below along with a brief description of how they would be addressed.

Concern: The line has been blurred between functions that are inherently governmental and those that are not, potentially leading to confusion and to inappropriate judgments about when contractors may perform work that should be reserved for performance by Federal employees.

Proposed actions: Adopt the FAIR Act definition of "inherently governmental function" as the single government-wide definition of this term. (The FAIR Act defines an activity as inherently governmental when it is so intimately related to the public interest as to mandate performance by Federal employees.) Develop guidance to help agencies identify whether a given function falls within the definition of "inherently governmental function" or is otherwise closely associated with the performance of inherently governmental functions. Provide tests for analyzing whether a function is inherently governmental based on the nature of the function and the level of discretion to be exercised in performing the function. Reinforce management responsibilities—both before and after contract award—to guard against contractor performance of inherently governmental functions.

Concern: Some government organizations may be overly reliant on contractors to perform critical functions that, while not inherently governmental, still need to be performed by Federal employees.

Proposed actions: Provide guidance for determining the criticality of functions. Identify criteria for determining when positions dedicated to performing critical functions must or should be reserved for Federal employee performance. Hold appropriate officials accountable for ensuring adequate analysis has been performed to establish the sufficiency of internal capability in the event that contractors are to perform part of the function.

Concern: There is insufficient management attention focused on ensuring work is properly reserved for federal employees and maintaining certain critical capability levels in-house. An appropriate governance and review structure must be established to support the successful performance of these duties.

Proposed actions: Require agencies to develop agency-level procedures, conduct training, periodically review internal controls used to monitor implementation of this authority, and designate one or more senior officials to be responsible for implementation and maintenance of the policy.

2. Inherently Governmental Functions

There are three main sources for definitions and guidance addressing inherently governmental function: (1) The FAIR Act, (2) the FAR, and (3) OMB Circular A–76.

a. *Definition.* The FAIR Act, FAR, and Circular A–76 each make clear that the term "inherently governmental function" addresses functions that are so intimately related to the public interest as to require performance by federal government employees. There are some variations in the language used by the three sources to describe the types of functions included in the definition. In particular, the FAIR Act states that the term includes activities that require the "exercise of discretion" in applying "Federal Government authority," whereas the Circular speaks in terms of the exercise of "substantial discretion" in applying "sovereign" Federal government authority. It is unclear what the impact of this type of variation has been. This notwithstanding, these variations can create confusion and uncertainty.

The proposed policy letter adopts the FAIR Act definition as the single, government-wide definition. This definition reflects longstanding OFPP guidance that had been set out in OFPP Policy Letter 92–1. 57 FR 45096 (September 30, 1992). Most public commenters expressed general satisfaction with the statutory definition in the FAIR Act, while also acknowledging uncertainties as to its construction and application in particular circumstances.

b. *Guidance.* The proposed policy letter provides guidance to help agencies determine whether a given function meets the definition of an "inherently governmental function." The proposed policy letter retains a list of examples of inherently governmental functions, currently found in FAR Subpart 7.5. OFPP would also create tests for agencies to use in determining whether functions not appearing on the list otherwise fall within the definition of inherently governmental. The "nature of the function" test would ask agencies to consider whether the direct exercise of sovereign power is involved. Such functions are uniquely governmental and, therefore, inherently governmental. The "discretion" test would ask agencies to evaluate whether the discretion associated with the function, when exercised by a contractor, would have the effect of committing the government to a course of action. This test was included in OFPP Policy Letter 92–1, *Inherently Governmental Functions,* and currently may be found in OMB Circular A–76 (see Attachment A, para. B(1)(b)), which rescinded Policy Letter 92–1.

OFPP seeks to clarify and reinforce that agencies have both pre-award and post-award responsibilities for evaluating whether a function is inherently governmental and taking steps to avoid transferring inherently governmental authority to a contractor, such as through inadequate attention to contract administration. For proposed work, a determination that the work is not inherently governmental should be made prior to issuance of the

solicitation, preferably during acquisition planning. For ongoing contracts, agencies should review how work is performed, focusing, in particular, on functions that are closely associated with inherently governmental activities and professional and technical services, to ensure the scope of the work or the circumstances have not changed to the point that inherently governmental authority has been transferred to the contractor.

3. Functions That Are Closely Associated With Inherently Governmental Functions

Policy guidance addressing inherently governmental functions must also address functions closely associated with inherently governmental functions to properly ensure that work that is intimately related to the public interest is performed by Federal employees. Closely associated functions approach the status of inherently governmental work because of the nature of these functions and the risk that their performance, if not appropriately managed, may materially limit Federal officials' performance of inherently governmental functions.

The proposed policy letter retains an illustrative list of functions closely associated with inherently governmental functions from current FAR coverage. The guidance requires agencies to take a number of steps related to these functions. First, the proposed policy letter reiterates the requirement set forth in section 736 of Division D of the Omnibus Appropriations Act, 2009, Public Law 111–8, to give special consideration to reserving these functions to performance by federal employees. Second, the proposed policy letter lays out the responsibilities agencies must perform if they determine that contractor performance of a function closely associated with an inherently governmental function is appropriate. These responsibilities include pre-establishing in the contract specified ranges of acceptable decisions, subjecting the contractor's discretionary decision to final approval by an agency official, assigning a sufficient number of qualified federal employees with appropriate expertise to administer the work, and taking steps to avoid or mitigate conflicts of interest. Each of these actions is designed to help ensure that the contractor's activities do not expand to include inherently governmental responsibilities. Although these actions should currently be taken, they are not enumerated in one guidance document and often are given insufficient management attention (see paragraph 5, below, for additional discussion on new agency responsibilities for management and monitoring).

4. Critical functions

Since at least the early 1990s, government-wide policy addressing when work must be reserved for Federal employees has focused almost exclusively on the definition of "inherently governmental" functions and functions closely associated with inherently governmental functions. This narrow focus has been cited as a cause of inadequate attention to maintaining a residual Federal core capability when considering contractor performance of critical functions that are tied to an agency's mission. The Acquisition Advisory Panel, established by Congress in 2003 to review the federal acquisition system, concluded in its 2007 report that the consequences of this inattention to contractor performance of critical functions include "the loss of institutional memory, the inability to be certain whether the contractor is properly performing the specified work at a proper price and the inability to be sure that decisions are being made in the public interest rather than in the interest of the contractors performing the work." Following the issuance of the Panel's report, Congress, in the FY 2009 NDAA, directed OMB to develop criteria for agencies to use in identifying "critical" functions and in determining when such functions, or parts thereof, must be retained for performance by federal employees.

Consistent with section 321 of the FY 2009 NDAA, the proposed policy letter provides guidance to address the handling of critical functions and the maintenance of a core capability by Federal employees. The proposed policy letter would define critical function to mean a function whose importance to the agency's mission and operation requires that at least a portion of the function must be reserved to federal employees in order to ensure the agency has sufficient internal capability to effectively perform and maintain control of its mission and operations. Agencies would be held responsible for ensuring a sufficient number of positions performing critical work are filled by federal employees with appropriate training, experience, and expertise to understand the agency's requirements, formulate alternatives, manage the work product, and manage any contractors used to support the Federal workforce. The proposed guidance would also require agencies to evaluate whether they have sufficient internal capability on a case-by-case basis, taking into account factors such as the agency's mission, the complexity of the function and need for specialized skill, and the effect of contractor default on mission performance. The proposed guidance is built around the general principle that the more critical a function is, the greater the need for internal capability to maintain control of the agency's mission and operations. This is most obviously the case where the function is critical to achievement of the agency's core mission, but even for functions that may not be viewed as critical, such as functions that are not directly involved in performing the core mission, the agency may determine that the function is, nonetheless, sensitive enough as to require that many, most, or, in some situations, all positions be filled by Federal employees.

Finally, if an agency determines that it has sufficient internal capability to control its mission and operations, the proposed policy would require the consideration of cost to establish the extent to which additional critical work is performed by Federal employees, unless performance and risk considerations in favor of Federal employee performance would clearly outweigh cost considerations.

5. Management Attention

A clear understanding of responsibilities and heightened management attention will be required to ensure that work that should be performed by Federal employees is reserved for performance by them.

The proposed policy letter lays out the determinations that must be documented by the agency head or designated requirements official before a contract solicitation is issued to show that functions to be acquired by contract are not inherently governmental. It would also require agencies to determine (also before issuing a solicitation) that they have sufficient internal capability to control their mission and operations. During contract performance, agencies would be required to (1) monitor how contractors are performing contracts, especially those involving work closely associated with inherently governmental functions or professional and technical services, and (2) take appropriate action where internal control of mission and operations is at risk due to inappropriate or excessive reliance on contractors to perform critical functions.

Finally, the proposed policy letter would require agencies to strengthen internal agency management. Each agency with 100 or more full-time federal employees in the prior fiscal year would be required to identify one

or more senior officials to be accountable for the development and implementation of agency policies, procedures, and training to ensure the appropriate reservation of work for federal employees. The selected officials would be expected to facilitate the meaningful involvement of all relevant offices. In addition, agencies would be expected to develop and maintain (1) internal procedures, to be reviewed by agency management every two years, and (2) training plans to help their employees understand and meet their responsibilities.

D. Solicitation of Public Comment

OFPP welcomes comments on the proposed policy letter. Respondents are also encouraged to offer their views on the following questions, many of which are designed to help elicit feedback on specific aspects of the draft guidance.

1. Definitions

a. If the FAIR Act definition of "inherently governmental" is adopted, what additional definitional clarification is needed, if any?

b. What additional guidance should be provided to make clear that identifying "critical" work is driven by mission and circumstance, which will differ between agencies and within agencies over time? Is there a term other than "critical" that might be used to more clearly convey this principle?

c. What, if any, additional guidance should be provided to address what is meant by the term "public interest"?

2. Inherently Governmental Functions

a. Does the "discretion" test (which is derived from OMB Circular A–76, Attachment A and, before that, OFPP Policy Letter 92–1) help or hinder identification of inherently governmental functions? How might the language in the proposed policy letter be improved to make it more useful?

b. Does the proposed "nature of the function" test help in the identification of inherently governmental functions? How might the coverage of this test in the proposed policy letter be improved to make it more useful?

c. Should consideration be given to establishing a "principal-agent" test that would require agencies to identify functions as inherently governmental where serious risks could be created by the performance of these functions by those outside government, because of the difficulty of ensuring sufficient control over such performance?

d. What, if any, additional guidance might help agencies differentiate between circumstances where contractors are being used appropriately to inform government officials and those where contractors are limiting or constraining government exercise of inherently governmental responsibilities?

e. What, if any, changes should be made to existing laws that currently deem specific functions or the work performed by specific organizations to be inherently governmental?

3. Closely Associated and Critical Functions

a. Should the policy letter set out a presumption, or a requirement, in favor of performance of "closely associated" and/or critical functions by federal employees?

b. What, if any, additional guidance may help agencies differentiate between critical functions and functions that are closely associated with the performance of inherently governmental functions?

c. Should these categories be merged and treated in identical fashion? Why or why not?

d. What, if any, additional guidance might be provided to help agencies identify the extent to which a critical function may be performed by a contractor?

e. Should the policy clarify whether determinations regarding criticality are to be made at the departmental or component level?

4. Non-critical Functions

a. What, if any, additional guidance may help agencies differentiate between functions that are critical and those that are not?

b. Should guidance allow agency heads to identify categories of service contracts that may be presumed to be non-critical? Why or why not?

5. Specific Functions

a. What functions, in particular, are the most difficult to properly classify as inherently governmental, closely associated with inherently governmental, critical, or non-critical—and why? What specific steps should be taken to address this challenge?

b. What should guidance say—in place of, or in addition to, the draft guidance or currently existing federal regulations or policies—to address the use (if any) of contractors performing any of the following functions?

i. Pre-award acquisition support, such as acquisition planning, market research, development of independent government cost estimates, and preparation of documentation in support of contract award, including preparation of: price negotiation memoranda and price reasonableness determinations, technical evaluations, determinations of responsibility, determinations and findings, and justifications;

ii. Post-award acquisition support, such as functions involving the use of contractors to manage other contractors, the development of contractor performance assessments, review of contract claims, and the preparation of termination settlement proposals;

iii. Procurement management reviews;

iv. Management of Federal grantees;

v. Strategic planning;

vi. Lead systems integration;

vii. Physical security involving:

A. Guard services, convoy security services, pass and identification services, plant protection services, the operation of prison or detention facilities;

B. Security services other than those described in A; or

C. The use of deadly force, including combat, security operations performed in direct support of combat, and security that could evolve into combat;

viii. Cyber security, including IT network security;

ix. Support for intelligence activities, such as covert operations;

x. The assistance, reinforcement or rescue of individuals who become engaged in hostilities or offensive responses to hostile acts or demonstrated hostile intentions; and

xi. Intelligence interrogation of detainees, including interrogations in connection with hostilities.

c. Should the guidance provide an illustrative list of functions that are presumed to be critical? Why or why not? If so, what functions should be included on the list?

6. Human Capital Planning

a. How, if at all, should this guidance address the problem of limitations on the number of authorized Federal positions and the impact of such limitations on decisions about reserving work for Federal employees?

b. How, if at all, should this guidance address the potential nexus between decisions regarding reserving work for Federal employees and the unavailability of certain capabilities and expertise among Federal employees (e.g., "hard to fill" labor categories), and the impact of Federal salary limits on hiring people with those capabilities and expertise?

c. Should the guidance address when it is appropriate to temporarily contract for performance of work that is generally reserved for Federal employees?

d. How, if at all, should this guidance address situations where there is no basis to reserve work for Federal

employees, but the government is not in a position to provide adequate oversight of a contractor, whether due to the unavailability of federal employees with the skills needed for contract management or for other reasons?

e. What, if any, additional guidance might be provided to help an agency analyze whether it has the best mix of private and public sector labor? Are there benchmarks that exist to help agencies make this determination? Can the concept of "overreliance" be effectively understood without also providing guidance on "underreliance"? Why or why not?

7. Scope of Coverage

a. How, if at all, should the draft guidance address advisory and assistance services? What, if any, changes should be considered to FAR Subpart 37.2 to improve how agencies draw upon the skills of the public and private sectors?

b. How, if at all, should the draft guidance address personal services contracting? What, if any, changes should be considered to FAR Subpart 37.104 to improve how agencies draw upon the skills of the public and private sectors?

c. What additional guidance, if any, would be beneficial to improve understanding and implementation of policies addressing functions that must be reserved for performance by Federal employees?

d. What additional guidance, if any, would be beneficial to improve understanding and implementation of policies addressing functions that may be performed by contractors?

8. Form of Coverage

Is an OFPP policy letter an effective vehicle to serve as the main document for consolidated policy guidance on the subject of work reserved for Federal employees and maintaining certain critical capability levels in-house? Does it effectively address the affected stakeholder communities? If not, which communities are not properly addressed and what form should the guidance take and why?

9. Implementation

a. What best practices (e.g., flowcharts, decision trees, checklists, handbooks) exist to help agencies identify which functions should be reserved for performance by Federal employees? **Note:** Respondents are encouraged to submit copies of, or provide citations to, relevant documents with their responses.

b. What questions arise most frequently that might be suitably addressed in a question and answer format? Examples of questions might include the following:

- What steps should contractor employees be required to take when working on a government site to ensure their status is clearly understood?
- Under what, if any, circumstances may a contractor attend a policy-making meeting?
- Under what, if any, circumstances may a contractor represent an agency at a policy-making meeting?

10. Management Responsibilities

What, if any, additional guidance should be provided to ensure the policies and practices discussed in the draft guidance are given appropriate management attention?

11. Inventories of Federal and Contractor Employees

a. What is the best way to optimize the value of Federal employee inventories that agencies prepare under the FAIR Act and OMB Circular A–76 to support policies for identifying work to be reserved for performance by Federal employees?

b. What is the best way to optimize the value of the contractor employee inventory required by section 743 of Division C of the FY 2010 Consolidated Appropriations Act, Public Law 111–117 (for civilian agencies) and section 807 of the National Defense Authorization Act for FY 2008, Public Law 110–181 (for defense agencies), to support policies for identifying work to be reserved for performance by Federal employees and those that may continue to be performed by contractors?

Daniel I. Gordon,

Administrator, Office of Federal Procurement Policy.

Policy Letter No. 10–XX

To the Heads of Executive Departments And Establishments

Subject: Work Reserved for Performance by Federal Government Employees

1. Purpose. This guidance establishes Executive Branch policy addressing when work must be reserved for performance by federal employees. The policy is intended to assist agency officers and employees in ensuring that only federal employees perform work that is inherently governmental or otherwise needs to be reserved to the public sector.

Nothing in this guidance is intended to discourage the appropriate use of contractors. Contractors can provide expertise, innovation, and cost-effective support to federal agencies for a wide range of services. Reliance on contractors is not, by itself, a cause for concern, provided that the work that they perform is not work that should be reserved for federal employees and that federal officials are appropriately managing contractor performance.

2. Authority. This policy letter is issued pursuant to section 6(a) of the Office of Federal Procurement Policy Act, 41 U.S.C. 405(a), the President's March 4, 2009, *Memorandum on Government Contracting,* and section 321 of the FY 2009 National Defense Authorization Act, Public Law 110–417.

3. Definitions.

"*Inherently governmental function,*" as defined in section 5 of the Federal Activities Inventory Reform Act, Public Law 105–270, means a function that is so intimately related to the public interest as to require performance by Federal Government employees.

(a) The term includes functions that require either the exercise of discretion in applying Federal Government authority or the making of value judgments in making decisions for the Federal Government, including judgments relating to monetary transactions and entitlements. An inherently governmental function involves, among other things, the interpretation and execution of the laws of the United States so as—

(1) To bind the United States to take or not to take some action by contract, policy, regulation, authorization, order, or otherwise;

(2) To determine, protect, and advance United States economic, political, territorial, property, or other interests by military or diplomatic action, civil or criminal judicial proceedings, contract management, or otherwise;

(3) To significantly affect the life, liberty, or property of private persons;

(4) To commission, appoint, direct, or control officers or employees of the United States; or

(5) To exert ultimate control over the acquisition, use, or disposition of the property, real or personal, tangible or intangible, of the United States, including the collection, control, or disbursement of appropriations and other Federal funds.

(b) The term does not normally include—

(1) Gathering information for or providing advice, opinions, recommendations, or ideas to Federal Government officials; or

(2) Any function that is primarily ministerial and internal in nature (such as building security, mail operations, operation of cafeterias, housekeeping, facilities operations and maintenance, warehouse operations, motor vehicle fleet management operations, or other routine electrical or mechanical services).

"*Critical function*" means a function that is necessary to the agency being able to effectively perform and maintain control of its mission and operations. A function that would not expose the agency to risk of mission failure if performed entirely by contractors is not a critical function.

4. Policy. It is the policy of the Executive Branch to ensure that government action is taken as a result of informed, independent judgments made by government officials. Adherence to this policy will ensure that the act of governance is performed, and decisions of significant public interest are made, by officials who are ultimately accountable to the President and bound by laws controlling the conduct and performance of Federal employees that are intended to protect or

benefit the public and ensure the proper use of funds appropriated by Congress. To implement this policy, agencies must reserve certain work for performance by federal employees and take special care to retain sufficient management oversight over how contractors are used to support government operations and ensure that Federal employees have the technical skills and expertise needed to maintain control of the agency mission and operations.

(a) *Performance of work by federal employees.* To ensure that work that should be performed by federal employees is properly reserved for government performance, agencies shall:

(1) Ensure that service contractors do not perform inherently governmental functions (see section 5–1);

(2) Give special consideration to federal employee performance of functions closely associated with inherently governmental functions and, when such work is performed by contractors, provide greater attention and an enhanced degree of management oversight of the contractors' activities to ensure that contractors' duties do not expand to include performance of inherently governmental functions (see section 5–2a); and

(3) Ensure that federal employees perform critical functions to the extent necessary for the agency to operate effectively and maintain control of its mission and operations (see section 5–2b).

(b) *Management of federal contractors.* When work need not be reserved for Federal performance and contractor performance is appropriate, agencies shall take steps to employ an adequate number of government personnel to ensure that contract administration protects the public interest through the active and informed management and oversight of contractor performance, especially where contracts have been awarded for the performance of critical functions, functions closely associated with the performance of inherently governmental functions, or where, due to the nature of the contract services provided, there is a potential for confusion as to whether an activity is being performed by government employees or contractors. Contract management should be appropriate to the nature of the contract, ensure that the contract is under the control of government officials at all times, and make clear to the public when citizens are receiving service from contractors.

(c) *Strategic human capital planning.* (1) As part of strategic human capital planning, agencies shall—

(i) Dedicate a sufficient amount of work on critical functions to performance by federal employees in order to build competencies (both knowledge and skills), provide for continuity of operations, and retain institutional knowledge of government operations, including those unique to the agency's mission;

(ii) Ensure that sufficient personnel is available to manage and oversee the contractor's performance and evaluate and approve or disapprove the contractor's work products and services, recruiting and retaining the necessary federal talent where it is lacking; and

(iii) Consider the impact of decisions to establish a specified level of government employee authorizations (or military end strength) or available funding on the ability to use Federal employees for work that should be reserved for performance by such employees.

(2) Agencies' annual Human Capital Plan for Acquisition shall identify specific strategies and goals for addressing both the size and capability of the acquisition workforce, including program managers and contracting officer technical representatives. The number of personnel required to administer a particular contract is a management decision to be made after analysis of a number of factors. These include, among others:

(i) The scope of the activity in question;

(ii) The technical complexity of the project or its compontents;

(iii) The technical capability, numbers, and workload of federal mangement officials;

(iv) The inspection techniques available;

(v) The proven adequacy and reliability of contractor project management;

(vi) The sophistication and track record of contract administration organizations within the agency; and

(vii) The importance and criticality of the function.

5. Implementation guidelines and responsibilities. Agencies shall use the guidelines below to determine (1) whether their requirements involve the performance of inherently government functions, functions closely associated with inherently governmental functions, or critical functions; and (2) the type and level of management attention necessary to ensure that functions that should be reserved for federal performance are not materially limited by or effectively transferred to contractors. The latter determination typically requires agencies to consider the totality of circumstances surrounding how, where, and when work is to be performed.

5–1. Inherently governmental functions. Agencies shall ensure that inherently governmental functions are reserved exclusively for performance by federal employees.

(a) *Determining whether a function is inherently governmental.* Every federal government organization performs some work that is so intimately related to the public interest as to require performance by federal government employees. Agencies should review the definition of inherently governmental function in section 3, any other statutory provisions that identify a function as inherently governmental, and the illustrative list of inherently governmental functions in Appendix A. In no case should any function described in the definition, identified in statute as inherently governmental, or appearing on the list be considered for contract performance. If a function is not listed in Appendix A or identified in a statutory provision as inherently governmental, agencies should determine whether the function otherwise falls within the definition in section 3 by evaluating, on a case-by-case basis, the nature of the work and the level of discretion associated with performance of the work using the tests below. A function meeting either of these tests would be inherently governmental.

(1) The nature of the function. Functions which involve the exercise of sovereign powers—that is, powers that are uniquely governmental—are inherently governmental by their very nature. Examples of functions that, by their nature, are inherently governmental are an ambassador representing the United States, a police officer arresting a person, and a judge sentencing a person convicted of a crime to prison. A function may be classified as inherently governmental based strictly on its uniquely governmental nature and without regard to the type or level of discretion associated with the function.

(2) The exercise of discretion. (i) A function requiring the exercise of discretion shall be deemed inherently governmental if the exercise of such discretion commits the government to a course of action where two or more alternative courses of action exist and decision making is not already limited or guided by existing policies, procedures, directions, orders, and other guidance that:

(A) Identify specified ranges of acceptable decisions or conduct concerning the overall policy or direction of the action; and

(B) Subject the discretionary authority to final approval or regular oversight by agency officials.

(ii) The fact that decisions are made, and discretion exercised, by a contractor in performing its duties under the contract—such as how to allocate the contractor's own or subcontract resources, what conclusions to emphasize and, unless specified in the contract, what techniques and procedures to employ, whether and whom to consult, what research alternatives to explore given the scope of the contract, or how frequently to test—is not determinative of whether the contractor is performing an inherently government function. A function involving the exercise of discretion may be appropriately performed consistent with the restrictions in this section where the contractor does not have the authority to decide on the overall course of action, but is tasked to develop options or implement a course of action, and the agency official has the ability to countervail the contractor's action. By contrast, contractor performance would be inappropriate where the contractor's involvement is or would be so extensive, or the contractor's work product so close to a final agency product, as to effectively preempt the federal officials' decision-making process, discretion or authority.

(b) *Responsibilities*—(1) *Pre-award.* Agencies shall determine prior to issuance of a solicitation that none of the functions to be contracted are inherently governmental. The agency head or designated requirements official shall provide the contracting officer, concurrent with transmittal of the statement of work (or any modification thereof), a written determination that none of the functions to be performed are inherently governmental. If a function is not listed in Appendix A, it still may be inherently governmental. Accordingly, the determination should take into consideration, as necessary, the tests in

paragraph (a). The file should include the analysis that supports the determination and this analysis should establish, at a minimum, that:

(i) The function to be contracted does not appear on the list in Appendix A;

(ii) A statute, such as an annual appropriations act, does not identify the function as inherently governmental or otherwise require it to be performed by Federal employees; and

(iii) The proposed role for the contractor is not so extensive that the ability of senior agency management to develop and consider options is or would be preempted or inappropriately restricted.

(2) *Post-award.* Agencies should review, on an ongoing basis, the functions being performed by their contractors, paying particular attention to the way in which contractors are performing, and agency personnel are managing, contracts involving functions that are closely associated with inherently governmental functions (see subsections 5–2a and Appendix B) or contracts for professional and technical services. If a determination is made that the contractor is performing work that is inherently governmental (or involves unauthorized personal services), but the contract, properly defined, does not entail performance of inherently governmental functions, the agency shall take prompt action to ensure performance by government employees of the inherently governmental responsibilities. In some cases, government control over, and performance of, these responsibilities can be reestablished by strengthening contract oversight using government employees with appropriate subject matter expertise and following the protocols identified in FAR 37.114 (see also section 5.2a, below). In other cases, agencies may need to in-source work on an accelerated basis through the timely development and execution of a hiring plan timed, if possible, to permit the non-exercise of an option or the termination of that portion of the contract being used to fulfill inherently governmental responsibilities.

5–2. Other work that must be reserved for federal employees. In some cases, work that is not inherently governmental must also be reserved for performance by federal employees. Such reservation will be required under certain circumstances for functions that are closely associated with the performance of inherently governmental functions and critical functions.

5–2a. Functions closely associated with the performance of inherently governmental functions. Agencies shall give special consideration to federal employee performance of functions closely associated with inherently governmental functions.

(a) *Determining whether a function is closely associated with the performance of an inherently governmental function.* Certain services and actions that generally are not considered to be inherently governmental functions may approach being in that category because of the nature of the function and the risk that performance may impinge on federal officials' performance of an inherently governmental function. Appendix B provides a list of examples of functions that are closely associated with the performance of inherently governmental functions.

(b) *Special consideration for federal employee performance.*

(1) If the agency determines the function is closely associated with the performance of an inherently governmental function, section 736 of Division D of the Omnibus Appropriations Act, 2009, Public Law 111–8, requires civilian agencies subject to the FAIR Act to give special consideration to using federal employees to perform the function. Civilian agencies shall refer to OMB Memorandum M–09–26, Managing the Multi-Sector Workforce (July 29, 2009), Attachment 3 for criteria addressing the in-sourcing of work under Public Law 111–8. Memorandum M–09–26 explains that federal employee performance would be expected if either contractor performance causes the agency to lack sufficient internal expertise to maintain control of its mission and operations or analysis suggests that public sector performance is more cost effective and it is feasible to hire federal employees to perform the function. The OMB Memorandum is available at *http://www.whitehouse.gov/omb/assets/memoranda_fy2009/m-09-26.pdf.*

(2) The Department of Defense shall—

(i) Ensure special consideration is given to federal employee performance consistent with the requirements of 10 U.S.C. 2463; and

(ii) To the maximum extent practicable, minimize reliance on contractors performing functions closely associated with inherently governmental functions consistent with 10 U.S.C. 2330a.

(c) *Responsibilities.* If the agency determines that contractor performance of a function closely associated with an inherently governmental function is appropriate and cost-effective, the agency shall—

(1) Limit or guide a contractor's exercise of discretion and retain control of government operations by both—

(i) Pre-establishing in the contract specified ranges of acceptable decisions and/or conduct; and

(ii) Pre-establishing a process for subjecting the contractor's discretionary decisions and/or conduct to final approval by the agency official;

(2) Assign a sufficient number of qualified government employees, with expertise to administer or perform the work, to give heightened management attention to the contractor's activities, in particular, to ensure that they do not expand to include inherently governmental functions, are not performed in ways not contemplated by the contract so as to become inherently governmental, do not undermine the integrity of the government's decision-making process, and do not interfere with federal employees' performance of the closely-associated inherently governmental functions (see section 5–1(b)(2) for guidance on steps to take where a determination is made that the contract is being used to fulfill responsibilities that are inherently governmental);

(3) Ensure that a reasonable identification of contractors and contractor work products is made whenever there is a risk that Congress, the public, or other persons outside of the government might confuse contractor personnel or work products with government officials or work products, respectively; and

(4) Take appropriate steps to avoid or mitigate conflicts of interest, such as by:

(i) Conducting pre-award conflict of interest reviews, to ensure contract performance is in accordance with objective standards and contract specifications, and developing a conflict of interest mitigation plan, if needed, that identifies the conflict and specific actions that will be taken to lessen the potential for conflict of interest or reduce the risk involved with a potential conflict of interest;

(ii) Physically separating contractor personnel from government personnel at the worksite;

(iii) Ensuring contractors are clearly identified as such in work product and on work support systems, such as in electronic mail systems and phone messaging systems, and on signature blocks, security and other identification badges, and office name plates;

(iv) Having contractor personnel work off-site, if cost-effective and without derogation to the work to be performed;

(v) Excluding contractors from subsequent competitions if conflicts cannot be avoided; or

(vi) Performing work with federal employees if (A) contractor conflicts cannot be satisfactorily resolved or (B) decision-making would be at risk of being transferred to the private sector because contractors have such influence and insight into government decision making or government officials would rely too heavily on contractor inputs (or rely almost exclusively on contractor fact-finding or memory).

(5) Make a written determination concurrent with transmittal of the statement of work (or any modification thereof) to the contracting officer that

(i) The function is closely associated with an inherently governmental function;

(ii) Private sector performance of the function is appropriate and the most cost effective source of support for the agency; and

(iii) The agency has sufficient internal capability to control its missions and operations, oversee the contractor's performance of the contract, limit or guide the contractor's exercise of discretion, ensure reasonable identification of contractors and contractor work products, and avoid or mitigate conflicts of interest and unauthorized personal services.

5–2b. Critical functions. Agencies shall dedicate a sufficient number of federal employees to the performance of critical functions so that federal employees may maintain control of agencies' mission and operations.

(a) *Criteria for determining when critical positions must be reserved for federal employee performance.* Determining the criticality of a function requires the exercise of informed judgment by agency officials. In making that determination, the officials shall consider the importance that a function holds for the agency and its mission and operations. The more critical the function, the more important that the agency have internal capability to maintain control of its

mission and operations. Examples of highly critical functions might include: designing and constructing the next generation of satellites at the National Aeronautics and Space Administration, analyzing areas of tax law that impose significant compliance burdens on taxpayers for the Internal Revenue Service's Office of the Taxpayer Advocate, and performing mediation services for the Federal Mediation and Conciliation Service. Where a critical function is not inherently governmental, the agency may appropriately consider filling positions dedicated to the function with both federal employees and contractors. However, to meet its fiduciary responsibility to the taxpayers, the agency must have a sufficient internal capability to control its mission and operations and must ensure it is cost effective to contract for the services.

(1) Sufficient internal capability—

(i) Generally requires that an agency have an adequate number of positions filled by federal employees with appropriate training, experience, and expertise (organic and technical) to understand the agency's requirements, formulate alternatives, take other appropriate actions to properly manage and be accountable for the work product, and continue critical operations in the event of contractor default; and

(ii) Further requires that an agency have the ability and internal expertise to manage any contractors used to support the federal workforce and evaluate their work product.

(2) Determinations concerning what constitutes sufficient internal capability must be made on a case-by-case basis taking into account, among other things:

(i) The agency's mission;

(ii) The complexity of the function and the need for specialized skill;

(iii) The current strength of the agency's in-house organic and technical expertise;

(iv) The current strength (capability and capacity) of the agency's acquisition workforce;

(v) The effect of contractor default on mission performance; and

(vi) The enforceability of criminal sanctions for crimes performed by contractors as compared to those applicable to federal employees.

(b) *Responsibilities*—(1) *Pre-award.* (i) Agencies shall determine prior to issuance of a solicitation for private-sector performance of any aspect of a critical function that the agency has sufficient internal capability to control its mission and operations. The agency head or designated requirements or human capital official shall provide the contracting officer, concurrent with transmittal of the statement of work (or any modification thereof) a written determination and analysis.

(ii) If an agency has sufficient internal capability to control its mission and operations, the extent to which additional work is performed by federal employees should be determined consistent with the parameters set forth in subsection (2)(ii) below.

(2) *Post-award.* (i) Agencies should be alert for situations where internal control of mission and operations is at risk due to overreliance on contractors to perform critical functions. In these situations, requiring activities should work with their human capital office to develop and execute a hiring and/or development plan. Requiring activities should also work with the acquisition office to address the handling of ongoing contracts and the budget and finance offices to secure the necessary funding to support the needed in-house capacity. Agencies should also consider application of the responsibilities outlined in 5–2a(c), as appropriate.

(ii) If an agency has sufficient internal capability to control its mission and operations, the extent to which additional work is performed by federal employees should be based on cost considerations unless performance and risk considerations in favor of federal employee performance will clearly outweigh cost considerations. Supporting cost analysis should address the full costs of government and private sector performance and provide like comparisons of costs that are of a sufficient magnitude to influence the final decision on the most cost effective source of support for the organization.

6. Additional agency responsibilities. (a) *Duty of federal employees.* Every federal employee has an obligation to help avoid the performance by contractors of responsibilities that should be reserved to federal employees. As part of this obligation, federal employees who rely on contracts or their work product must take appropriate steps, in accordance with agency procedures, to ensure that any final agency action complies with the laws and policies of the United States and reflects the independent conclusions of agency officials and not those of contractors, who may not be motivated solely by the public interest, and who may be beyond the reach of management controls applicable to federal employees. These steps shall include increased attention and examination where contractor work product involves advice, opinions, recommendations, reports, analyses, and similar deliverables that are to be considered in the course of a federal employee's official duties and may have the potential to influence the authority, accountability, and responsibilities of the employee.

(b) *Development of agency procedures.* Agencies shall develop and maintain internal procedures to address the requirements of this guidance. Such procedures shall be reviewed by agency management no less than every two years.

(c) *Training.* Agencies shall develop training plans to help their employees understand and meet their responsibilities under this guidance. The plan should include training, no less than every two years, to improve employee awareness of their responsibilities.

(d) *Review of internal management controls.* Agencies should periodically evaluate the effectiveness of their internal management controls for reserving work for federal employees and identify any material weaknesses in accordance with OMB Circular A–123, Management's Responsibility for Internal Control, and OFPP's Guidelines for Assessing the Acquisition Function, available at *http://www.whitehouse.gov/omb/assets/omb/procurement/memo/a123_guidelines.pdf*

(e) *Designation of responsible management official(s).* Each federal agency with 100 or more full-time employees in the prior fiscal year shall identify one or more senior officials to be accountable for the development and implementation of agency policies, procedures, and training to ensure the appropriate reservation of work for federal employees in accordance with this guidance. Each such agency shall submit the names and titles of the designated officials, along with contact information, to OMB by June 30 of each year. This information may be provided with the agency's submission of commercial and inherently governmental activities submitted pursuant to the FAIR Act and OMB Circular A–76.

7. Federal Acquisition Regulatory Council. Pursuant to subsections 6(a) and 25(f) of the Office of Federal Procurement Policy Act, 41 U.S.C. 405(a) and 421(f), the Federal Acquisition Regulatory Council shall ensure that the policies established herein that pertain to the acquisition of services are incorporated in the FAR in a timely manner.

8. Judicial review. This policy letter is not intended to provide a constitutional or statutory interpretation of any kind and it is not intended, and should not be construed, 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. It is intended only to provide policy guidance to agencies in the exercise of their discretion concerning federal contracting. Thus, this policy letter is not intended, and should not be construed, to create any substantive or procedural basis on which to challenge any agency action or inaction on the ground that such action or inaction was not in accordance with this policy letter.

9. Effective date. This policy letter is effective [insert date 30 days after issuance of final policy letter]

Appendix A. Examples of inherently governmental functions

The following is an illustrative list of functions considered to be inherently governmental.

1. The direct conduct of criminal investigation.

2. The control of prosecutions and performance of adjudicatory functions (other than those relating to arbitration or other methods of alternative dispute resolution).

3. The command of military forces, especially the leadership of military personnel who are members of the combat, combat support or combat service support role.

4. The conduct of foreign relations and the determination of foreign policy.

5. The determination of agency policy, such as determining the content and application of regulations, among other things.

6. The determination of Federal program priorities or budget requests.

7. The direction and control of Federal employees.

8. The direction and control of intelligence and counter-intelligence operations.

9. The selection or non-selection of individuals for Federal Government employment.

10. The approval of position descriptions and performance standards for Federal employees.

11. The determination of what Government property is to be disposed of and on what terms (although an agency may give contractors authority to dispose of property at prices with specified ranges and subject to other reasonable conditions deemed appropriate by the agency).

12. In Federal procurement activities with respect to prime contracts:

(a) determining what supplies or services are to be acquired by the Government (although an agency may give contractors authority to acquire supplies at prices within specified ranges and subject to other reasonable conditions deemed appropriate by the agency);

(b) participating as a voting member on any source selection boards;

(c) approval of any contractual documents, to include documents defining requirements, incentive plans, and evaluation criteria;

(d) awarding contracts;

(e) administering contracts (including ordering changes in contract performance or contract quantities, taking action based on evaluations of contractor performance, and accepting or rejecting contractor products or services);

(f) terminating contracts;

(g) determining whether contract costs are reasonable, allocable, and allowable; and

(h) participating as a voting member on performance evaluation boards.

13. The approval of agency responses to Freedom of Information Act requests (other than routine responses that, because of statute, regulation, or agency policy, do not require the exercise of judgment in determining whether documents are to be released or withheld), and the approval of agency responses to the administrative appeals of denials of Freedom of Information Act requests.

14. The conduct of administrative hearings to determine the eligibility of any person for a security clearance, or involving actions that affect matters of personal reputation or eligibility to participate in government programs.

15. The approval of federal licensing actions and inspections.

16. The determination of budget policy, guidance, and strategy.

17. The collection, control, and disbursement of fees, royalties, duties, fines, taxes and other public funds, unless authorized by statute, such as title 31 U.S.C. 952 (relating to private collection contractors) and title 31 U.S.C. 3718 (relating to private attorney collection services), but not including:

(a) collection of fees, fines, penalties, costs or other charges from visitors to or patrons of mess halls, post or base exchange concessions, national parks, and similar entities or activities, or from other persons, where the amount to be collected is easily calculated or predetermined and the funds collected can be easily controlled using standard cash management techniques, and

(b) routine voucher and invoice examination.

18. The control of the Treasury accounts.

19. The administration of public trusts.

20. The drafting of Congressional testimony, responses to Congressional correspondence, or agency responses to audit reports from the Inspector General, the Government Accountability Office, or other federal audit entity.

Appendix B. Examples of functions closely associated with the performance of inherently governmental functions

The following is an illustrative list is of functions that are closely associated with the performance of inherently governmental functions.

1. Services that involve or relate to budget preparation, including workforce modeling, fact finding, efficiency studies, and should-cost analyses.

2. Services that involve or relate to reorganization and planning activities.

3. Services that involve or relate to analyses, feasibility studies, and strategy options to be used by agency personnel in developing policy.

4. Services that involve or relate to the development of regulations.

5. Services that involve or relate to the evaluation of another contractor's performance.

6. Services in support of acquisition planning.

7. Assistance in contract management (particular where a contractor might influence official evaluations of other contractors' offers).

8. Technical evaluation of contract proposals.

9. Assistance in the development of statements of work.

10. Support in preparing responses to Freedom of Information Act requests.

11. Work in any situation that permits or might permit access to confidential business information and/or any other sensitive information (other than situations covered by the National Industrial Security Program described in FAR 4.402(b)).

12. Dissemination of information regarding agency policies or regulations, such as attending conferences on behalf of an agency, conducting community relations campaigns, or conducting agency training courses.

13. Participation in any situation where it might be assumed that participants are agency employees or representatives.

14. Participation as technical advisors to a source selection board or as nonvoting members of a source evaluation board.

15. Service as arbitrators or provision of alternative dispute resolution (ADR) services.

16. Construction of buildings or structures intended to be secure from electronic eavesdropping or other penetration by foreign governments.

17. Provision of inspection services.

18. Drafting of legal advice and interpretations of regulations and statutes to government officials.

19. Provision of special non-law-enforcement security activities that do not directly involve criminal investigations, such as prisoner detention or transport and non-military national security details.

[FR Doc. 2010–7329 Filed 3–30–10; 8:45 am]

BILLING CODE P

MORRIS K. UDALL AND STEWART L. UDALL FOUNDATION

Sunshine Act Meetings

Time and Date: 9 a.m. to 12 p.m., Friday, April 16, 2010.

Place: The offices of the Morris K. Udall and Stewart L. Udall Foundation, 130 South Scott Avenue, Tucson, AZ 85701.

Status: This meeting will be open to the public, unless it is necessary for the Board to consider items in executive session.

Matters To Be Considered: (1) A report on the U.S. Institute for Environmental Conflict Resolution; (2) A report from the Udall Center for Studies in Public Policy; (3) A report on the Native Nations Institute; (4) Program Reports; and (5) A Report from the Management Committee.

Portions Open to the Public: All sessions with the exception of the session listed below.

Portions Closed to the Public: Executive session.

Contact Person for More Information: Ellen K. Wheeler, Executive Director, 130 South Scott Avenue, Tucson, AZ 85701, (520) 901–8500.

Dated: March 24, 2010.

Ellen K. Wheeler,

Executive Director, Morris K. Udall and Stewart L. Udall Foundation, and Federal Register Liaison Officer.

[FR Doc. 2010–7012 Filed 3–30–10; 8:45 am]

BILLING CODE 6820–FN–M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (10–036)]

NASA Advisory Council; Space Operations Committee; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council Space Operations Committee.

DATES: Tuesday, April 13, 2010, 3–5 p.m. CDT.

ADDRESSES: NASA Johnson Space Center's Gilruth Center, Lone Star

Room, 18753 Space Center Blvd., Houston, TX 77058.

FOR FURTHER INFORMATION CONTACT: Mr. Jacob Keaton, Space Operations Mission Directorate, National Aeronautics and Space Administration Headquarters, Washington, DC 20546, 202/358–1507, *Jacob.keaton@nasagov.*

SUPPLEMENTARY INFORMATION: The agenda for the meeting includes the following topics:

—Space Shuttle Program Transition Plan.

The meeting will be open to the public up to the seating capacity of the room. It is imperative that the meeting be held on this date to accommodate the scheduling priorities of the key participants.

March 25, 2010.

P. Diane Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2010–7156 Filed 3–30–10; 8:45 am]

BILLING CODE P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice at least once monthly of certain Federal agency requests for records disposition authority (records schedules). Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. They authorize the preservation of records of continuing value in the National Archives of the United States and the destruction, after a specified period, of records lacking administrative, legal, research, or other value. Notice is published for records schedules in which agencies propose to destroy records not previously authorized for disposal or reduce the retention period of records already authorized for disposal. NARA invites public comments on such records schedules, as required by 44 U.S.C. 3303a(a).

DATES: Requests for copies must be received in writing on or before April 30, 2010. Once the appraisal of the records is completed, NARA will send a copy of the schedule. NARA staff usually prepare appraisal memorandums that contain additional information concerning the records covered by a proposed schedule. These, too, may be requested and will be provided once the appraisal is completed. Requesters will be given 30 days to submit comments.

ADDRESSES: You may request a copy of any records schedule identified in this notice by contacting the Life Cycle Management Division (NWML) using one of the following means:

Mail: NARA (NWML), 8601 Adelphi Road, College Park, MD 20740–6001.

E-mail: request.schedule@nara.gov.

FAX: 301–837–3698.

Requesters must cite the control number, which appears in parentheses after the name of the agency which submitted the schedule, and must provide a mailing address. Those who desire appraisal reports should so indicate in their request.

FOR FURTHER INFORMATION CONTACT: Laurence Brewer, Director, Life Cycle Management Division (NWML), National Archives and Records Administration, 8601 Adelphi Road, College Park, MD 20740–6001. Telephone: 301–837–1539. E-mail: *records.mgt@nara.gov.*

SUPPLEMENTARY INFORMATION: Each year Federal agencies create billions of records on paper, film, magnetic tape, and other media. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval, using the Standard Form (SF) 115, Request for Records Disposition Authority. These schedules provide for the timely transfer into the National Archives of historically valuable records and authorize the disposal of all other records after the agency no longer needs them to conduct its business. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

The schedules listed in this notice are media neutral unless specified otherwise. An item in a schedule is media neutral when the disposition instructions may be applied to records regardless of the medium in which the records are created and maintained. Items included in schedules submitted to NARA on or after December 17, 2007, are media neutral unless the item is limited to a specific medium. (See 36 CFR 1225.12(e).)

No Federal records are authorized for destruction without the approval of the Archivist of the United States. This approval is granted only after a thorough consideration of their administrative use by the agency of origin, the rights of the Government and of private persons directly affected by the Government's activities, and whether or not they have historical or other value.

Besides identifying the Federal agencies and any subdivisions requesting disposition authority, this public notice lists the organizational unit(s) accumulating the records or indicates agency-wide applicability in the case of schedules that cover records that may be accumulated throughout an agency. This notice provides the control number assigned to each schedule, the total number of schedule items, and the number of temporary items (the records proposed for destruction). It also includes a brief description of the temporary records. The records schedule itself contains a full description of the records at the file unit level as well as their disposition. If NARA staff has prepared an appraisal memorandum for the schedule, it too includes information about the records. Further information about the disposition process is available on request.

Schedules Pending:

1. Department of Agriculture, Office of Procurement and Property (N1–16–09–4, 1 item, 1 temporary item). Master files of an electronic information system used to track and manage property assets and related financial information.

2. Department of Agriculture, Food and Nutrition Service (N1–462–09–6, 1 item, 1 temporary item). Master files of an electronic information system that serves as a central repository of product information relating to the Women, Infants, and Children program.

3. Department of Agriculture, Food and Nutrition Service (N1–462–09–8, 1 item, 1 temporary item). Master files of an electronic information system that contains information on recipients or potential recipients of supplemental nutrition assistance who have been or are disqualified from receiving benefits.

4. Department of Defense, Defense Commissary Agency (N1–506–09–2, 2 items, 2 temporary items). Master files and outputs of an electronic information system that tracks sales and receipts, products, pricing, ordering, and inventories at military commissaries.

5. Department of Defense, Defense Commissary Agency (N1–506–09–3, 4

items, 4 temporary items). General correspondence files and informational documents relating to communications and planning.

6. Department of Defense, Defense Commissary Agency (N1–506–09–4, 2 items, 2 temporary items). Master files and outputs of electronic information systems that maintain data on processed meat products sold by military commissaries.

7. Department of Defense, Defense Commissary Agency (N1–506–09–6, 2 items, 2 temporary items). Master files and outputs of an electronic information system used in connection with the pricing and promotion of products at military commissaries.

8. Department of Defense, Defense Security Service (N1–446–09–5, 12 items, 12 temporary items). Records relating to contractor facilities involved in the National Industrial Security Program. Records pertain to such matters as security clearance of facilities, cancellation of clearances, security agreements, and related administrative actions.

9. Department of Education, Office of Management (N1–441–09–21, 2 items, 2 temporary items). Case files relating to complaints by borrowers in connection with Federal student loans. An electronic case tracking system is also included.

10. Department of Education, Office of Management (N1–441–09–20, 1 item, 1 temporary item). Master files of an electronic information system that contains data concerning student loans, including name of recipient, type of loan, loan period, and loan amount.

11. Department of Energy, Southwestern Power Administration (N1–387–10–1, 2 items, 2 temporary items). Records relating to power accounting and billing invoices.

12. Department of Health and Human Services, Centers for Medicare & Medicaid Services (N1–440–09–5, 1 item, 1 temporary item). Master files of an electronic information system that contains information concerning appeals of fee-for-service and managed care decisions under the Medicare program.

13. Department of Homeland Security, U.S. Customs and Border Protection (N1–568–09–1, 1 item, 1 temporary item). Master files of an electronic information system used to manage and track importer compliance audits.

14. Department of the Interior, Office of the Secretary (N1–48–08–22, 22 items, 17 temporary items). Records relating to management and administration, including such records as development files, planning files, audit records, records inventories, records relating to budget matters, committee records, and paperwork reduction files. Also included is the agency web site. Proposed for permanent retention are such records as Indian Fiduciary Trust management and reform records, Freedom of Information Act appeals related to the Indian Fiduciary Trust, and executive committee and board membership records.

15. Department of the Interior, Office of Planning and Performance Management (N1–48–09–10, 8 items, 1 temporary item). Records of the office other than those proposed for permanent retention. Proposed for permanent retention are such records as strategic planning files, performance and accountability report files, budgets and associated performance information relating to agency components, and performance management governance files.

16. Department of Justice, Criminal Division (N1–60–07–2, 3 items, 1 temporary item). Organized Crime Drug Enforcement Task Force case files that have been incorporated into an electronic management information system. Proposed for permanent retention are master files of the electronic information system containing case information as well as older case files, which have not been incorporated into the system.

17. Department of Justice, Executive Office for United States Attorneys (N1–60–10–10, 2 items, 2 temporary items). Master files and outputs of an electronic information system containing emergency contact information for employees.

18. Department of Justice, United States Attorney's Office for the District of South Carolina (N1–118–09–1, 19 items, 8 temporary items). Records relating to a pilot project for intermodal and maritime security at the Port of Charleston. Included are such records as electronic information systems used for situational awareness and property asset tracking, intelligence working files, vessel arrival files, and routine reference and research photographs. Proposed for permanent retention are such records as organizational records, briefing materials, operating manuals, public relations records, subject files, and photographs of significant activities.

19. Department of State, Bureau of Public Affairs (N1–59–09–4, 4 items, 2 temporary items). Web site records that contain information duplicated in other agency recordkeeping systems. Also included are records that relate to management and operation of the Web site. Proposed for permanent retention are the agency's official blog and snapshots of the entire public Web site taken at the end of each Presidential administration.

20. Department of the Treasury, Internal Revenue Service (N1–58–09–48, 3 items, 3 temporary items). Master files, outputs, and system documentation for an electronic information system which is used to store data from estate tax returns and generate estate tax closing letters.

21. Department of the Treasury, Internal Revenue Service (N1–58–09–90, 2 items, 2 temporary items). Master files and system documentation for an electronic information system which is used to disclose tax return information to participating state and local governments.

22. Department of the Treasury, Internal Revenue Service (N1–58–09–91, 4 items, 4 temporary items). Master files and system documentation for an electronic information system which is used to monitor upcoming legal actions, media interest, and outreach activities related to criminal investigations.

23. Department of the Treasury, Internal Revenue Service (N1–58–09–93, 2 items, 2 temporary items). Master files and system documentation for an electronic information system which is used to provide account transcripts to state tax collection agencies.

24. Department of the Treasury, Internal Revenue Service (N1–58–09–94, 2 items, 2 temporary items). Master files and system documentation for an electronic information system which is used to assist agency employees in processing taxpayer penalty relief requests.

25. Department of the Treasury, Internal Revenue Service (N1–58–09–98, 3 items, 3 temporary items). Master files, inputs, and system documentation for an electronic information system which is used to transmit electronically filed tax returns to the appropriate tax processor.

26. Department of the Treasury, Internal Revenue Service (N1–58–09–99, 6 items, 6 temporary items). Master files, outputs, and system documentation for an electronic information system which is used to track remittances that cannot be credited to the taxpayer and are considered excess collections.

27. Department of the Treasury, Internal Revenue Service (N1–58–09–100, 6 items, 6 temporary items). Master files, outputs, and system documentation for an electronic information system which is used to track remittances that cannot be immediately credited because the taxpayer has not been positively identified.

28. Department of the Treasury, Internal Revenue Service (N1–58–09–102, 4 items, 4 temporary items). Master files, inputs, outputs, and system documentation for an electronic information system which is used to maintain information concerning applicants for and participants in the Health Coverage Tax Credit program.

29. Central Intelligence Agency, Agency-wide (N1–263–06–3, 14 items, 13 temporary items). Records relating to records and information management activities. Included are such records as security classified records control and tracking logs, library services files, forms files, subject files relating to records management, indexes to temporary records, and records disposition schedules. Proposed for permanent retention are indexes to records scheduled for permanent retention.

30. Export-Import Bank of the United States, Chief Information Office (N1–275–09–4, 3 items, 3 temporary items). Master files of an electronic information system used to facilitate the Bank's loan pre-approval process.

31. Federal Maritime Commission, Office of the Secretary (N1–358–09–6, 2 items, 2 temporary items). Informal complaints and dispute resolution case files relating to shipping disputes. Also included are master files of an electronic information system that is used to assign cases to staff and monitor their status.

32. Federal Maritime Commission, Bureau of Certification and Licensing (N1–358–09–4, 1 item, 1 temporary item). Master files of an electronic information system that contains data about passenger vessels and their insurance coverage against potential claims.

33. Federal Maritime Commission, Bureau of Certification and Licensing (N1–358–09–5, 1 item, 1 temporary item). Master files of an electronic information system that contains data about potentially unlicensed ocean transportation intermediaries.

Dated: March 25, 2010.

Michael J. Kurtz,

Assistant Archivist for Records Services—Washington, DC.

[FR Doc. 2010–7334 Filed 3–30–10; 8:45 am]

BILLING CODE 7515–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2010–0120]

Agency Information Collection Activities: Submission for the Office of Management and Budget (OMB) Review; 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 invites public comment about our intention to request the OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** 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:* The Office of Federal and State Materials and Environmental Management Programs Requests to Agreement States for Information.

2. *Current OMB approval number:* 3150–0029.

3. *How often the collection is required:* One time or as needed.

4. *Who is required or asked to report:* Thirty-seven Agreement States who have signed Section 274(b) Agreements with NRC.

5. *The number of annual respondents:* 37.

6. *The number of hours needed annually to complete the requirement or request:* 1,480.

7. *Abstract:* The Agreement States are asked on a one-time or as-needed basis to respond to a specific incident, to gather information on licensing and inspection practices or other technical and statistical information. Information is also exchanged for training purposes, such as, student travel submissions. In 2007, the NRC policy changed to begin funding training for Agreement State materials licensing and inspection staff and associated travel to attend courses offered through the NRC training program. The results of such information requests, which are authorized under Section 274(b) of the Atomic Energy Act, are utilized in part by the NRC in preparing responses to Congressional inquiries. The Agreement State comments are also solicited in the areas of proposed procedure and policy development.

Submit, by June 1, 2010, 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, Maryland 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 submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2010–0120. You may submit your comments by any of the following methods. *Electronic comments:* Go to *http://www.regulations.gov* and search for Docket No. NRC–2010–0120. Mail comments to NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, by telephone at 301–415–6258, or by e-mail to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 22nd day of March 2010.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2010–7190 Filed 3–30–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–266 and 50–301; NRC–2010–0123]

FPL Energy Point Beach, LLC; Point Beach Nuclear Plant, Units 1 and 2; Exemption

1.0 Background

FPL Energy Point Beach, LLC (FPLE, the licensee) is the holder of Renewed Facility Operating License Nos. DPR–24 and DPR–27, which authorize operation of the Point Beach Nuclear Plant, Units 1 and 2 (PBNP). The licenses provide, among other things, that the facility is subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, the Commission) now or hereafter in effect.

The facility consists of two pressurized water reactors located in Manitowoc County, Wisconsin.

2.0 Request/Action

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 73, "Physical protection of plants and materials," Section 73.55, "Requirements for physical protection of licensed activities in nuclear power reactors against radiological sabotage," published in the **Federal Register** on March 27, 2009, effective May 26, 2009, with a full implementation date of March 31, 2010, requires licensees to protect, with high assurance, against radiological sabotage by designing and implementing comprehensive site security plans. The amendments to 10 CFR 73.55 published on March 27, 2009 establish and update generically applicable security requirements similar to those previously imposed by Commission orders issued after the terrorist attacks of September 11, 2001, and implemented by licensees. In addition, the amendments to 10 CFR 73.55 include additional requirements to further enhance site security based upon insights gained from implementation of the post-September 11, 2001, security orders. It is from one of these new requirements that PBNP now seeks an exemption from the March 31, 2010, implementation date. All other physical security requirements established by this recent rulemaking have already been or will be implemented by the licensee by March 31, 2010.

By letter dated February 26, 2010, which was superseded by letter dated March 11, 2010, the licensee requested an exemption in accordance with 10 CFR 73.5, "Specific exemptions." Enclosures 1 to the February 26, and March 11, 2010, letters contain security-related information and, accordingly, are not available to the public. Redacted versions of the licensee's exemption requests dated February 26, and March 11, 2010, are publicly available in the Agencywide Documents Access and Management System (ADAMS) Accession Nos. ML100600565 and ML100710739, respectively. The licensee has requested an exemption from the March 31, 2010, compliance date stating that it must accommodate unforeseen delays such as adverse weather, material delivery delays, and testing constraints that could result in non-compliance with the March 31, 2010, compliance deadline. Specifically, the request is for one requirement that would be met by May 28, 2010, versus the March 31, 2010, deadline. Granting this exemption for the one item would afford the licensee additional time to perform necessary upgrades to meet or exceed the regulatory requirements.

3.0 Discussion of Part 73 Schedule Exemptions From the March 31, 2010, Full Implementation Date

Pursuant to 10 CFR 73.55(a)(1), "By March 31, 2010, each nuclear power reactor licensee, licensed under 10 CFR Part 50, shall implement the requirements of this section through its Commission-approved Physical Security Plan, Training and Qualification Plan, Safeguards Contingency Plan, and Cyber Security Plan referred to collectively hereafter as 'security plans.'" Pursuant to 10 CFR 73.5, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 73 when the exemptions are authorized by law, and will not endanger life or property or the common defense and security, and are otherwise in the public interest.

NRC approval of this exemption, as noted above, would allow an extension from March 31, 2010, until May 28, 2010, for the implementation date for one specific requirement of the new rule. As stated above, 10 CFR 73.5 allows the NRC to grant exemptions from the requirements of 10 CFR 73. The NRC staff has determined that granting of the licensee's proposed exemption would not result in a violation of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

In the draft final Power Reactor Security rule sent to the Commission, the NRC staff proposed that the requirements of the new regulation be met within 180 days. The Commission directed a change from 180 days to approximately 1 year for licensees to fully implement the new requirements. This change was incorporated into the final rule. From this, it is clear that the Commission wanted to provide a reasonable timeframe for licensees to reach full compliance.

As noted in the final rule, the Commission also anticipated that licensees would have to conduct site-specific analyses to determine what changes were necessary to implement the rule's requirements, and that changes could be accomplished through a variety of licensing mechanisms, including exemptions. Since issuance of the final rule, the Commission has rejected a request generically to extend the rule's compliance date for all operating nuclear power plants, but noted that the Commission's regulations provide mechanisms for individual licensees, with good cause, to apply for relief from the compliance date, as documented in the letter from R. W. Borchardt (NRC) to M. S. Fertel (Nuclear Energy Institute) dated June 4, 2009. The licensee's request for an exemption is therefore consistent with the approach set forth by the Commission and discussed in the June 4, 2009, letter.

PBNP Schedule Exemption Request

The licensee provided detailed information in Enclosure 1 of its letter dated March 11, 2010, requesting an exemption. The licensee is requesting additional time to perform necessary upgrades to the PBNP security system due to unforeseen delays such as adverse weather, material delivery delays, and testing constraints, and provides a timeline for achieving full compliance with the new regulation. Enclosure 1 to the licensee's letter contains security-related information regarding the site security plan, details of the specific requirement of the regulation for which the site cannot be in compliance by the March 31, 2010, deadline, justification for the exemption request, the required changes to the site's security configuration, and a timeline with critical path activities that will bring the licensee into full compliance by May 28, 2010. The timeline provides dates indicating when the critical equipment will be installed, tested, and become operational.

Notwithstanding the schedular exemptions for these limited requirements, the licensee will continue to be in compliance with all other applicable physical security requirements as described in 10 CFR 73.55 and reflected in its current NRC-approved physical security program. By May 28, 2010, PBNP will be in full compliance with all the regulatory

requirements of 10 CFR 73.55, as issued on March 27, 2009.

4.0 Conclusion for Part 73 Schedule Exemption Request

The staff has reviewed the licensee's submittals and concludes that the licensee has justified its request for an extension of the compliance date with regard to one specified requirement of 10 CFR 73.55 until May 28, 2010.

Accordingly, the Commission has determined that pursuant to 10 CFR 73.5, "Specific exemptions," an exemption from the March 31, 2010, compliance date is authorized by law and will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants the requested exemption.

The long-term benefits that will be realized when the PBNP security modifications are complete justifies exceeding the full compliance date in the case of this particular licensee. The security measure for which PBNP needs additional time to implement is a new requirement imposed by March 27, 2009, amendments to 10 CFR 73.55, and is in addition to those required by the security orders issued in response to the events of September 11, 2001. Therefore, the NRC concludes that the licensee's actions are in the best interest of protecting the public health and safety through the security changes that will result from granting this exemption.

As per the licensee's request and the NRC's regulatory authority to grant an exemption from the March 31, 2010, deadline for the one item specified in Enclosure 1 of PBNP letter dated March 11, 2010, the licensee is required to be in full compliance with 10 CFR 73.55 by May 28, 2010. In achieving compliance, the licensee is reminded that it is responsible for determining the appropriate licensing mechanism (*i.e.,* 10 CFR 50.54(p) or 10 CFR 50.90) for incorporation of all necessary changes to its security plans.

Pursuant to 10 CFR 51.32, "Finding of no significant impact," the Commission has previously determined that the granting of this exemption will not have a significant effect on the quality of the human environment [75 FR 14206; March 24, 2010].

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 24th day of March 2010.

For the Nuclear Regulatory Commission.

Joseph G. Giitter,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2010–7189 Filed 3–30–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[DC/COL–ISG–017; NRC–2009–0380]

Office of New Reactors; Interim Staff Guidance on Ensuring Hazard-Consistent Seismic Input for Site Response and Soil Structure Interaction Analyses

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of availability.

SUMMARY: The NRC staff is issuing its Final Interim Staff Guidance (ISG) DC/COL–ISG–017 titled "Ensuring Hazard-Consistent Seismic Input for Site Response and Soil Structure Interaction Analyses," (Agencywide Documents Access and Management System (ADAMS) Accession No. ML100570203). This ISG supplements the guidance provided to the NRC staff in Sections 2.5 and 3.7 of NUREG–0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants," March 2007, and DC/COL–ISG–01, "Interim Staff Guidance on Seismic Issues Associated with High Frequency Ground Motion in Design Certification and Combined License Applications," issued May 19, 2008 (ADAMS Accession No. ML081400293). The NRC staff issues DC/COL–ISGs to facilitate timely implementation of current staff guidance and to facilitate activities associated with review of applications for design certifications and combined licenses by the Office of New Reactors. The NRC staff intends to incorporate the final approved DC/COL–ISG–017 into the next revision of SRP Sections 2.5 and 3.7 and Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants (LWR Edition)," June 2007.

Disposition: On August 31, 2009, the NRC staff issued the proposed ISG, DC/COL–ISG–017, "Ensuring Hazard-Consistent Seismic Input for Site Response and Soil Structure Interaction Analyses," (ADAMS Accession No. ML092230455) to solicit public and industry comment. The NRC staff received comments on the proposed guidance. This final issuance incorporates changes from the comments. The NRC staff responses to these comments can be found in ADAMS Accession No. ML100570289.

ADDRESSES: The NRC maintains ADAMS, which provides text and image files of NRC's public documents. These documents may be accessed through the NRC's Public Electronic Reading Room on the Internet at *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC Public Document Room reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr.resource@nrc.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Kimberly A. Hawkins, Chief, Structural Engineering Branch 2, Division of Engineering, Office of the New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; *telephone:* 301–415–0564 or *e-mail: Kimberly.Hawkins@nrc.gov.*

SUPPLEMENTARY INFORMATION: The agency posts its issued staff guidance in the agency external web page (*http://www.nrc.gov/reading-rm/doc-collections/isg/*).

Dated at Rockville, Maryland, this 24th day of March 2010.

For the Nuclear Regulatory Commission.

William F. Burton,

Chief, Rulemaking and Guidance Development Branch, Division of New Reactor Licensing, Office of New Reactor.

[FR Doc. 2010–7202 Filed 3–30–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2008–0644]

Notice of Issuance of Regulatory Guide

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of Issuance and Availability of Regulatory Guide (RG) 1.126, Revision 2, "An Acceptable Model and Related Statistical Methods for the Analysis of Fuel Densification."

FOR FURTHER INFORMATION CONTACT: John C. Voglewede, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 251–7555 or e-mail *John.Voglewede@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The U.S. Nuclear Regulatory Commission (NRC) is issuing a revision to an existing guide in the agency's "Regulatory Guide" series. This series was developed to describe and make

available to the public information such as methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

Revision 2 of RG 1.126 was issued with a temporary identification as Draft Regulatory Guide, DG–1189. This guide describes an analytical model and related assumptions and procedures that the staff of the NRC considers acceptable for predicting the effects of fuel densification in light-water-cooled nuclear power reactors. To meet these objectives, the guide describes statistical methods related to product sampling that will ensure that this and other approved analytical models will adequately describe the effects of densification for each initial core and reload fuel quantity produced.

II. Further Information

In December 2008, DG–1189 was published with a public comment period of 60 days from the issuance of the guide. No formal comments were received and the public comment period closed on February 9, 2009. Electronic copies of RG 1.126 are available through the NRC's public Web site under "Regulatory Guides" at *http://www.nrc.gov/reading-rm/doc-collections/.*

In addition, regulatory guides are available for inspection at the NRC's Public Document Room (PDR) located at Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852–2738. The PDR's mailing address is USNRC PDR, Washington, DC 20555–0001. The PDR can also be reached by telephone at (301) 415–4737 or (800) 397–4209, by fax at (301) 415–3548, and by e-mail to *pdr.resource@nrc.gov.*

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

Dated at Rockville, Maryland, this 22nd day of March 2010.

For the Nuclear Regulatory Commission.

Andrea D. Valentin,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2010–7226 Filed 3–30–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on EPR; Notice of Meeting

The ACRS Subcommittee on the U.S. Evolutionary Power Reactor (EPR) will hold a meeting on April 20–21, 2010, at 11545 Rockville Pike, T2–B1, Rockville, Maryland.

The entire meeting will be open to public attendance, with the exception of a portion that may be closed to protect information that is proprietary to AREVA NP, pursuant to 5 U.S.C. 552b(c)(4).

The proposed agenda for the subject meeting shall be as follows:

Tuesday, April 20, 2010, 8:30 a.m.–5 p.m.

The Subcommittee will review Chapters 4, 5 and 17 of the Safety Evaluation Report with Open Items associated with the staff's review of the Calvert Cliff's Unit 3 Combined License Application (COLA).

Wednesday, April 21, 2010, 8:30 a.m.–5 p.m.

The Subcommittee will review Chapter 12 of the Safety Evaluation Report with Open Items associated with the staff's review of the Calvert Cliff's Unit 3 COLA, and complete review of Chapter 19 of the Safety Evaluation Report with Open Items associated with the staff's review of the U.S. EPR Design Certification application.

The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated Federal Official (DFO), Mr. Derek Widmayer (Telephone 301–415–7366, E-mail: *Derek.Widmayer@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be e-mailed to the DFO one day before meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009 (74 FR 58268–58269).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in major inconvenience.

Dated: March 25, 2010.

Antonio F. Dias,

Branch Chief, Reactor Safety Branch B, Advisory Committee on Reactor Safeguards.

[FR Doc. 2010–7224 Filed 3–30–10; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards (ACRS); Meeting of the ACRS Subcommittee on Power Uprates; Notice of Meeting

The ACRS Subcommittee on Power Uprates will hold a meeting on April 23, 2010, at 11545 Rockville Pike, Rockville, Maryland, Room T2 B3.

The meeting will be open to public attendance, with the exception of a portion that may be closed to protect fuel design information that is proprietary to General Electric Hitachi (GEH) and Global Nuclear Fuels (GNF), pursuant to 5 U.S.C. 552b(c)(4).

The agenda for the subject meeting shall be as follows:

Friday, April 23, 2010,—8:30 a.m.–5 p.m.

The Subcommittee will review Supplement 3 to Topical Report NEDC–33173P–A, "Applicability of GE Methods to Expanded Domains." This supplement extends the GEH/GNF computational methods to include GNF–2 fuel design.

The Subcommittee will gather information, analyze relevant issues and facts, and formulate proposed positions and actions, as appropriate, for deliberation by the Full Committee.

Members of the public desiring to provide oral statements and/or written comments should notify the Designated

Federal Official (DFO), Zena Abdullahi (Telephone: 301–415–8716, E-mail: *Zena.Abdullahi@nrc.gov*) five days prior to the meeting, if possible, so that appropriate arrangements can be made. Thirty-five hard copies of each presentation or handout should be provided to the DFO thirty minutes before the meeting. In addition, one electronic copy of each presentation should be emailed to the DFO one day before the meeting. If an electronic copy cannot be provided within this timeframe, presenters should provide the DFO with a CD containing each presentation at least thirty minutes before the meeting. Electronic recordings will be permitted only during those portions of the meeting that are open to the public. Detailed procedures for the conduct of and participation in ACRS meetings were published in the **Federal Register** on October 14, 2009 (74 FR 58268–58269).

Detailed meeting agendas and meeting transcripts are available on the NRC Web site at *http://www.nrc.gov/reading-rm/doc-collections/acrs.* Information regarding topics to be discussed, changes to the agenda, whether the meeting has been canceled or rescheduled, and the time allotted to present oral statements can be obtained from the Web site cited above or by contacting the identified DFO. Moreover, in view of the possibility that the schedule for ACRS meetings may be adjusted by the Chairman as necessary to facilitate the conduct of the meeting, persons planning to attend should check with these references if such rescheduling would result in major inconvenience.

Dated: March 25, 2010.

Antonio F. Dias,

Branch Chief, Reactor Safety Branch B, Advisory Committee on Reactor Safeguards.

[FR Doc. 2010–7188 Filed 3–30–10; 8:45 am]

BILLING CODE 7590–01–P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before April 30, 2010. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: *Agency Clearance Officer,* Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and *OMB Reviewer,* Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7044.

SUPPLEMENTARY INFORMATION:

Title: SBA Express and Pilot Loan Program Export Express Community Express and Patriot Express.

Frequency: On occasion.

SBA Form Numbers: 1919, 1920SX, A, B, C 2237, 2238.

Description of Respondents: Small Business Clients.

Responses: 98,200.

Annual Burden: 52,474.

Title: Lenders Disbursement & Collection Report.

Frequency: On occasion.

SBA Form Number: 1502R.

Description of Respondents: Eligible Dealers associated with the Dealer floor plan.

Responses: 300.

Annual Burden: 140.

Title: Form of Detached assignment for U.S. Small Business Administration Loan Pool or Guaranteed Interest Certificate.

Frequency: On occasion.

SBA Form Number: 1088.

Description of Respondents: Secondary market participants.

Responses: 6,500.

Annual Burden: 9,750.

Title: Federal Agency Comment Forms.

Frequency: On occasion.

SBA Form Number: 1993.

Description of Respondents: Small business owners and farmers.

Responses: 350.

Annual Burden: 263.

Title: Federal Cash Transaction Report, Financial Status Report, Program Income Report, Narrative Program Report.

Frequency: On occasion.

SBA Form Numbers: SF 269, SF–272, SBA Form 2113.

Description of Respondents: Eligible Dealers associated with the Dealer floor plan.

Responses: 126.

Annual Burden: 8,568.

Title: Application for 8(a) Business Development (BD) and Small Disadvantaged Business (SDB) Certification.

Frequency: On occasion.

SBA Form Numbers: 1010, 1010–IND, 1010–AIT, 1010–ANC, 1010–CDC, 1010–NHO, 1010–REP, 1010–RECERT and 1010C.

Description of Respondents: Eligible Small Disadvantage Businesses and 8(a) businesses.

Responses: 9,971.

Annual Burden: 36,210.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 2010–7247 Filed 3–30–10; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

Region II Buffalo District Advisory Council; Public Meeting

AGENCY: U.S. Small Business Administration.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the location, date, time, and agenda for the next meeting of the Region II Buffalo District Advisory Council. The meeting will be open to the public.

DATES: The meeting will be held on April 14, 2010 from approximately 9:30 a.m. to 11:30 a.m. Eastern Standard Time.

ADDRESSES: The meeting will be held at the Canisius College Amherst Conference Center, 300 Corporate Parkway, Amherst, New York 14226.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), SBA announces the meeting of the Region II Buffalo District Advisory Council. The Region II Buffalo District Advisory Council is tasked with providing information of public interest.

The purpose of the meeting is so the council can provide advice and opinions regarding the effectiveness of and need for SBA programs, particularly the local districts which members represent. The agenda will include: District office, SBA programs and services, ARRA, government contracting, disaster updates, lending

activity reports, small business week, event announcements, and roundtable discussion on small business issues.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public however advance notice of attendance is requested. Anyone wishing to attend and/or make a presentation to the Region II Buffalo District Advisory Council must contact Franklin J. Sciortino, District Director, Buffalo District Office by October 8, by fax or email in order to be placed on the agenda. Franklin J. Sciortino, District Director, Buffalo District Office, U.S. Small Business Administration, 540 Niagara Center, 130 S. Elmwood Avenue, Buffalo, New York 14202; telephone (716) 551–4301 or fax (716) 551–4418.

Additionally, if you need accommodations because of a disability or require additional information, please contact Kelly Lotempio, BDS/PIO, Buffalo District Office, U.S. Small Business Administration, 540 Niagara Center, 130 S. Elmwood Avenue, Buffalo, New York 14202; telephone (716) 551–4301, *kelly.lotempio@sba.gov or fax (716) 551–4418.*

For more information, please visit our Web site at *http://www.sba.gov/ny/buffalo.*

Meghan Burdick,

Deputy Chief of Staff/Committee Management Officer.

[FR Doc. 2010–6816 Filed 3–30–10; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. IC–29190; File No. 812–13700]

MetLife Insurance Company of Connecticut, et al.

March 25, 2010.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of application for an order pursuant to Section 26(c) of the Investment Company Act of 1940 (the "Act") approving certain substitutions of securities and an order of exemption pursuant to Section 17(b) of the Act from Section 17(a) of the Act.

Applicants: MetLife Insurance Company of Connecticut ("MetLife of CT"), MetLife of CT Separate Account Eleven for Variable Annuities ("Separate Account Eleven"), MetLife of CT Separate Account QPN for Variable Annuities ("Separate Account QPN"), MetLife of CT Fund UL for Variable Life Insurance ("Fund UL"), MetLife Investors Insurance Company ("MetLife Investors"), MetLife Investors Variable Annuity Account One ("VA Account One"), MetLife Investors Variable Life Account One ("VL Account One"), MetLife Investors Variable Life Account Eight ("VL Account Eight"), First MetLife Investors Insurance Company ("First MetLife Investors"), First MetLife Investors Variable Annuity Account One ("First VA Account One"), MetLife Investors USA Insurance Company ("MetLife Investors USA"), MetLife Investors USA Separate Account A ("Separate Account A"), Metropolitan Life Insurance Company ("MetLife"), Metropolitan Life Separate Account DCVL ("Separate Account DCVL"), Metropolitan Life Separate Account UL ("Separate Account UL"), Security Equity Separate Account Twenty-Six ("SE Separate Account Twenty-Six"), Security Equity Separate Account Twenty-Seven ("SE Separate Account Twenty-Seven"), Security Equity Separate Account No. 13S ("SE Separate Account 13S"), Security Equity Separate Account No. 485 ("SE Separate Account 485"), General American Life Insurance Company ("General American") (together with MetLife of CT, MetLife Investors, First MetLife Investors, MetLife Investors USA and MetLife, the "Insurance Companies"), General American Separate Account Twenty-Eight ("GA Separate Account Twenty-Eight"), General American Separate Account Twenty-Nine ("GA Separate Account Twenty-Nine"), (together with Separate Account Eleven, Separate Account QPN, Fund UL, VA Account One, VL Account One, VL Account Eight, First VA Account One, Separate Account A, Separate Account DCVL, Separate Account UL, SE Separate Account Twenty-Six, SE Separate Account Twenty-Seven, SE Separate Account 13S, SE Separate Account 485 and GA Separate Account Twenty-Eight, the "Separate Accounts"), Met Investors Series Trust ("MIST") and Metropolitan Series Fund, Inc. ("Met Series Fund"), (together with MIST, the "Investment Companies").

The Insurance Companies and the Separate Accounts are referred to as the "Substitution Applicants." The Insurance Companies, the Separate Accounts and the Investment Companies are referred to as the "Section 17 Applicants."

SUMMARY: *Summary of Application:* Applicants seek an order approving the substitution of certain series of the Investment Companies for shares of series of other unaffiliated registered investment companies held by the Separate Accounts to fund certain group and individual variable annuity contracts and variable life insurance policies issued by the Insurance Companies (collectively, the "Contracts"). The Section 17 Applicants seek an order pursuant to Section 17(b) of the Act to permit certain in-kind transactions in connection with certain of the Substitutions.

DATES: *Filing Date:* The application was filed on September 21, 2009, and an amended and restated application was filed on March 23, 2010.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Secretary of the Commission and serving Applicants with a copy of the request personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 19, 2010, and should be accompanied by proof of service on Applicants, in the form of an affidavit or for lawyers a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request and the issue contested. Persons may request notification of a hearing by writing to the Secretary of the Commission.

ADDRESSES: Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. Applicants c/o Paul G. Cellupica, Chief Counsel—Securities Regulation and Corporate Services, MetLife Group, 1095 Avenue of the Americas, 40th Floor, New York, NY 10036 and Robert N. Hickey, Esq., Sullivan & Worcester LLP, 1666 K Street, NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: Alison T. White, Senior Counsel, or Joyce M. Pickholz, Branch Chief, Office of Insurance Products, Division of Investment Management, at (202) 551–6795.

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm,* or by calling (202) 551–8090.

Applicants' Representations

1. MetLife of CT is a stock life insurance company organized in 1863 under the laws of Connecticut. MetLife Investors is a stock life insurance company organized on August 17, 1981 under the laws of Missouri. First MetLife Investors is a stock life insurance company organized on

December 31, 1992 under the laws of New York. MetLife Investors USA is a stock life insurance company organized on September 13, 1960 under the laws of Delaware. MetLife is a stock life insurance company organized in 1868 under the laws of New York. General American is a stock life insurance company organized in 1933 under the laws of Missouri.

2. Separate Account Eleven, Fund UL, VA Account One, VL Account One, First VA Account One, Separate Account A, Separate Account UL, SE Separate Account Twenty-Six, SE Separate Account Twenty-Seven, Separate Account 13S, GA Separate Account Twenty-Eight, and GA Separate Account Twenty-Nine are registered under the Act as unit investment trusts for the purpose of funding the Contracts. Security interests under the Contracts have been registered under the Securities Act of 1933.

3. Separate Account QPN is exempt from registration under the Act. Security interests under the Contracts have been registered under the Securities Act of 1933.

4. VL Account Eight, Separate Account DCVL and Separate Account 485 serve as separate account funding vehicles for certain Contracts that are exempt from registration under Section 4(2) of the Securities Act of 1933 and Regulation D thereunder.

5. Although Separate Account QPN, VL Account Eight, Separate Account DCVL and Separate Account 485 are exempt from registration under the Act, they would be subject to the investment limitations of Section 12 but for the exclusion contained in Section 12(d)(1)(E) of the Act. To rely on such exclusion, an investment company that is not a registered investment company must, among other things, agree to refrain from substituting a security unless the Commission approves the substitution in the manner provided in Section 26 of the Act.

6. MIST and Met Series Fund are each registered under the Act as open-end management investment companies of the series type, and their securities are registered under the Securities Act of 1933. Metlife Advisers, LLC serves as investment adviser to MIST and Met Series Fund.

7. The annuity contracts permit the Insurance Companies to substitute shares of one fund with shares of another, including a fund of a different registered investment company. The prospectuses for the Contracts and the Separate Accounts contain the appropriate disclosures of this right.

8. Each Insurance Company, on its behalf and on behalf of the Separate Accounts proposes to make certain substitutions of shares of 11 funds (the "Existing Funds") held in sub-accounts of its respective Separate Accounts for certain series (the "Replacement Funds") of MIST and Met Series Fund.

9. The proposed substitutions are as follows: (a) BlackRock Money Market Portfolio for AIM V.I. Money Market Fund and Legg Mason Western Asset Variable Money Market Portfolio; (b) RCM Technology Portfolio for AIM V.I. Technology Fund and DWS Technology VIP; (c) Oppenheimer Global Equity Portfolio for DWS Global Opportunities VIP; (d) Met/Artisan Mid Cap Value Portfolio for Janus Aspen Perkins Mid Cap Value Portfolio; (e) Met/Templeton Growth Portfolio for Legg Mason Batterymarch Variable Global Equity Portfolio; (f) MetLife Stock Index Portfolio for Legg Mason Batterymarch S&P 500 Index Portfolio; (g) BlackRock High Yield Portfolio for Pioneer High Yield VCT Portfolio; (h) Lord Abbett Growth and Income Portfolio for Putnam VT Growth and Income Fund; (i) Met/AIM Small Cap Growth Portfolio for UIF Small Company Growth Portfolio.

10. The following is a summary of the investment objectives and policies of each Existing Fund and its corresponding Replacement Fund. Additional information including asset sizes, risk factors and comparative performance history for each Existing Fund and Replacement Fund can be found in the Application.

Existing fund	Replacement fund
AIM V.I. Money Market Fund—seeks to provide as high a level of current income as is consistent with the preservation of capital and liquidity. The Fund invests only in high-quality U.S. dollar-denominated short term debt obligations.	BlackRock Money Market Portfolio—seeks a high level of current income consistent with preservation of capital. The Portfolio invests in accordance with industry-standard requirements for money market funds for the quality, maturity and diversification of investments.
AIM V.I. Technology Fund—seeks capital growth. The Fund normally invests at least 80% of its assets in equity securities (principally common stocks) of issuers engaged primarily in technology-related industries.	RCM Technology Portfolio—seeks capital appreciation; no consideration is given to income. The Portfolio normally invests at least 80% of its assets in common stocks of companies which utilize new, creative or different, or "innovative," technologies to gain a strategic competitive advantage in their industry, as well as companies that provide and service those technologies.
DWS Technology VIP—seeks capital growth. Under normal circumstances, the Portfolio invests at least 80% of net assets in common stocks of companies in the technology sector.	RCM Technology Portfolio—seeks capital appreciation; no consideration is given to income.The Portfolio normally invests at least 80% of its assets in common stocks of companies which utilize new, creative or different, or "innovative," technologies to gain a strategic competitive advantage in their industry, as well as companies that provide and service those technologies.
DWS Global Opportunities VIP—seeks above-average capital appreciation over the long term. The Portfolio invests at least 65% of total assets in common stocks and other equities of small companies throughout the world (companies with market values similar to the smallest 20% of the S&P Developed Small Cap Index).	Oppenheimer Global Equity Portfolio—seeks capital appreciation. The Portfolio invests under normal circumstances at least 80% of its assets in equity securities (primarily common stock) of U.S. and foreign-based companies. The Portfolio can invest without limit in foreign securities and can invest in any country, including countries with developed or emerging markets.
Janus Aspen Perkins Mid Cap Value Portfolio—seeks capital appreciation. The Portfolio pursues its investment objective by investing primarily in common stocks selected for their capital appreciation potential.	Met/Artisan Mid Cap Value Fund—seeks long term capital growth. The Portfolio invests at least 80% of its net assets in the common stocks of medium-sized companies.
Legg Mason Batterymarch Variable Global Equity Portfolio—seeks long-term capital growth. Dividend income, if any, is a secondary consideration. The Portfolio invests primarily in the common stock of U.S. and non-U.S. issuers, particularly issuers located in countries included in the Morgan Stanley Capital International World Index.	Met/Templeton Growth Portfolio—seeks long-term capital growth. Under normal market conditions, the Portfolio invests primarily in the equity securities of companies with various market capitalizations located anywhere in the world, including emerging markets.

Existing fund	Replacement fund
Legg Mason Batterymarch S&P 500 Index Fund—seeks investment results that, before expenses, correspond to the price and yield performance of the S&P 500 Index.	MetLife Stock Index Portfolio—seeks to equal the performance of the S&P 500 Index (before expenses).
Legg Mason Western Asset Variable Money Market Portfolio—seeks to maximize current income consistent with preservation of capital. The Portfolio invests exclusively in high quality U.S. dollar denominated short-term debt securities.	BlackRock Money Market Portfolio—seeks a high level of current income consistent with preservation of capital. The Portfolio invests in accordance with industry-standard requirements for money market funds for the quality, maturity and diversification of investments.
Pioneer High Yield VCT Portfolio—seeks to maximize total return through a combination of income and capital appreciation. Normally, the Portfolio invests at least 80% of its total assets in below investment grade high yield debt securities (junk bonds) and preferred stocks.	BlackRock High Yield Portfolio—seeks to maximize total return consistent with income generation and prudent investment. The Portfolio will invest primarily in non-investment grade bonds with maturities of ten years or less. The Portfolio will normally invest at least 80% of its assets in high yield ("junk") bonds, including convertible and preferred securities.
Putnam VT Growth and Income Fund—seeks capital growth and current income. The Fund invests mainly in common stocks of U.S. companies, with a focus on value stocks that offer the potential for capital growth, current income, or both.	Lord Abbett Growth and Income Fund—seeks long-term growth of capital and income without excessive fluctuation in market value. The Portfolio primarily purchases equity securities of large, seasoned, U.S. and multinational companies that the portfolio manager believes are undervalued.
UIF Small Company Growth Portfolio—seeks long-term capital appreciation. The portfolio manager seeks long-term capital appreciation by investing at least 80% of the Portfolio's assets in growth-oriented equity securities of small U.S. and foreign companies, including emerging market securities.	Met/AIM Small Cap Growth Portfolio—seeks long-term growth of capital. The Portfolio invests normally at least 80% of its assets in securities of small-cap companies.

11. The management fees, 12b–1 fees (if applicable), other expenses and total operating expenses for each Existing and Replacement Fund are as follows:

	Management fees (Percent)	12b–1 fees (Percent)	Other expenses (Percent)	Waiver/Reimbursement (Percent)	Total expenses (Percent)
New Fund: BlackRock Money Market Portfolio	.32		.02	.01	.33
Old Fund: AIM V.I. Money Market Fund	.40		.50		.90
New Fund: RCM Technology Fund	.88		.08		.96
Old Fund: AIM V.I. Technology Fund	.75		.45		1.20
New Fund: RCM Technology Fund	.88	.15 (.25)	.08		1.11
Old Fund: DWS Technology VIP	.67	.25	.26		1.18
New Fund: Oppenheimer Global Equity Portfolio	.53	.25 (.50)	.11		.89
Old Fund: DWS Global Opportunities VIP	.89	.25	.28		1.42
New Fund: Met/Artisan Mid Cap Value Portfolio	.82	.25 (.50)	.05		1.12
Old Fund: Janus Aspen Perkins Mid Cap Value Portfolio	.77	.25	.36	.04	1.34
New Fund: Met/Templeton Growth Portfolio	.69	.25 (.50)	.18	.07	1.05
Old Fund: Legg Mason Batterymarch Variable Global Equity Portfolio	.75	.25	.39	.39	1.00
New Fund: BlackRock Money Market Portfolio	.32	.15 (.25)	.02	.01	.48
Old Fund: Legg Mason Western Asset Variable Money Market Portfolio	.45		.05		.50
New Fund: Met Life Stock Index Portfolio	.25		.03	.01	.27
Old Fund: Legg Mason Batterymarch S&P 500 Index Portfolio	.25	.20	.16	.02	.59
New Fund: BlackRock High Yield Portfolio	.60	.25 (.50)	.07		.92
Old Fund: Pioneer High Yield VCT Portfolio	.65	.25	.15		1.05
New Fund: Lord Abbett Growth and Income Portfolio—Class A	.53		.03		.56
Old Fund: Putnam VT Growth & Income Portfolio—Class IA	.48		.10		.58
New Fund: Lord Abbett Growth and Income Portfolio—Class B	.53	.25 (.50)	.03		.81
Old Fund: Putnam VT Growth & Income Portfolio—Class B	48	.25	.10		.83
New Fund: Met/AIM Small Cap Growth Portfolio	.86	.25 (.50)	.04		1.15
Old Fund: UIF Small Company Growth Portfolio	.92	.35	.44		1.71

12. MetLife Advisers, LLC is the adviser of each of the Replacement Funds. Each Replacement Fund currently offers up to four classes of shares, three of which, Class A, Class B and Class E are involved in the substitutions.

13. The Applicants believe the substitutions will provide significant benefits to Contract owners, including improved selection of sub-advisers and simplification of fund offerings through the elimination of overlapping offerings.

14. As a result of the substitutions, the number of investment options offered under substantially all of the Contracts will not change (currently ranges in number from 3 to 122). For a limited number of Contracts which currently have at least 21 investment options available, after the substitutions there will be available at least 20 investment options.

15. Those substitutions which replace investment options advised by investment advisers that are not affiliated with the Substitution Applicants with funds for which MetLife Advisers, LLC acts as investment adviser will permit each adviser, under the Multi-Manager Order, [IC–22824 (1997) and IC–23859 (1999)], to hire, monitor and replace sub-advisers as necessary to achieve optimal performance.

16. Contract owners with sub-account balances invested (through the separate account) in shares of the Replacement Funds, except for the Legg Mason Batterymarch Variable Global Equity Portfolio/Met/Templeton Growth Portfolio, will have lower total expense ratios taking into account fund expenses and current fee waivers.

17. In the following substitutions, the management fee and/or applicable Rule 12b–1 fee of the Replacement Fund are either currently higher, or, at certain management fee breakpoints, may be higher than those of the respective Existing Fund: Legg Mason Western Asset Variable Money Market Portfolio/BlackRock Money Market Portfolio; AIM V. I. Technology Fund/RCM Technology Portfolio; DWS Technology VIP/RCM Technology Portfolio; DWS Global Opportunities VIP/Oppenheimer Global Equity Portfolio; Putnam VT Growth and Income Portfolio/Lord Abbett Growth and Income Portfolio; UIF Small Company Growth Portfolio/Met/AIM Small Cap Growth Portfolio; and Janus Aspen Perkins Mid Cap Value Portfolio/Met/Artisan Mid Cap Value Portfolio.

18. The Substitution Applicants propose to limit Contract charges attributable to Contract value invested in the Replacement Funds following the proposed substitutions to a rate that would offset the difference in the expense ratio between each Existing Fund's net expense ratio and the net expense ratio for the respective Replacement Fund.

19. Except for the Legg Mason Batterymarch Variable Global Equity Portfolio/Met/Templeton Growth Portfolio substitution where there is an increase in net expenses after waivers of 0.05%, the substitutions will result in decreased net expense ratios ranging from 2 basis points to 57 basis points. Moreover, there will be no increase in Contract fees and expenses, including mortality and expense risk fees and administration and distribution fees charged to the Separate Accounts as a result of the substitutions.

20. The Substitution Applicants believe that the Replacement Funds have investment objectives, policies and risk profiles that are either substantially the same as, or sufficiently similar to, the corresponding Existing Funds to make those Replacement Funds appropriate candidates as substitutes.

21. In addition, after the substitutions, neither MetLife Advisers, LLC nor any of their affiliates will receive compensation from the charges to the Separate Accounts related to the Contracts or from Rule 12b–1 fees or revenue sharing from the Replacement Funds in excess of the compensation currently received from the investment advisers or distributors of the Existing Funds.

22. The share classes of the Replacement Funds are either identical to or less than the share classes of the Existing Funds with respect to the imposition of Rule 12b–1 fees currently imposed, except with respect to the substitution of BlackRock Money Market Portfolio for Legg Mason Western Asset Variable Money Market Portfolio.

23. Each MIST and Met Series Fund Replacement Fund's Class B and Class E Rule 12b–1 fees can be raised to 0.50% of net assets by the Replacement Fund's Board of Directors/Trustees without shareholder approval. However, Met Series Fund and MIST represent that Rule 12b–1 fees of the Class B and Class E shares of the Replacement Funds issued in connection with the proposed substitutions will not be raised above the current rate without approval of a majority in interest of the respective Replacement Funds' shareholders after the substitutions.

24. The distributors of the Existing Funds pay to the Insurance Companies, or their affiliates, any 12b–1 fees associated with the class of shares sold to the Separate Accounts. Similarly, the distributors for MIST and Met Series Fund will receive from the applicable class of shares held by the Separate Accounts Rule 12b–1 fees in the same amount or a lesser amount than the amount paid by the Existing Funds, except as described above.

25. Further, in addition to any Rule 12b–1 fees, the investment advisers or distributors of the Existing Funds pay the Insurance Companies or one of their affiliates from 0 to 43 basis points for the Existing Funds' classes of shares involved in the substitutions. Following the substitutions, these payments will not be made on behalf of the Replacement Funds. Rather, the Insurance Companies or their affiliates will have available both the 25 and 15 basis points in Rule 12b–1 fees from the Replacement Funds (with respect to Class B and Class E shares, respectively) and, as owners of the Replacement Funds' adviser, profit distributions from the adviser. These profits from investment advisory fees may be more or less than the fees being paid by the Existing Funds.

Applicants' Legal Analysis and Conditions

1. The Substitution Applicants request that the Commission issue an order pursuant to Section 26(c) of the Act approving the proposed substitutions.

2. Applicants represent that the Contracts permit the applicable Insurance Company, subject to compliance with applicable law, to substitute shares of another investment company for shares of an investment company held by a sub-account of the Separate Accounts. The prospectuses for the Contracts and the Separate Accounts contain appropriate disclosure of this right.

3. By a supplement to the prospectuses for the Contracts and the Separate Accounts, each Insurance Company has notified all owners of the Contracts of its intention to take the necessary actions, including seeking the order requested by this Application, to substitute shares of the funds as described herein. The supplement has advised Contract owners that from the date of the supplement until the date of the proposed substitution, owners are permitted to make one transfer of Contract value (or annuity unit exchange) out of the Existing Fund sub-account to one or more other sub-accounts without the transfer (or exchange) being treated as one of a limited number of permitted transfers (or exchanges) or a limited number of transfers (or exchanges) permitted without a transfer charge. The supplement also has informed Contract

owners that the Insurance Company will not exercise any rights reserved under any Contract to impose additional restrictions on transfers until at least 30 days after the proposed substitutions. The supplement has also advised Contract owners that for at least 30 days following the proposed substitutions, the Insurance Companies will permit Contract owners affected by the substitutions to make one transfer of Contract value (or annuity unit exchange) out of the Replacement Fund sub-account to one or more other sub-accounts without the transfer (or exchange) being treated as one of a limited number of permitted transfers (or exchanges) or a limited number of transfers (or exchanges) permitted without a transfer charge.

4. The proposed substitutions will take place at relative net asset value with no change in the amount of any Contract owner's Contract value, cash value, or death benefit or in the dollar value of his or her investment in the Separate Accounts.

5. The process for accomplishing the transfer of assets from each Existing Fund to its corresponding Replacement Fund will be determined on a case-by-case basis. In most cases, it is expected that the substitutions will be effected by redeeming shares of an Existing Fund for cash and using the cash to purchase shares of the Replacement Fund. In certain other cases, it is expected that the substitutions will be effected by redeeming the shares of an Existing Fund in-kind; those assets will then be contributed in-kind to the corresponding Replacement Fund to purchase shares of that Fund. All in-kind redemptions from an Existing Fund of which any of the Substitution Applicants is an affiliated person will be effected in accordance with the conditions set forth in the Commission's no-action letter issued to *Signature Financial Group, Inc.* (available December 28, 1999).

6. Contract owners will not incur any fees or charges as a result of the proposed substitutions, nor will their rights or an Insurance Company's obligations under the Contracts be altered in any way. All expenses incurred in connection with the proposed substitutions, including brokerage, legal, accounting, and other fees and expenses, will be paid by the Insurance Companies. In addition, the proposed substitutions will not impose any tax liability on Contract owners. The proposed substitutions will not cause the Contract fees and charges currently being paid by existing Contract owners to be greater after the proposed substitutions than before the proposed substitutions. No fees will be charged on the transfers made at the time of the proposed substitutions because the proposed substitutions will not be treated as a transfer for the purpose of assessing transfer charges or for determining the number of remaining permissible transfers in a Contract year.

7. In addition to the prospectus supplements distributed to owners of Contracts, within five business days after the proposed substitutions are completed, Contract owners will be sent a written notice informing them that the substitutions were carried out and that they may make one transfer of all Contract value or cash value under a Contract invested in any one of the sub-accounts on the date of the notice to one or more other sub-accounts available under their Contract at no cost and without regard to the usual limit on the frequency of transfers from the variable account options to the fixed account options. The notice will also reiterate that (other than with respect to "market timing" activity) the Insurance Company will not exercise any rights reserved by it under the Contracts to impose additional restrictions on transfers or to impose any charges on transfers until at least 30 days after the proposed substitutions. The Insurance Companies will also send each Contract owner current prospectuses for the Replacement Funds involved to the extent that they have not previously received a copy.

8. Each Insurance Company also is seeking approval of the proposed substitutions from any State insurance regulators whose approval may be necessary or appropriate.

9. The Substitution Applicants agree that for those who were Contract owners on the date of the proposed substitutions, the Insurance Companies will reimburse, on the last business day of each fiscal period (not to exceed a fiscal quarter) during the twenty-four months following the date of the proposed substitutions, those Contract owners whose sub-account invests in the Replacement Fund such that the sum of the Replacement Fund's net operating expenses (taking into account fee waivers and expense reimbursements) and sub-account expenses (asset-based fees and charges deducted on a daily basis from sub-account assets and reflected in the calculation of sub-account unit values) for such period will not exceed, on an annualized basis, the sum of the Existing Fund's net operating expenses taking into account fee waivers and expense reimbursements and sub-account expenses for fiscal year 2009, except with respect to the AIM V.I. Technology Fund/RCM Technology Portfolio, DWS Technology VIP/RCM Technology Portfolio, DWS Global Opportunities VIP/Oppenheimer Global Equity Portfolio, Janus Aspen Perkins Mid Cap Value Portfolio/Met/Artisan Mid Cap Value Portfolio, Legg Mason Western Asset Variable Money Market Portfolio/BlackRock Money Market Portfolio, Putnam VT Growth and Income Portfolio/Lord Abbett Growth and Income Portfolio, and UIF Small Company Growth Portfolio/Met/AIM Small Cap Growth Portfolio substitutions.

10. With respect to the AIM V.I. Technology Fund/RCM Technology Portfolio, DWS Technology VIP/RCM Technology Portfolio, DWS Global Opportunities VIP/Oppenheimer Global Equity Portfolio, Janus Aspen Perkins Mid Cap Value Portfolio/Met/Artisan Mid Cap Value Portfolio, Legg Mason Western Asset Variable Money Market Portfolio/BlackRock Money Market Portfolio, Putnam VT Growth and Income Portfolio/Lord Abbett Growth and Income Portfolio and UIF Small Company Growth Portfolio/Met/AIM Small Cap Growth Portfolio substitutions, the reimbursement agreement with respect to the Replacement Fund's operating expenses and sub-account expenses, will extend for the life of each Contract outstanding on the date of the proposed substitutions.

11. The Substitution Applicants further agree that, except with respect to the AIM V.I. Technology Fund/RCM Technology Portfolio, DWS Technology VIP/RCM Technology Portfolio, DWS Global Opportunities VIP/Oppenheimer Global Equity Portfolio, Janus Aspen Perkins Mid Cap Value Portfolio/Met/Artisan Mid Cap Value Portfolio, Legg Mason Western Asset Variable Money Market Portfolio/BlackRock Money Market Portfolio, Putnam VT Growth and Income Portfolio/Lord Abbett Growth and Income Portfolio, and UIF Small Company Growth Portfolio/Met/AIM Small Cap Growth Portfolio substitutions, the Insurance Companies will not increase total separate account charges (net of any reimbursements or waivers) for any existing owner of the Contracts on the date of the substitutions for a period of two years from the date of the substitutions.

12. With respect to the AIM V.I. Technology Fund/RCM Technology Portfolio, DWS Technology VIP/RCM Technology Portfolio, DWS Global Opportunities VIP/Oppenheimer Global Equity Portfolio, Janus Aspen Perkins Mid Cap Value Portfolio/Met/Artisan Mid Cap Value Portfolio, Legg Mason

Western Asset Variable Money Market Portfolio/BlackRock Money Market Portfolio, Putnam VT Growth and Income Portfolio/Lord Abbett Growth and Income Portfolio and UIF Small Company Growth Portfolio/Met/AIM Small Cap Growth Portfolio substitutions, the agreement not to increase the separate account charges will extend for the life of each Contract outstanding on the date of the proposed substitutions.

13. In each case, the applicable Insurance Companies believe that it is in the best interests of the Contract owners to substitute the Replacement Fund for the Existing Fund. The Insurance Companies believe that in cases where the Replacement Fund has a new sub-adviser, the new sub-adviser will, over the long term, be positioned to provide at least comparable performance to that of the Existing Fund's sub-adviser.

14. The Substitution Applicants anticipate that Contract owners will be better off with the array of sub-accounts offered after the proposed substitutions than they have been with the array of sub-accounts offered prior to the substitutions.

15. The Substitution Applicants submit that none of the proposed substitutions is of the type that Section 26(c) was designed to prevent.

16. The Substitution Applicants request an order of the Commission pursuant to Section 26(c) of the Act approving the proposed substitutions by the Insurance Companies.

17. The Section 17 Applicants request an order under Section 17(b) exempting them from the provisions of Section 17(a) to the extent necessary to permit the Insurance Companies to carry out each of the proposed substitutions.

18. Section 17(a)(1) of the Act, in relevant part, prohibits any affiliated person of a registered investment company, or any affiliated person of such person, acting as principal, from knowingly selling any security or other property to that company. Section 17(a)(2) of the Act generally prohibits the persons described above, acting as principals, from knowingly purchasing any security or other property from the registered company.

19. Because shares held by a separate account of an insurance company are legally owned by the insurance company, the Insurance Companies and their affiliates collectively own of record substantially all of the shares of MIST and Met Series Fund. Therefore, MIST and Met Series Fund and their respective funds are arguably under the control of the Insurance Companies notwithstanding the fact that Contract owners may be considered the beneficial owners of those shares held in the Separate Accounts. If MIST and Met Series Fund and their respective funds are under the control of the Insurance Companies, then each Insurance Company is an affiliated person or an affiliated person of an affiliated person of MIST and Met Series Fund and their respective funds. If MIST and Met Series Fund and their respective funds are under the control of the Insurance Companies, then MIST and Met Series Fund and their respective funds are affiliated persons of the Insurance Companies.

20. Regardless of whether or not the Insurance Companies can be considered to control MIST and Met Series Fund and their respective funds, because the Insurance Companies own of record more than 5% of the shares of each of them and are under common control with each Replacement Fund's investment adviser, the Insurance Companies are affiliated persons of both MIST and Met Series Fund and their respective funds. Likewise, their respective funds are each an affiliated person of the Insurance Companies.

21. The Insurance Companies, through their separate accounts in the aggregate own more than 5% of the outstanding shares of the following Existing Funds: Legg Mason Batterymarch Variable Global Equity Portfolio, Legg Mason Western Asset Variable Money Market Portfolio, Legg Mason Batterymarch S&P 500 Index Portfolio, Pioneer High Yield VCT Portfolio, UIF Small Company Growth Portfolio. Therefore, each Insurance Company is an affiliated person of those funds.

22. Because the substitutions may be effected, in whole or in part, by means of in-kind redemptions and purchases, the substitutions may be deemed to involve one or more purchases or sales of securities or property between affiliated persons. The proposed transactions may involve a transfer of portfolio securities by the Existing Funds to the Insurance Companies; immediately thereafter, the Insurance Companies would purchase shares of the Replacement Funds with the portfolio securities received from the Existing Funds. Accordingly, as the Insurance Companies and certain of the Existing Funds listed above, and the Insurance Companies and the Replacement Funds, could be viewed as affiliated persons of one another under Section 2(a)(3) of the Act, it is conceivable that this aspect of the substitutions could be viewed as being prohibited by Section 17(a).

23. Section 17(b) of the Act provides that the Commission may, upon application, grant an order exempting any transaction from the prohibitions of Section 17(a) if the evidence establishes that: (a) The terms of the proposed transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned; (b) the proposed transaction is consistent with the policy of each registered investment company concerned, as recited in its registration statement and records filed under the Act; and (c) the proposed transaction is consistent with the general purposes of the Act.

24. The Section 17 Applicants submit that for all the reasons stated above the terms of the proposed in-kind purchases of shares of the Replacement Funds by the Insurance Companies, including the consideration to be paid and received, as described in this Application, are reasonable and fair and do not involve overreaching on the part of any person concerned. The Section 17 Applicants also submit that the proposed in-kind purchases by the Insurance Companies are consistent with the policies of: (a) MIST and of its RCM Technology, Met/Templeton Growth, BlackRock High Yield, Lord Abbett Growth and Income and Met/AIM Small Cap Growth Portfolios; and (b) Met Series Fund and of its BlackRock Money Market, Oppenheimer Global Equity, Met/Artisan Mid Cap Value and MetLife Stock Index Portfolios, as recited in the current registration statements and reports filed by each under the Act. Finally, the Section 17 Applicants submit that the proposed substitutions are consistent with the general purposes of the Act.

25. To the extent that the in-kind purchases by the Insurance Company of the Replacement Funds' shares are deemed to involve principal transactions among affiliated persons, the procedures described below should be sufficient to assure that the terms of the proposed transactions are reasonable and fair to all participants. The Section 17 Applicants maintain that the terms of the proposed in-kind purchase transactions, including the consideration to be paid and received by each fund involved, are reasonable, fair and do not involve overreaching principally because the transactions will conform with all but one of the conditions enumerated in Rule 17a–7. The proposed transactions will take place at relative net asset value in conformity with the requirements of Section 22(c) of the Act and Rule 22c–1 thereunder with no change in the

amount of any Contract owner's contract value or death benefit or in the dollar value of his or her investment in any of the Separate Accounts. Contract owners will not suffer any adverse tax consequences as a result of the substitutions. The fees and charges under the Contracts will not increase because of the substitutions. Even though the Separate Accounts, the Insurance Companies, MIST and Met Series Fund may not rely on Rule 17a–7, the Section 17 Applicants believe that the Rule's conditions outline the type of safeguards that result in transactions that are fair and reasonable to registered investment company participants and preclude overreaching in connection with an investment company by its affiliated persons. In addition, as stated above, the in-kind redemptions will only be made in accordance with the conditions set out in the *Signature Financial Group* no-action letter (December 29, 1999).

26. The boards of MIST and Met Series Fund have adopted procedures, as required by paragraph (e)(1) of Rule 17a–7, pursuant to which the series of each may purchase and sell securities to and from their affiliates. The Section 17 Applicants will carry out the proposed Insurance Company in-kind purchases in conformity with all of the conditions of Rule 17a–7 and each series' procedures thereunder, except that the consideration paid for the securities being purchased or sold may not be entirely cash. Nevertheless, the circumstances surrounding the proposed substitutions will be such as to offer the same degree of protection to each Replacement Fund from overreaching that Rule 17a–7 provides to them generally in connection with their purchase and sale of securities under that Rule in the ordinary course of their business. In particular, the Insurance Companies (or any of their affiliates) cannot effect the proposed transactions at a price that is disadvantageous to any of the Replacement Funds. Although the transactions may not be entirely for cash, each will be effected based upon (1) the independent market price of the portfolio securities valued as specified in paragraph (b) of Rule 17a–7, and (2) the net asset value per share of each fund involved valued in accordance with the procedures disclosed in its respective investment company registration statement and as required by Rule 22c–1 under the Act. No brokerage commission, fee, or other remuneration will be paid to any party in connection with the proposed in kind purchase transactions.

27. The sale of shares of Replacement Funds for investment securities, as contemplated by the proposed Insurance Company in-kind purchases, is consistent with the investment policies and restrictions of the Investment Companies and the Replacement Funds because (a) the shares are sold at their net asset value, and (b) the portfolio securities are of the type and quality that the Replacement Funds would each have acquired with the proceeds from share sales had the shares been sold for cash. To assure that the second of these conditions is met, MetLife Advisers, LLC and the sub-adviser, as applicable, will examine the portfolio securities being offered to each Replacement Fund and accept only those securities as consideration for shares that it would have acquired for each such fund in a cash transaction.

28. The Section 17 Applicants submit that the proposed Insurance Company in-kind purchases are consistent with the general purposes of the Act as stated in the Findings and Declaration of Policy in Section 1 of the Act and that the proposed transactions do not present any of the conditions or abuses that the Act was designed to prevent.

29. The Section 17 Applicants represent that the proposed in-kind purchases meet all of the requirements of Section 17(b) of the Act and request that the Commission issue an order pursuant to Section 17(b) of the Act exempting the Separate Accounts, the Insurance Companies, MIST, Met Series Fund and each Replacement Fund from the provisions of Section 17(a) of the Act to the extent necessary to permit the Insurance Companies on behalf of the Separate Accounts to carry out, as part of the substitutions, the in-kind purchase of shares of the Replacement Funds which may be deemed to be prohibited by Section 17(a) of the Act.

Conclusion

Applicants assert that for the reasons summarized above that the proposed substitutions and related transactions meet the standards of Section 26(c) of the Act and are consistent with the standards of Section 17(b) of the Act and that the requested orders should be granted.

For the Commission, by the Division of Investment Management pursuant to delegated authority.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7207 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 29191; File No. 812–13694]

MCG Capital Corporation; Notice of Application

March 25, 2010.

AGENCY: Securities and Exchange Commission ("Commission").

ACTION: Notice of an application for an order under section 23(c)(3) of the Investment Company Act of 1940 (the "Act") for an exemption from section 23(c) of the Act.

SUMMARY: *Summary of the Application:* MCG Capital Corporation (the "Applicant"), requests an order to amend a prior order (the "Prior Order") [1] that permits the Applicant to issue restricted shares of its common stock ("Restricted Stock") to Applicant's employees and non-employee directors ("Participants") pursuant to the MCG Capital Corporation 2006 Employee Restricted Stock Plan and the MCG Capital Corporation 2006 Non-Employee Director Restricted Stock Plan (together, the "Plans").[2] Applicant seeks to amend the Prior Order in order to engage in certain transactions, provided for in the MCG Capital Corporation Second Amended and Restated 2006 Employee Restricted Stock Plan and the MCG Capital Corporation Second Amended and Restated Non-Employee Director Restricted Stock Plan (together, the "Amended Plans") that may constitute purchases by the Applicant of its own securities within the meaning of section 23(c) of the Act.

DATES: *Filing Dates:* The application was filed on September 4, 2009 and amended on January 19, 2010 and March 16, 2010.

Hearing or Notification of Hearing: An order granting the application will be issued unless the Commission orders a hearing. Interested persons may request a hearing by writing to the Commission's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the Commission by 5:30 p.m. on April 19, 2010, and should be accompanied by proof of service on applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's interest, the reason for the request, and the issues

[1] MCG Capital Corporation, Investment Company Act Release Nos. 27258 (Mar. 8, 2006) (notice) and 27280 (Apr. 4, 2006) (order).

[2] The Plans were each amended and restated on April 23, 2008.

contested. Persons who wish to be notified of a hearing may request notification by writing to the Commission's Secretary.

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090. Applicant, c/o Steven F. Tunney, President and Chief Executive Officer, MCG Capital Corporation, 1100 Wilson Boulevard, Suite 3000, Arlington, Virginia 22209.

FOR FURTHER INFORMATION CONTACT: Barbara T. Heussler, Senior Counsel, at (202) 551–6990, or Jennifer L. Sawin, Branch Chief, at (202) 551–6821, (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's Web site by searching for the file number, or an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicant's Representations

1. The Applicant is an internally managed, non-diversified, closed-end management investment company that has elected to be regulated as a business development company ("BDC") under the Act. The Plans authorize the Applicant to issue Restricted Stock to the Participants in accordance with the terms and conditions of the Prior Order. The Applicant seeks to amend the Prior Order to permit the Applicant to withhold shares of the Applicant's common stock or purchase shares of the Applicant's common stock from the Participants to satisfy tax withholding obligations related to the vesting of Restricted Stock that were or will be granted pursuant to the Plans or the Amended Plans. The Applicant will continue to comply with all of the terms and conditions of the Prior Order.

2. The Plans and the Amended Plans authorize the Applicant to issue shares of Restricted Stock; at the time of issuance these shares are subject to certain forfeiture restrictions. On the date that any Restricted Stock vests, such vested shares of the Restricted Stock are released to the Participant and are available for sale or transfer. For Participants who are employees, the value of the vested shares is deemed to be wage compensation for the employee. Applicant states that any compensation income recognized by an employee is generally subject to Federal withholding for income and employment tax purposes.[3] The Amended Plans provide that each Participant must satisfy all applicable Federal, State, and local or other income and employment tax withholding obligations before the Applicant will deliver stock certificates or otherwise recognize ownership of common stock under an award.

3. The Amended Plans will be subject to approval by the Applicant's board of directors as well as the required majority of the Applicant's directors within the meaning of section 57(o) of the Act. The Amended Plans explicitly permit the Applicant to withhold shares of the Applicant's common stock or purchase shares of the Applicant's common stock from the Participants to satisfy tax withholding obligations related to the vesting of Restricted Stock.[4]

Applicant's Legal Analysis

1. Section 23(c) of the Act, which is made applicable to BDCs by section 63 of the Act, generally prohibits a BDC from purchasing any securities of which it is the issuer except in the open market, pursuant to tender offers or under other circumstances as the Commission may permit to ensure that the purchase is made on a basis that does not unfairly discriminate against any holders of the class or classes of securities to be purchased. Applicant states that the withholding of the Applicant's common stock or purchase of shares of Applicant's common stock to satisfy tax withholding obligations related to the vesting of Restricted Stock might be deemed to be purchases by the Applicant of its own securities within the meaning of section 23(c), and that section 23(c) of the Act may therefore prohibit these transactions.

2. Section 23(c)(3) of the Act permits a BDC to purchase securities of which it is the issuer "under such * * * circumstances as the Commission may permit by * * * orders for the protection of investors in order to insure that such purchases are made in a manner or on a basis which does not unfairly discriminate against any holders of the class or classes of securities to be purchased." Applicant believes that the requested relief meets the standards of section 23(c)(3) of the Act.

3. The Applicant states that any such purchases will be made in a manner that does not unfairly discriminate against the Applicant's other stockholders because any shares that the Participants deliver to the Applicant to satisfy tax withholding obligations will be valued at the closing sales price of Applicant's shares of common stock on the NASDAQ Global Select Market (or any other such exchange on which its shares of common stock may be traded in the future) as of the date of the transaction. Applicant further states that no transaction will be conducted pursuant to the requested order on days when there are no reported market transactions involving the Applicant's shares. Applicant submits that because all of the transactions between the Applicant and the Participants with respect to the Amended Plans will take place at the public market price for the Applicant's common stock, these transactions will not be significantly different than could be achieved by any stockholder selling in a market transaction.

4. Applicant submits that the withholding provisions in the Amended Plans do not raise concerns about preferential treatment of the Applicant's insiders because the Amended Plans are a bona fide compensation plan of the type that is common among corporations generally. Further, the vesting schedule is determined at the time of the initial grant of the Restricted Stock. Applicant represents that that the transactions may be made only as permitted by the Amended Plans. The Applicant believes that its request for the order is consistent with the policies underlying the provisions of the Act permitting the use of equity compensation as well as prior exemptive relief granted by the Commission for relief under section 23(c) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7206 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

[3] During the restricted period (*i.e.*, prior to the lapse of applicable forfeiture restrictions), the Restricted Stock generally may not be sold, transferred, pledged, hypothecated, margined, or otherwise encumbered by a Participant.

[4] The Amended Plans provide that shares withheld from an award to satisfy tax withholding obligations are not returned to the plan reserve, but are counted against the number of shares available under the relevant plan.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61769; File No. SR–BX–2010–020]

Self-Regulatory Organizations; The NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 3121 To Reflect Changes to Corresponding FINRA Rule

March 24, 2010.

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, 2010, The NASDAQ OMX BX, Inc. (the "Exchange" or "BX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a non-controversial rule change under Rule 19b–4(f)(6) under the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing this proposed rule change to amend BX Rule 3121 to reflect recent changes to a corresponding rule of the Financial Industry Regulatory Authority ("FINRA"). The Exchange will implement the proposed rule change thirty days after the date of the filing. Proposed new language is in italics and proposed deletions are in brackets.

* * * * *

[3121]*4570.* Custodian of [the]*Books and* Record*s*

A member who files a [Securities and Exchange Commission] Form BDW shall designate on the Form BDW, as the custodian of the *member's books and* record*s,* a person associated with the member at the time that the Form BDW is filed.

* * * * *

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of 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

Many of BX's rules are based on rules of FINRA (formerly the National Association of Securities Dealers ("NASD")). During 2008, FINRA embarked on an extended process of moving rules formerly designated as "NASD Rules" into a consolidated FINRA rulebook. In most cases, FINRA has renumbered these rules, and in some cases has substantively amended them. Accordingly, BX also proposes to initiate a process of modifying its rulebook to ensure that BX rules corresponding to FINRA rules continue to mirror them as closely as practicable. In some cases, it will not be possible for the rule numbers of BX rules to mirror corresponding FINRA rule numbers, because existing or planned BX rules make use of those numbers. However, wherever possible, BX plans to update its rules to reflect changes to corresponding FINRA rules.

This filing addresses BX Rule 3121, which formerly corresponded to NASD 3121. In SR–FINRA–2009–080,[4] FINRA redesignated NASD Rule 3121 as FINRA Rule 4570 with minor technical changes. FINRA Rule 4570 requires a member to designate, as the custodian of its required books and records on Form BDW, a person who is associated with the firm at the time Form BDW is filed. The rule is intended to enhance the SRO's ability to obtain required books and records from firms that are no longer conducting business and to ensure that the custodian of the books and records has been subject to certain background checks. The FINRA Rule 4570 text makes minor technical changes by adopting terminology consistent with that used in Form BDW.

BX is adopting the new FINRA rule in full, and redesignating BX Rule 3121 to be BX Rule 4570, so as to correspond to the new FINRA rule number.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[5] in general, and with Sections 6(b)(5) of the Act,[6] in particular, in that the proposal is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. The proposed changes will conform BX Rule 3121 to recent changes made to a corresponding FINRA rule, to promote application of consistent regulatory standards.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6)[8] thereunder in that it effects a change that: (i) Does not significantly affect the protection of investors or the public interest; (ii) does not impose any significant burden on competition; and (iii) by its terms, does not become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate if consistent

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] Securities Exchange Act Release No. 61332 (January 12, 2010), 75 F.R. 3270 (January 20, 2010) (SR–FINRA–2009–080).

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires that a self-regulatory organization submit to 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 of filing of the proposed rule change, or such shorter time as designated by the Commission. The Commission notes that the Exchange has satisfied the five-day pre-filing notice requirement.

with the protection of investors and the public interest.

In its guidance on the proposed rules of Self-Regulatory Organizations ("SROs"),[9] the Commission concluded that filings based on the rules of another SRO already approved by the Commission are eligible for immediate effectiveness under Rule 19b–4(f)(6).[10] The Commission noted that "a proposed rule change appropriately may be filed as an immediately effective rule so long as it is based on and similar to another SRO's rule and each policy issue raised by the proposed rule (i) has been considered previously by the Commission when the Commission approved another exchange's rule (that was subject to notice and comment), and (ii) the rule change resolves such policy issue in a manner consistent with such prior approval."[11] The Exchange notes that the change is identical to a change by FINRA approved by the Commission.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as amended, 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–BX–2010–020 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BX–2010–020. 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 Web site viewing and printing 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 such filing also will be available for inspection and copying at the principal office of the Exchange. 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–BX–2010–020 and should be submitted on or before April 21, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7104 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

[9] Securities Exchange Act Release No. 58092 (July 3, 2008), 73 FR 40144 (July 11, 2008).

[10] 17 CFR 240.19b–4(f)(6).

[11] *See* supra note 9 at 40149.

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61783; File No. SR–NSCC–2010–03]

Self-Regulatory Organizations; The National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Expand the Eligibility of Securities Processed Through the ID Net Service

March 25, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on March 5, 2010, the National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by NSCC. NSCC filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act[2] and Rule 19b–4(f)(4)[3] thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change amends NSCC's rules regarding the eligibility of securities processed through the ID Net Service ("ID Net").

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC 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. NSCC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[4]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

On June 2, 2008, the Commission approved a rule change that provided for the settlement of institutional transactions through a joint service of NSCC and The Depository Trust Company ("DTC") called ID Net. ID Net enables subscribers to the service to net all eligible affirmed institutional transactions at DTC against Continuous Net Settlement ("CNS") transactions[5] at NSCC. ID Net accepts affirmed institutional transactions that are eligible for ID Net from clearing agencies,[6] entities exempt from clearing agency registration with the Commission, and "qualified vendors"[7] and nets the broker-dealer's affirmed institutional transactions side of such transaction with the broker-dealer's CNS obligations.

Participation in ID Net is voluntary. Eligibility for ID Net requires that a

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78s(b)(3)(A)(iii).

[3] 17 CFR 240.19b–4(f)(4).

[4] The Commission has modified the text of the summaries prepared by NSCC.

[5] NSCC's Continuous Net Settlement System (CNS) is an automated accounting and securities settlement system that centralizes and nets the settlement of compared and recorded security transactions and maintains an orderly flow of security and money balances. CNS provides clearance for equities, corporate bonds, unit investment trusts, and municipal bonds that are eligible for book-entry transfer at DTC.

[6] The clearing agency must be registered pursuant to Section 17A of the Act or obtain an exemption.

[7] The term "qualified vendor" is defined in the rules of the New York Stock Exchange, the National Association of Securities Dealers, and other self-regulatory organizations.

broker-dealer be a DTC participant and an NSCC member eligible for CNS processing. The custodian bank must be a DTC participant. In addition, eligibility for ID Net processing is based on the underlying security being processed, the type of transaction submitted for processing, and the timing of affirmation. Most equity securities that are eligible for CNS are eligible for ID Net processing. However, the following securities were initially excluded from ID Net eligibility: (1) Corporate and municipal bonds and unit investment trust issues; (2) new issue securities; (3) securities that are IPO tracked (because the use of omnibus accounts will bypass the tracking system); (4) trades in issues that are currently undergoing a mandatory or voluntary reorganization; (5) trades in CUSIPs with a CNS buy-in; and (6) trades in securities appearing on the SEC's Regulation SHO list. At its inception, NSCC noted that because ID Net was a new service, it was excluding certain securities that could potentially have a relatively high rate of delivery failure or disrupt normal processing of transactions in ID Net in order to ensure that the system ran smoothly. NSCC also noted that as its experience with ID Net grew, it would revaluate the exclusion of certain issues.

Since the implementation of ID Net, the service has operated with minimal disruption, thus allaying the concerns regarding the addition of certain securities previously excluded from the service. In order to enhance processing efficiency and at the request of its members, NSCC is expanding ID Net to allow NSCC at its discretion from time to time to make eligible for ID Net any security that is eligible for CNS processing.

NSCC will announce by "Important Notice" particular securities or classes of securities are made eligible for processing through ID Net.

The proposed rule change is consistent with Section 17A of the Act,[8] as amended, and the rules and regulations thereunder applicable to NSCC. The proposed rule change will promote the prompt and accurate clearance and settlement of securities transactions by leveraging the capabilities of the NSCC system to provide for more streamlined securities deliveries and to extend netting benefits and efficiencies to more ID Net transactions.

(B) Self-Regulatory Organization's Statement on Burden on Competition

NSCC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change were not and are not intended to be solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(iii) of the Act[9] and Rule 19b–4(f)(4)[10] thereunder because the proposed rule change effects a change in an existing service of NSCC that: (i) Does not adversely affect the safeguarding of securities or funds in the custody or control of NSCC or for which it is responsible and (ii) does not significantly affect the respective rights or obligations of NSCC or persons using the service. At any time within sixty days of the filing of the 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–NSCC–2010-03 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NSCC–2010–03. 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 such filings also will be available for inspection and copying at the principal office of NSCC and on NSCC's Web site at *http://www.dtcc.com/downloads/legal/rule_filings/2010/nscc/2010-03.pdf.* 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–NSCC–2010–03 and should be submitted on or before April 21, 2010.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[11]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7204 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

[8] 15 U.S.C. 78q–1.

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 17 CFR 240.19b–4(f)(4).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61784; File No. SR–DTC–2010–05]

Self-Regulatory Organizations; the Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Update Its Settlement Service Guide as It Relates to the ID Net Service

March 25, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] notice is hereby given that on March 5, 2010, the Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change described in Items I, II, and III below, which items have been prepared primarily by DTC. DTC filed the proposal pursuant to Section 19(b)(3)(A)(iii) of the Act[2] and Rule 19b–4(f)(4)[3] thereunder so that the proposal was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change amends DTC's rules in order to update its Settlement Service Guide as it relates to the ID Net Service ("ID Net").

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, DTC 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. DTC has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of these statements.[4]

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

On June 2, 2008, the Commission approved a rule change that provided for the settlement of institutional transactions through a service called ID Net. ID Net enables subscribers to the service to net all eligible affirmed institutional transactions at DTC against Continuous Net Settlement ("CNS") transactions at the National Securities Clearing Corporation ("NSCC"). ID Net accepts affirmed institutional transactions from clearing agencies, entities exempt from clearing agency registration with the Commission, and "qualified vendors,"[5] and nets the broker-dealer's affirmed institutional transactions with the broker-dealer's CNS obligations.

Participation in ID Net is voluntary. Eligibility for ID Net requires that a broker-dealer be a DTC participant and an NSCC member eligible for CNS processing. The custodian bank must be a DTC participant. In addition, eligibility for ID Net processing is based on the underlying security being processed, the type of transaction submitted for processing, and the timing of affirmation. Most equity securities that are eligible for CNS are eligible for ID Net processing. However, DTC initially excluded the following securities from ID Net: (1) Corporate and municipal bonds and unit investment trust issues; (2) new issue securities; (3) securities that are IPO tracked (because the use of omnibus accounts will bypass the tracking system); (4) trades in issues that are currently undergoing a mandatory or voluntary reorganization; (5) trades in CUSIPs with a CNS buy-in; and (6) trades in securities appearing on the SEC's Regulation SHO list. At its inception, DTC noted that because ID Net was a new service, it was excluding certain securities that could potentially have a relatively high rate of delivery failure or disrupt normal processing of transactions in ID Net in order to ensure that the system ran smoothly. DTC also noted that as its experience with ID Net grew, it would revaluate the exclusion of certain issues.

Since the implementation of ID Net, the service has operated with minimal disruption, thus allaying the concerns regarding the addition of certain securities previously excluded from the service. In order to enhance processing efficiency and at the request of its participants, DTC is expanding ID Net to allow at DTC's discretion from time to time to make eligible for ID Net any security that is eligible for CNS processing.

DTC will notify its participants by "Important Notice" of the effective date of this change.

The proposed rule change is consistent with Section 17A of the Act,[6] as amended, and the rules and regulations thereunder applicable to DTC. The proposed rule change will promote the prompt and accurate clearance and settlement of securities transactions by leveraging the capabilities of the DTC system to provide for more streamlined securities deliveries and to extend netting benefits and efficiencies to more ID Net transactions.

(B) Self-Regulatory Organization's Statement on Burden on Competition

DTC does not believe that the proposed rule change will have any impact or impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change were not and are not intended to be solicited or received. DTC will notify the Commission of any written comments received by DTC.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing proposed rule change has become effective upon filing pursuant to Section 19(b)(3)(A)(iii) of the Act[7] and Rule 19b–4(f)(4)[8] thereunder because the proposed rule change effects a change in an existing service of DTC that: (i) Does not adversely affect the safeguarding of securities or funds in the custody or control of DTC or for which it is responsible and (ii) does not significantly affect the respective rights or obligations of DTC or persons using the service. At any time within sixty days of the filing of the 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

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78s(b)(3)(A)(iii).

[3] 17 CFR 240.19b–4(f)(4).

[4] The Commission has modified the text of the summaries prepared by FICC.

[5] The term "qualified vendor" is defined in the rules of the New York Stock Exchange, the National Association of Securities Dealers, and other self-regulatory organizations.

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78s(b)(3)(A)(iii).

[8] 17 CFR 240.19b–4(f)(4).

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–DTC–2010–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–DTC–2010–05. 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 such filings also will be available for inspection and copying at the principal office of DTC and on DTC's Web site at *http://www.dtcc.com/downloads/legal/rule_filings/2010/dtc/2010–05.pdf.* 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–DTC–2010–05 and should be submitted on or before April 21, 2010.

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[9]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7203 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61775; File No. SR–NYSEArca–2010–17]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NYSE Arca, Inc. Regarding the Listing of the ProShares Ultra MSCI Mexico Investable Market Fund

March 24, 2010.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on March 18, 2010, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange, through its wholly-owned subsidiary NYSE Arca Equities, Inc. ("NYSE Arca Equities"), proposes to list and trade shares ("Shares") of the following fund of the ProShares Trust ("Trust"): ProShares Ultra MSCI Mexico Investable Market. The text of the proposed rule change is available at the Exchange, the Commission's Public Reference Room, and *http://www.nyse.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 self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares of the following fund under NYSE Arca Equities Rule 5.2(j)(3), the Exchange's listing standards for Investment Company Units ("ICUs"):[4] ProShares Ultra MSCI Mexico Investable Market (the "Fund").

The Fund is an "index fund" that seeks to provide daily investment results that, before fees and expenses, correspond to twice (200%) of the daily performance of the MSCI Mexico Investable Market Index ("Index"). The Fund does not seek to achieve its stated objective over a period of time greater than one day.

According to the Trust's Registration Statement,[5] the Index measures the performance of the Mexican equity market. The Index is a capitalization-weighted index that aims to capture 99% of the publicly available total market capitalization. Component companies are adjusted for available float and must meet objective criteria for inclusion in the Index, taking into consideration unavailable strategic shareholdings and limitations to foreign ownership. As of February 26, 2010, the Index was concentrated in the telecommunications services industry group, which comprised 35.84% of the market capitalization of the Index, and included companies with capitalizations between $124.10 million and 44.68 billion. The average capitalization of the companies comprising the Index was approximately $5.84 billion.

The Exchange is submitting this proposed rule change because the Index for the Fund does not meet all of the "generic" listing requirements of Commentary .01(a)(B) to NYSE Arca Equities Rule 5.2(j)(3) applicable to listing of ICUs based on international or

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[9] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a *et seq.*

[3] 17 CFR 240.19b–4.

[4] An Investment Company Unit is a security that represents an interest in a registered investment company that holds securities comprising, or otherwise based on or representing an interest in, an index or portfolio of securities (or holds securities in another registered investment company that holds securities comprising, or otherwise based on or representing an interest in, an index or portfolio of securities). *See* NYSE Arca Equities Rule 5.2(j)(3)(A).

[5] *See* the Trust's Registration Statement on Form N–1A, dated February 26, 2010 (File Nos. 333–89822 and 811–21114) ("Registration Statement").

global indexes. The Index meets all such requirements except for those set forth in Commentary .01(a)(B)(3).[6] The Exchange represents that (1) except for the requirement under Commentary .01(a)(B)(3) to NYSE Arca Equities Rule 5.2(j)(3) that the most heavily weighted component stock shall not exceed 25% of the weight of the Index, the Shares of the Fund currently satisfy all of the generic listing standards under NYSE Arca Equities Rule 5.2(j)(3); (2) the continued listing standards under NYSE Arca Equities Rules 5.2(j)(3) and 5.5(g)(2) applicable to ICUs shall apply to the Shares; and (3) the Trust is required to comply with Rule 10A–3 [7] under the Securities Exchange Act of 1934 (the "Act") for the initial and continued listing of the Shares. In addition, the Exchange represents that the Shares will comply with all other requirements applicable to ICUs including, but not limited to, requirements relating to the dissemination of key information such as the Index value and Intraday Indicative Value, rules governing the trading of equity securities, trading hours, trading halts, surveillance,[8] and Information Bulletin to ETP Holders, as set forth in Exchange rules for ICUs and in prior Commission orders approving the generic listing rules applicable to the listing and trading of ICUs.[9]

Detailed descriptions of the Fund, the Index, procedures for creating and redeeming Shares, transaction fees and expenses, dividends, distributions, taxes, risks, and reports to be distributed to beneficial owners of the Shares can be found in the Trust's Registration Statement or on the Web site for the Fund (*http://www.proshares.com*), as applicable.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) [10] of the Act, in general, and furthers the objectives of Section 6(b)(5),[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system. The Exchange believes that the proposed rule change will facilitate the listing and trading of an additional type of exchange-traded product that will enhance competition among market participants, to the benefit of investors and the marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [12] and Rule 19b–4(f)(6) thereunder.[13] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 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, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6) [16] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[17] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change does not significantly affect the protection of investors or the public interest and does not impose any significant burden on competition. In addition, the Exchange believes that it has developed adequate trading rules, procedures, surveillance programs, and listing standards for the continued listing and trading of the Shares.

The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. The Commission notes that the Index fails to meet only one of the requirements set forth in Commentary .01(a)(B)(3) to NYSE Arca Equities Rule 5.2(j)(3) by only a small amount and that the Exchange has represented that the Shares of the Fund currently satisfy all of the other generic listing standards under NYSE Arca Equities Rule 5.2(j)(3) and all other requirements applicable to ICUs, as set forth in Exchange rules and prior Commission orders approving the generic listing rules applicable to the listing and trading of ICUs. Therefore, the Commission believes that the listing and trading of the Shares do not present any novel or significant issues or impose any significant burden on competition, and that waiving the 30-day operative delay will benefit the market and investors by providing market participants with additional investing choices. For these reasons, the Commission designates the proposed rule change as operative under upon filing.[18]

At any time within 60 days of the filing of the proposed rule change, the Commission may summarily abrogate such rule change if it appears to the Commission that such action is

[6] Specifically, the Index fails to meet the requirement that the most heavily weighted component stock shall not exceed 25% of the weight of the Index. As of February 26, 2010, the most heavily weighted component stock (America Movil S.A.B. de C.V.) represented 27.50% of the Index weight.

[7] 17 CFR 240.10A–3.

[8] The Exchange may obtain information for surveillance purposes via the Intermarket Surveillance Group ("ISG") from other exchanges who are members of ISG. For a list of current members of ISG, see *http://www.isgportal.org.* However, the Exchange does not have in place a comprehensive surveillance agreement with the Bolsa Mexicana de Valores and such exchange is not an ISG member.

[9] *See, e.g.* Securities Exchange Act Release Nos. 55621 (April 12, 2007), 72 FR 19571 (April 18, 2007) (SR–NYSEArca–2006–86) (order approving generic listing standards for ICUs based on international or global indexes); 44551 (July 12, 2001), 66 FR 37716 (July 19, 2001) (SR–PCX–2001–14) (order approving generic listing standards for ICUs and Portfolio Depositary Receipts); 41983 (October 6, 1999), 64 FR 56008 (October 15, 1999) (SR–PCX–98–29) (order approving rules for listing and trading of ICUs).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's 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 of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–NYSEArca–2010–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2010–17. 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 Web site viewing and printing 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 such filing also will be available for inspection and copying at the principal office of the Exchange. 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–NYSEArca–2010–17 and should be submitted on or before April 21, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7110 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61776; File No. SR–Phlx–2010–44]

Self-Regulatory Organizations; NASDAQ OMX PHLX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Relating to Extension of Sponsored Access Pilot Program

March 24, 2010.

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 17, 2010, NASDAQ OMX PHLX, Inc. ("Phlx" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend its sponsored access rule for a pilot period ending on September 15, 2010. The current pilot expires on March 15, 2010.

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.com/NASDAQOMXPHLX/Filings/,* 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to attract additional business by extending its sponsored access rule, which is similar to that of other exchanges. During the previous pilot program, very few member organizations availed themselves of the program, but the Exchange seeks to make it available for an additional pilot period expiring September 15, 2010.

A Sponsored Participant is a non-member of the Exchange, such as an institutional investor, that gains access to the Exchange and trades under a Sponsoring Member's execution and clearing identity pursuant to a sponsorship arrangement between such non-member and a member organization. Specifically, the Exchange proposes to permit Sponsored Participants to be sponsored by Sponsoring Member Organizations, and thereby access the Exchange, subject to certain requirements. These requirements are intended to confirm that the Sponsored Participant is required to and had procedures in place to comply with Exchange rules, and that the Sponsoring Member Organization takes responsibility for the Sponsored Participant's activity on the Exchange.

First, the Sponsored Participant and its Sponsoring Member Organization must have entered into and maintained an Access Agreement with the Exchange. The Sponsoring Member Organization must designate the Sponsored Participant by name in an addendum to the Access Agreement.

Second, there must be a Sponsored Participant Agreement between the Sponsoring Member Organization and the Sponsored Participant that contains the following sponsorship provisions, enumerated in full in Rule 1094(b)(ii):

(i) The orders of the Sponsored Participant are binding in all respects on the Sponsoring Member Organization;

(ii) The Sponsoring Member Organization is responsible for the actions of the Sponsored Participant;

(iii) In addition to the Sponsoring Member Organization being required to comply with the Exchange Certificate of Incorporation, By-laws, Rules and procedures of the Exchange, the

[19] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Sponsored Participant shall do so as if such Sponsored Participant were an Exchange member organization;

(iv) The Sponsored Participant shall maintain, keep current and provide to the Sponsoring Member Organization a list of individuals authorized to obtain access to the Exchange on behalf of the Sponsored Participant;

(v) The Sponsored Participant shall familiarize its authorized individuals with all of the Sponsored Participant's obligations under this Rule and will assure that they receive appropriate training prior to any use or access to the Exchange;

(vi) The Sponsored Participant may not permit anyone other than authorized individuals to use or obtain access to the Exchange; [3]

(vii) The Sponsored Participant shall take reasonable security precautions to prevent unauthorized use or access to the Exchange, including unauthorized entry of information into the Exchange, and agrees that it is responsible for any and all orders, trades and other messages and instructions entered, transmitted or received under identifiers, passwords and security codes of authorized individuals, and for the trading and other consequences thereof;

(viii) The Sponsored Participant acknowledges its responsibility to establish adequate procedures and controls that permit it to effectively monitor its employees', agents' and Participants' use and access to the Exchange for compliance with the terms of this agreement;

(ix) The Sponsored Participant shall pay when due all amounts, if any, payable to Sponsoring Member Organization, the Exchange, or any other third parties that arise from the Sponsored Participant's access to and use of the Exchange. Such amounts include, but are not limited to applicable exchange and regulatory fees.

Third, the Sponsoring Member Organization must provide the Exchange with a Sponsored Participant Addendum to its Access Agreement acknowledging its responsibility for the orders, executions and actions of its Sponsored Participant at issue.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [4] in general, and furthers the objectives of Section 6(b)(5) of the Act [5] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest by helping market participants seeking access to a marketplace.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [6] and Rule 19b–4(f)(6) [7] thereunder.

A proposed rule change filed under 19b–4(f)(6) normally may not become operative prior to 30 days after the date of filing.[8] However, Rule 19b–4(f)(6)(iii) [9] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that the proposal may become operative upon filing. The Exchange filed the proposed rule change on March 17, 2010. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest because such waiver would allow the Exchange to extend and continue its pilot program without delay. Accordingly, the Commission hereby grants the Exchange's request and designates the proposal operative upon filing.[10]

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–Phlx–2010–44 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–Phlx–2010–44. 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 Web site viewing and printing 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 such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only

[3] If the Exchange determines that an authorized individual has caused a Member Organization to violate the Exchange's Rules, the Exchange could direct the Member Organization to suspend or withdraw the person's status as an authorized individual.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. Phlx has satisfied this requirement.

[8] 17 CFR 240.19b–4(f)(6)(iii).

[9] *Id.*

[10] For the purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

information that you wish to make available publicly. All submissions should refer to File Number SR–Phlx–2010–44 and should be submitted on or before April 21, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7109 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61766; File No. SR–NASDAQ–2010–035]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing of Proposed Rule Change To Establish Strike Price Intervals and Trading Hours for Options on Index-Linked Securities

March 23, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act" or "Exchange Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 11, 2010, The NASDAQ Stock Market LLC ("NASDAQ" or "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

NASDAQ is filing with the Securities and Exchange Commission ("SEC" or "Commission") a proposal for the NASDAQ Options Market ("NOM" or "Exchange") to amend: Chapter IV, Section 6 (Series of Options Contracts Open for Trading) to establish strike-price intervals for options on Index-Linked Securities; [3] and Chapter VI, Section 2 (Days and Hours of Business) to establish trading hours for these products. The text of the proposed rule change is available on NASDAQ's Web site at *http://nasdaq.cchwallstreet.com/Filings/,* on the Commission's Web site at *http://www.sec.gov*, at NASDAQ, 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, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts 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 proposal is to amend Chapter IV, Section 6 and Chapter VI, Section 2 to establish strike price intervals and trading hours for options on Index-Linked Securities ("ILS"), also known as exchange-traded notes ("ETN"), prior to the Exchange proposing to list and trade these new products.

The Commission has approved the Exchange's proposal, as well as the proposals of other options exchanges, to enable the listing and trading of options on ILS (ETN).[4] Options trading has not commenced to date and is contingent upon the Commission's approval of The Options Clearing Corporation's ("OCC") proposed supplement to the Options Disclosure Document ("ODD") that will provide disclosure regarding options on Index-Linked Securities.[5]

$1 Strikes for ILS (ETN) Options

Prior to the commencement of trading options on Index-Linked Securities, the Exchange is proposing to establish that strike price intervals of $1 will be permitted where the strike price is less than $200. Where the strike price is greater than $200, $5 strikes will be permitted. These proposed changes are reflected by the addition of Chapter IV, Section 6, Supplementary Material .01(c) to Section 6.

The Exchange is seeking to establish $1 strikes for ILS (ETN) options where the strike price is less than $200 because the Exchange believes the marketplace and investors will be expecting these types of options to trade in a similar manner to options on exchange-traded funds ("ETFs").[6] Strike prices for ETF options are permitted in $1 or greater intervals where the strike price is $200 or less and $5 or greater where the strike price is greater than $200.[7] Accordingly, the Exchange believes that the rationale for permitting $1 strikes for ETF options equally applies to permitting $1 strikes for ILS (ETN) options, and that investors will be better served if $1 strike price intervals are available for ILS (ETN) options where the strike price is less than $200. The Exchange believes that $1 strike price intervals for options on Index-Linked Securities will provide investors with greater flexibility by allowing them to establish positions that are better tailored to meet their investment objectives.

Trading Hours for ILS (ETN) Options

The Exchange proposes to amend Chapter VI, Section 2(b) to provide that options contracts on exchange-traded notes including Index-Linked Securities, as defined in Chapter IV, Section 3(l), may be traded on the Exchange until 4:15 p.m. each business day. This will establish similar trading hours for ILS (ETN) options as the currently-established trading hours for ETF options.[8]

The Exchange has analyzed its capacity and believes the Exchange and the Options Price Reporting Authority ("OPRA") have the necessary systems capacity to handle the additional traffic associated with the listing and trading

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Index-Linked Securities, also known as exchange-traded notes, are long-term notes that are the non-convertible debt of an issuer with a term of at least one year but not greater than thirty years. These exchange-traded securities are designed for investors who desire to participate in a specific market segment by providing exposure to one or more identifiable underlying securities, commodities, currencies, derivative instruments or market indexes. The Exchange's listing standards for options on Index-Linked Securities were established in May 2009. *See* Securities Exchange Act Release No. 59923 (May 14, 2009), 74 FR 23902 (May 21, 2009) (SR–NASDAQ–2009–046) (notice of filing and immediate effectiveness). Other exchanges have established similar listing standards. *See* Securities Exchange Act Release Nos. 58571 (September 17, 2008), 73 FR 55188 (September 24, 2008) (SR–Phlx–2008–60) (notice of filing and immediate effectiveness); 58204 (July 22, 2008), 73 FR 43807 (July 28, 2008) (SR–CBOE–2008–64) (approval order); 58203 (July 22, 2008), 73 FR 43812 (July 28, 2008) (SR–NYSEArca–2008–57) (approval order); and 58985 (November 20, 2008), 73 FR 72538 (November 28, 2008) (SR–ISE–2008–86) (notice of filing and immediate effectiveness).

[4] *See* supra note 3.

[5] OCC previously received Commission approval to clear options based on Index-Linked Securities. *See* Securities Exchange Act Release No. 60872 (October 23, 2009), 74 FR 55878 (October 29, 2009) (SR–OCC–2009–14) (approval order).

[6] ETFs may also be known in the rules as Exchange Traded Funds or Fund Shares. *See, for example,* Chapter IV, Section 6(g) and Chapter 6, Section 2(b).

[7] *See* proposed Chapter IV, Section 6, Supplementary Material .01(b) to Section 6, which, like subsection (c), is renumbered for internal consistency.

[8] *See* Chapter VI, Section 2.

of $1 strikes where the strike price is less than $200 for ILS (ETN) options.

The Exchange expects that other option exchanges that have adopted rules providing for the listing and trading of options on Index-Linked Securities will submit similar proposals.[9]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [10] in general, and furthers the objectives of Section 6(b)(5) of the Act [11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanisms of a free and open market and a national market system, by having strike price intervals and trading hours established prior to the commencement of trading in options on Index-Linked Securities and thereby lessening the likelihood for investor confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve the 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 No. SR–NASDAQ–2010–035 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, Station Place, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2010–035. 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 Web site viewing and printing 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 inspection and copying at the principal office of the Exchange. 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–NASDAQ–2010–035 and should be submitted on or before April 15, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7105 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

[9] *See, for example,* Securities Exchange Act Release No. 61466 (February 2, 2010), 75 FR 6243 (February 8, 2010) (SR–CBOE–2010–005) (notice of filing).

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61774; File No. SR–NYSEAmex–2010–24]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by NYSE Amex LLC Relating to Exchange Liability

March 24, 2010.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act") [1] and Rule 19b–4 thereunder,[2] notice is hereby given that, on March 5, 2010, NYSE Amex LLC ("NYSE Amex" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a "non-controversial" rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes new Rule 905NY regarding the Exchange's liability for system outages. The text of the proposed rule change is attached as Exhibit 5 to the 19b–4 form. A copy of this filing is available on the Exchange's Web site at *http:www.nyse.com,* on the Commission's Web site at *http://www.sec.gov,* at the Exchange's principal office 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, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts 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 filing is to clarify that that [sic] the Exchange will generally not be held liable for any losses, expenses, damages or claims arising out of the use of its facilities, except to the extent that such losses, expenses, damages or claims are attributable to the willful misconduct, gross negligence, bad faith or fraudulent or criminal acts of the Exchange or its officers, employees or agents acting within the scope of their authority.

Currently, NYSE Amex Rule 60 limits the liability of the Exchange for claims arising out of use of NYSE Amex's Post Execution Reporting ("PER") and NYSE Alternext Options Switch ("AMOS") systems. NYSE Amex Rule 63 describes the Exchange's liability in general. These rules were intended to cover both the options and equities trading platforms of NYSE Amex. However, neither of these rules were revised following adoption of the Section 900NY rules governing the trading of options contracts.

The Exchange now proposes to adopt new NYSE Amex Rule 905NY to clarify that the Exchange (i) is generally not liable for losses, expenses, damages, or claims, arising out of the use of its facilities, but (ii) will assume some limited liability for damages arising out of the use of the NYSE Amex options trading platform under certain prescribed circumstances and capped at certain prescribed amounts. The proposed rule is substantially similar in scope to NYSE Amex Rules 60 and 63, but is modeled off NYSE Arca options Rule 14.2, Liability of Exchange. To the extent that a conflict may arise between the proposed Rule 905NY and either Rule 60 or 63, the new rule would take precedence. The Exchange is in the process of reviewing Rules 60 and 63 for possible revision or deletion. NYSE Arca Rule 14.2 offers a comprehensive and clear approach regarding liability, thus the Exchange seeks to harmonize its approach regarding liability with that of NYSE Arca.[4]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with Section 6(b)[5] of the Securities Exchange Act of 1934 (the "Act"), in general, and furthers the objectives of Section 6(b)(5)[6] in particular in that it is designed to promote just and equitable principles of trade, to prevent fraudulent and manipulative acts, to remove impediments to and to perfect the mechanism for a free and open market and a national market system and, in general, to protect investors and the public interest, by clarifying the extent of the Exchange's liability for claims arising out of the use of its options trading platform. Moreover, the proposed rule is based on NYSE Arca Rule 14.2, Liability of Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

(i) Significantly affect the protection of investors or the public interest;

(ii) Impose any significant burden on competition; and

(iii) Become operative for 30 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[7] and Rule 19b–4(f)(6) thereunder.[8]

The Exchange requested that the Commission waive the 30-day operative delay period. The Commission notes that the proposal is nearly identical to the rule of another self-regulatory organization,[9] and believes that no significant purpose is served by delaying its operative date. The Commission therefore believes that it is consistent with the protection of investors and the public interest to waive the 30-day operative delay and designates the proposal as operative upon filing.[10]

At any time within 60 days of the filing of the 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–NYSEAmex–2010–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEAmex–2010–24. 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

[4] This rule, as proposed shall apply only to the use of NYSE Amex options systems and facilities.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to submit to 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 of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[9] *See* NYSE Arca Rule 14.2.

[10] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

provisions of 5 U.S.C. 552, will be available for Web site viewing and printing 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 inspection and copying at the principal office of the Exchange. 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–NYSEAmex–2010–24 and should be submitted on or before April 21, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7106 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–61770; File No. SR–NASDAQ–2010–039]

Self-Regulatory Organizations; the NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Delay the Application of NASDAQ Rule 4611(d)

March 24, 2010.

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 17, 2010, The NASDAQ Stock Market LLC (the "Exchange" or "NASDAQ") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as constituting a non-controversial rule change under Rule 19b–4(f)(6) under the Act,[3] which renders the proposal effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing this proposed rule change to delay the application of NASDAQ Rule 4611(d) until 180 days following its approval. The text of the proposed rule change is available at *http://nasdaq.cchwallstreet.com/,* at the Exchange's principal office, 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, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On January 13, 2010, the Commission approved SR–NASDAQ–2008–104 which established new standards for sponsored access as set forth in NASDAQ Rule 4611(d), NASDAQ's Market Access Rule.[4] Based upon conversations with industry participants, NASDAQ believes that market participants need additional time to implement the Market Access Rule. Accordingly, NASDAQ is proposing to delay for 180 days from approval the implementation of new NASDAQ Rule 4611(d) as set forth in the NASDAQ Market Access Approval Order.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[5] in general and with Section 6(b)(5) of the Act,[6] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest. The proposal is consistent with these obligations because market participants require additional time to comply with the new market access provisions.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b-4(f)(6) thereunder.[8] 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–NASDAQ–2010–039 on the subject line.

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

[4] Securities Exchange Act Release No. 61345 (Jan. 13, 2010) ("NASDAQ Market Access Approval Order").

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. NASDAQ has satisfied this requirement.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street, NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2010–039. 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 Web site viewing and printing 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 such filing also will be available for inspection and copying at the principal office of the Exchange. 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–NASDAQ–2010–039, and should be submitted on or before April 21, 2010.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[9]

Florence E. Harmon,

Deputy Secretary.

[FR Doc. 2010–7107 Filed 3–30–10; 8:45 am]

BILLING CODE 8011–01–P

[9] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 6938]

Certifications Pursuant to Section 609 of Public Law 101–162

SUMMARY: On March 24, 2010, the Department of State notified Congress that it had withdrawn Mexico's certification under United States Public Law 101–162, Section 609, because Mexico's turtle excluder device (TED) program was not currently comparable to the United States program as required by the statute. Withdrawal of Mexican certification is primarily a compliance and environmental issue, but it does have trade implications. The United States government is providing the Government of Mexico with detailed technical recommendations and capacity-building support with a view to strengthening Mexico's sea turtle protection program. Both governments will continue to actively seek further engagement opportunities to ensure renewal of Mexican certification within the shortest period of time consistent with the requirements of U.S. law.

DATES: *Effective Date:* On publication.

FOR FURTHER INFORMATION CONTACT: James J. Hogan, III, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, Washington, DC 20520–7818; telephone: (202) 647–2252.

SUPPLEMENTARY INFORMATION: Section 609 of Public Law 101–162 prohibits imports of certain categories of shrimp unless the President certifies to the Congress not later than May 1 of each year either: (1) That the harvesting nation has adopted a program governing the incidental capture of sea turtles in its commercial shrimp fishery comparable to the program in effect in the United States and has an incidental take rate comparable to that of the United States; or (2) that the fishing environment in the harvesting nation does not pose a threat of the incidental taking of sea turtles. The President has delegated the authority to make this certification to the Department of State. Revised State Department guidelines for making the required certifications were published in the **Federal Register** on July 2, 1999 (Vol. 64, No. 130, Public Notice 3086).

The Department of State has communicated this decision under Section 609 to the Office of Field Operations of U.S. Customs and Border Protection.

This decision regarding withdrawal of Mexico's certification means that wild-harvest shrimp from Mexico's commercial trawl fisheries may not be imported into the United States until Section 609 certification for Mexico can be reinstated. A Department of State DS–2031 form signed by the exporter and importer must accompany all shrimp imports into the United States. If shrimp products are from a non-certified country, a government official of the harvesting nation must also certify the shrimp was caught without harming sea turtles. Users should check boxes 7(A)(1) for aquaculture shrimp products or 7(A)(3) for artisanal shrimp products. Users should note that exception 7.A.(2) on the form "Harvested Using TEDs," while a currently valid exception to the prohibition on imports from nations not certified under Public Law 101–162, is only available once the Department of State determines in advance that a country wishing to use this exception has in place an enforcement and catch segregation system for making such individual shipment certifications. Presently, only Brazil and Australia have shown that they have a system in place for specific fisheries. Exception 7(A)(4) is for other case-by-case, special circumstance determinations made by the Department of State in advance. For these reasons exceptions 7(A)(2) and 7(A)(4) are not applicable to imports of wild-caught shrimp from Mexico.

Dated: March 24, 2010.

David A. Balton,

Deputy Assistant Secretary for Oceans and Fisheries, Department of State.

[FR Doc. 2010–7221 Filed 3–30–10; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice 6463]

U.S. Department of State Advisory Committee on Private International Law: Organization of American States (OAS) Specialized Conference on Private International Law (CIDIP) Study Group

The OAS CIDIP Study Group will hold another public meeting to continue the discussion that began at the December 15, 2009 and continued at two additional meeting. This is not a meeting of the full Advisory Committee.

In the context of the Seventh Inter-American Specialized Conference on Private International Law (CIDIP–VII), the Committee on Juridical and Political Affairs (CJAP) of the Permanent Council of the OAS is carrying out work on consumer rights as part of its program on private international law. Three proposals have been put forward: A revised Brazilian draft convention on applicable law that has recently been expanded to include jurisdiction, a Canadian draft model law on applicable law and jurisdiction, and a United States proposal (with several components) for legislative guidelines/model laws/rules to promote consumer redress mechanisms such as small claims tribunals, collective procedures, on-line dispute resolution, and

government actions. The U.S. is considering the possibility of expanding its existing proposal.

The United States is also considering whether to pursue ratification of the Inter-American Convention on the Law Applicable to International Contracts (known as the Mexico City Convention), which was adopted at the Fifth Inter-American Specialized Conference on Private International Law (CIDIP–V). The United States is exploring the process for obtaining official corrections to the English text of the Convention to conform to the Spanish version. Copies of proposed corrections to the English text can be obtained through the contact points listed below. Other developments which may be relevant to work at the OAS include the proposal at UNCITRAL for future work on on-line dispute resolution and the establishment by the Permanent Bureau of the Hague Conference on Private International Law of an experts group to consider development of a non-binding instrument on choice of law in international commercial contracts.

Time and Place: The public meeting of the Study Group will take place in Room 240, South Building, 2430 E Street, NW., Washington, DC on April 9, 2010. Visitors should enter by the gate at the southwest corner of 23rd and C Streets not later than 12:45 p.m. EDT. The meeting will begin at 1 p.m. and is expected to last no later than 4 p.m. If you are unable to attend the public meeting and would like to participate from a remote location, teleconferencing will be available.

Public Participation: This Study Group meeting is open to the public, subject to the capacity of the meeting room. Access to the meeting building is controlled; persons wishing to attend should contact Tricia Smeltzer or Niesha Toms of the Department of State Legal Adviser's Office at *SmeltzerTK@state.gov* or *TomsNN@state.gov* and provide your name, e-mail address, and mailing address to get admission into the meeting or to get directions to the office. Please contact Ms. Smeltzer for additional meeting information, any of the documents referenced above, or dial-in information on the conference call. A member of the public needing reasonable accommodation should advise those same contacts not later than April 7th. Requests made after that date will be considered, but might not be able to be fulfilled. Persons who cannot attend or participate by conference call but who wish to comment on any of the topics referred to above are welcome to do so by e-mail to Michael Dennis at *DennisMJ@state.gov*.

Dated: March 25, 2010.

Michael Dennis,

Attorney-Adviser, Office of Private International Law, Office of the Legal Adviser, Department of State.

[FR Doc. 2010–7218 Filed 3–30–10; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice 6937]

Waiver of Restriction on Assistance to the Government of Libya

Pursuant to section 7086(c)(2) of the Department of State, Foreign Operations, and Related Programs Appropriations Act, 2010 (Division F, Pub. L. 111–117) ("the Act"), and Department of State Delegation of Authority Number 245–1, I hereby determine that it is important to the national interest of the United States to waive the requirements of section 7086(c)(1) of the Act with respect to the Government of Libya, and I hereby waive such restriction.

This determination shall be reported to the Congress, and published in the **Federal Register**.

Dated: March 22, 2010.

Jacob J. Lew,

Deputy Secretary of State for Management and Resources.

[FR Doc. 2010–7222 Filed 3–30–10; 8:45 am]

BILLING CODE 4710–31–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (Formerly Subpart Q) During the Week Ending March 20, 2010

The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (*See* 14 CFR 301.201 *et seq.*). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT–OST–2010–0067.

Date Filed: March 18, 2010.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 8, 2010.

Description: Application of Virgin America Inc. requesting a certificate of public convenience and necessity to engage in foreign scheduled air transportation of persons and mail between the United States and Canada.

Docket Number: DOT–OST–2010–0071.

Date Filed: March 19, 2010.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: April 9, 2010.

Description: Application of White Airways, S.A. ("White") requesting a foreign air carrier permit that will enable White to engage in: (i) Foreign charter air transportation of persons, property and mail from any point or points behind any Member State of the European Union, via any point or points in any Member State and via intermediate points to any point or points in the United States and beyond; (ii) foreign charter air transportation of persons, property and mail between any point or points in the United States and any point or points in any member of the European Common Aviation Area; and (iii) other charters. White also requests renewal of its exemption authority to enable White to engage in the above-described operations pending issuance of its foreign air carrier permit.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2010–7176 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending March 20, 2010

The following Agreements were filed with the Department of Transportation under sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1382 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within 21 days after the filing of the application.

Docket Number: DOT–OST–2010–0064.

Date Filed: March 16, 2010.

Parties: Members of the International Air Transport Association.

Subject: TC31 North & Central Pacific, Special Passenger Amending Resolution

from Korea (Rep. of) to Canada, Caribbean Mexico, Central America, South America (Memo 0509). Intended effective date: 1 April 2010.

Docket Number: DOT–OST–2010–0069.

Date Filed: March 19, 2010.

Parties: Members of the International Air Transport Association.

Subject: TC31 North & Central Pacific, Special Passenger Amending Resolution from Korea (Rep. of) to USA (Memo 0515). Intended effective date: 1 April 2010.

Renee V. Wright,

Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2010–7179 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2010–0037]

Reports, Forms, and Record Keeping Requirements

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes an Information Collection Request (ICR) for which NHTSA intends to seek OMB approval.

DATES: Comments must be submitted on or before June 1, 2010.

ADDRESSES: Direct all written comments to the U.S. Department of Transportation Dockets, 1200 New Jersey Ave., SE., Washington, DC 20590. Docket No. NHTSA–2010–0037.

FOR FURTHER INFORMATION CONTACT: Randolph Atkins, Ph.D., Contracting Officer's Technical Representative, Office of Behavioral Safety Research (NTI–131), National Highway Traffic Safety Administration, 1200 New Jersey Ave., SE., W46–500, Washington, DC 20590. Dr. Atkins' phone number is 202–366–5597 and his e-mail address is *randolph.atkins@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) 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;

(ii) 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;

(iii) How to enhance the quality, utility, and clarity of the information to be collected; and

(iv) How to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Title: Motivations for Speeding.

Type of Request: New information collection request—focus group follow-up with participants from an earlier on-road instrumented vehicle study.

OMB Clearance Number: N/A.

Form Number: This collection of information uses no standard forms.

Requested Expiration Date of Approval: September 3, 2011.

Summary of the Collection of Information: In Phase 1 of this study, the National Highway Traffic Safety Administration (NHTSA) conducted on-road instrumented vehicle data collection in Seattle, WA and College Station, TX with a total of 167 participants to examine driving speed patterns with the goals of understanding motivations for speeding. Based on speeding patterns in the data from the instrumented vehicle phase of this study, NHTSA plans to follow-up with these same subjects in focus groups in Phase 2 of the research to develop a better understanding of speeding and speeders, to develop a more accurate taxonomy of high/low speed driver subgroups and to gain a better understanding of the motives—as well as attitudes and habits—of these subgroups, and explore attitudes and behavioral influences pertinent to various countermeasures (*e.g.,* points reduction courses, speed awareness courses, engineering countermeasures, and automated enforcement) and the acceptance and potential effectiveness of the countermeasures. The focus groups will include: general discussions of speed choices and speeding behaviors and the factors that influence them, discussions of beliefs and attitudes toward speeding, reactions to and discussions about specific driving scenarios, and individual/group responses to various speeding countermeasures. The focus groups are expected to provide data relevant to descriptions of key motivations, attitudes, normative commitment to law, driving habits relevant to speeding and speeding countermeasures; descriptions of countermeasures with the greatest likely benefits; implementation issues and concerns associated with the countermeasures; and key advantages and disadvantages associated with various countermeasures.

Description of the Need for the Information and Proposed Use of the Information—The National Highway Traffic Safety Administration (NHTSA) was established by the Highway Safety Act of l970 (23 U.S.C. 101) to carry out a Congressional mandate to reduce the mounting number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. Speeding is one of the primary factors leading to vehicle crashes. In 2008, 31% of all fatal crashes were speeding-related. The estimated economic cost to society for speeding-related crashes is $40.4 billion per year. Driving at higher speeds reduces the ability of drivers to avoid obstacles or react to sudden changes in the roadway environment and increases crash severity. The pervasiveness of speeding behavior is reflected in a recent national survey that showed that approximately 75% of all drivers reported speeding in the past month. Since most drivers often do not see speeding as risky or dangerous behavior, it is imperative that NHTSA gain a better understanding of the motivations for speeding behaviors in order to develop and refine effective interventions and countermeasures. These focus groups, directly linked to the driving speed patterns of drivers in Phase 1 of the study, will provide important new information on the reasons drivers choose to drive at certain speeds and what

countermeasures would be most effective in reducing their speeding behaviors. In support of its mission, NHTSA will use the findings from these focus group sessions to improve current programs, interventions and countermeasures for speeding on our Nation's highways in order to achieve the greatest benefit in decreasing crashes and resulting injuries and fatalities, and provide informational support to States, localities, and law enforcement agencies that will aid them in their efforts to reduce traffic crashes.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—A subset of the participants who participated in the Phase 1 on-road study will be asked to participate in focus groups. Individual focus group sessions will be based on specific demographic or behavioral characteristics of the Phase 1 participants, with the constraint that the group composition should not be counterproductive to facilitating frank and open discussions of the key topics (*i.e.,* combining young males and females in the same group is not an effective approach). The selection strategy will involve three focus groups at each location, (1) younger male chronic speeders, (2) younger female chronic speeders, and (3) older male and female situational and chronic speeders. These focus groups are expected to take place in the July/August 2010 timeframe. Session participation would be voluntary and compensated with a $75 honorarium.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information—NHTSA will conduct six focus group sessions, three in Seattle, WA and three in College Station TX. Each focus group will consist of 8–12 participants and last approximately 80 minutes. Participants will be recruited by e-mail or telephone based on their driving behaviors in Phase 1 of the study and their demographic characteristics. Therefore, the total estimated annual burden is between 64 and 96 hours, depending on the number of participants (range 8—12) in each group. The respondents would not incur any reporting cost from the information collection. The respondents also would not incur any record keeping burden or record keeping cost from the information collection.

Authority: 44 U.S.C. 3506(c)(2)(A).

Issued on: March 25, 2010.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2010–7130 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA 2010–0005–N–6]

Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration, DOT.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and its implementing regulations, the Federal Railroad Administration (FRA) hereby announces that it is seeking re-approval of the following information collection activities that were previously approved by OMB under Emergency Clearance Procedures. Before submitting these information collection requirements for clearance by the Office of Management and Budget (OMB), FRA is soliciting public comment on specific aspects of the activities identified below.

DATES: Comments must be received no later than June 1, 2010.

ADDRESSES: Submit written comments on any or all of the following proposed activities by mail to either: Mr. Robert Brogan, Office of Safety, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 17, Washington, DC 20590, or Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 35, Washington, DC 20590. Commenters requesting FRA to acknowledge receipt of their respective comments must include a self-addressed stamped postcard stating, "Comments on OMB control number 2130–0587." Alternatively, comments may be transmitted via facsimile to (202) 493–6216 or (202) 493–6497, or via e-mail to Mr. Brogan at *Robert.Brogan@dot.gov*, or to Ms. Toone at *Kimberly.Toone@dot.gov*. Please refer to the assigned OMB control number and the title of the information collection in any correspondence submitted. FRA will summarize comments received in response to this notice in a subsequent notice and include them in its information collection submission to OMB for approval.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Office of Safety, RRS–21, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 17, Washington, DC 20590 (telephone: (202) 493–6292) or Ms. Kimberly Toone, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Ave., SE., Mail Stop 35, Washington, DC 20590 (telephone: (202) 493–6132). (These telephone numbers are not toll-free.)

SUPPLEMENTARY INFORMATION: The Paperwork Reduction Act of 1995 (PRA), Public Law 104–13, section 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 provide 60 days' notice to the public for comment on information collection activities before seeking approval of such activities by OMB. 44 U.S.C. 3506(c)(2)(A); 5 CFR 1320.8(d)(1), 1320.10(e)(1), 1320.12(a). Specifically, FRA invites interested respondents to comment on the following summary of proposed information collection activities regarding (i) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the activities will have practical utility; (ii) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (iii) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (iv) ways for FRA to minimize the burden of information collection activities on the public by automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submission of responses). *See* 44 U.S.C. 3506(c)(2)(A)(I)–(iv); 5 CFR 1320.8(d)(1)(I)–(iv). FRA believes that soliciting public comment will promote its efforts to reduce the administrative and paperwork burdens associated with the collection of information mandated by Federal regulations. In summary, FRA reasons that comments received will advance three objectives: (i) Reduce reporting burdens; (ii) ensure that it organizes information collection requirements in a "user friendly" format to improve the use of such information; and (iii) accurately assess the resources expended to retrieve and produce information requested. *See* 44 U.S.C. 3501.

Below is a brief summary of the information collection activities that FRA will submit for renewed clearance by OMB as required under the PRA:

Title: Notice of Funding Availability and Solicitation of Applications for Grants under the Railroad Safety Technology Grant Program.

OMB Control Number: 2130–0587.

Abstract: The Rail Safety Technology Program is a newly authorized program under the Rail Safety Improvement Act of 2008 (RSIA) (Pub. L. 110–432; October 16, 2008). The program was directed by Congress and passed into law in the aftermath of a series of major rail accidents that culminated in an accident at Chatsworth, California, in 2008. Twenty-five people were killed and 135 people were injured in the Chatsworth accident. This event turned the Nation's attention to rail safety and the possibility that new technologies, such as PTC, could prevent such accidents in the future. The RSIA ordered installation of PTC by all Class I railroads on any of their mainlines carrying poisonous inhalation hazard (PIH) materials and by all passenger and commuter railroads on their main lines not later than December 31, 2015.

As part of the RSIA, Congress provided $50 million to FRA to award, in one or more grants, to eligible projects by passenger and freight rail carriers, railroad suppliers, and State and local Governments. Funds will be awarded to projects that have a public benefit of improved railroad safety and efficiency, with priority given to projects that make PTC technologies interoperable between railroad systems; projects that accelerate the deployment of PTC technology on high-risk corridors, such as those that have high volumes of hazardous material shipments; and for projects over which commuter or passenger trains operate, or that benefit both passenger and freight safety and efficiency.

Funds provided under this grant program may constitute a maximum of 80 percent of the total cost of a selected project, with a minimum of 20 percent of costs funded from other sources. The funding provided under these grants will be made available to grantees on a reimbursement basis. FRA anticipates awarding grants to multiple eligible participants. FRA may choose to award a grant or grants within the available funds in any amount. Funding made available through grants provided under this program, together with funding from other sources that is committed by a grantee as part of a grant agreement, must be sufficient to complete the funded project and achieve the anticipated technology development. FRA will begin accepting grant applications 10 days after publication of the separate Notice of Funds Availability, which will be published on March 29, 2010, in the **Federal Register** detailing the terms of the Railroad Safety Technology Grant Program. Applications may be submitted until July 1, 2010. Selection announcements will be made on or around September 3, 2010.

Form Number(s): FRA F 6180.146; SF–269; SF–270.

Other Instruments: Information Published with the Notice of Funds Availability (NOFA) to be published shortly in the **Federal Register**.

Affected Public: Businesses.

Respondent Universe: 50 railroads.

Frequency of Submission: On occasion.

REPORTING BURDEN

Grant program	Respondent universe	Total annual responses	Average time per response	Total annual burden hours
Pre-Application Process:				
—Certification Statements (Form FRA F 6180.146).	50 Railroads	50 statements/forms	2 minutes	2
—Application Process	50 Railroads	50 grant applications	250 hours	12,500
—Meeting requests with FRA Associate Administrator.	50 Railroads	25 meeting requests	30 minutes	13
—Face to Face Meetings with Associate Admin.	50 Railroads	25 project meetings	2 hours	50
—Revisions to Grant Applications	50 Railroads	10 grant application revisions.	40 hours	400
—Execution Process (Progress Reports).	50 Railroads	120 progress reports	1 hour	120
—Close-Out Procedures:				
—Financial Status Report (SF–269)	50 Railroads	10 forms	30 minutes	5
—Audit (OMB A–133 or 49 CFR 19.26).	50 Railroads	10 audit documents	34 hours	340
—Audit Correction Plan	50 Railorads	1 plan	24 hours	24
—Final Progress Report	50 Railroads	10 reports	3 hours	30
—Final Request for Payment (SF–270).	50 Railroads	10 forms	1 hour	10
—Federal Owner Property Report	50 Railroads	5 reports	3 hours	15
—Final Technical Report	50 Railroads	10 reports	40 hours	400

Total Responses: 336.

Estimated Total Annual Burden 13,909 hours.

Status: Re-Approval under Regular Clearance Procedures

Pursuant to 44 U.S.C. 3507(a) and 5 CFR 1320.5(b), 1320.8(b)(3)(vi), FRA informs all interested parties that it may not conduct or sponsor, and a respondent is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC on March 26, 2010.

Donna Alwine,

Acting Director, Office of Financial Management, Federal Railroad Administration.

[FR Doc. 2010–7201 Filed 3–30–10; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Urbanized Area Formula Program: Notice of Final Circular

AGENCY: Federal Transit Administration (FTA), DOT.

ACTION: Notice of Availability of Final Circular.

SUMMARY: The Federal Transit Administration (FTA) is issuing Circular 9030.1D to provide comprehensive assistance to grantees in implementing the Urbanized Area Formula Program (Section 5307) for capital, planning, and some operating grants in urbanized areas.

DATES: The effective date of this circular is May 1, 2010.

ADDRESSES: A copy of the circular and comments and material received from the public, as well as any documents indicated in the preamble as being available in the docket, are part of docket FTA–2009–0010 and are available for inspection or copying at the Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave., SE., West Building Ground Floor, Room W12–140, Washington, DC between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

You may also review the circular, comments, and supporting documents online through the Federal Document Management System (FDMS) at Web site: *http://regulations.gov.* Enter the docket number FTA–2009–0010 in the search field. The FDMS is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

This notice does not include the final circular. Electronic versions of the final circular will be posted on *http:/regulations.gov* as well as on the FTA Web site *http://www.fta.dot.gov.* Paper copies of the final circular may be obtained by contacting FTA's Administrative Services Help Desk, at 202–366–4865.

FOR FURTHER INFORMATION CONTACT: Henrika Buchanan-Smith, Office of Program Management, Federal Transit Administration, 1200 New Jersey Ave., SE., East Building, Fourth Floor, Washington, DC 20590, phone: (202) 366–5080, fax: (202) 366–7951, or e-mail, *Henrika.Buchanan-Smith@dot.gov;* or Richard Wong, Office of Chief Counsel, Federal Transit Administration, 1200 New Jersey Ave., SE., East Building, Fifth Floor, Washington, DC 20590, phone: (202) 366–0675, fax: (202) 366–3809, or e-mail, *Richard.Wong@dot.gov.*

SUPPLEMENTARY INFORMATION:

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I. Overview

This notice provides a summary of changes to FTA Circular 9030.1C, Urbanized Area Formula Program: Program Guidance and Grant Application Instructions and addresses comments received in response to FTA's September 30, 2009 **Federal Register** publication announcing the availability of the proposed circular (74 FR 50273). The final Circular 9030.1D supersedes FTA Circular 9030.1C. Readers familiar with the former FTA Circular 9030.1C will notice that FTA is proposing a complete reorganization to make this circular consistent with the style of other circulars FTA has updated. Substantive changes in content are discussed in the chapter-by-chapter analysis.

Seven commenters responded to the notice of availability, including a public transportation trade association, a vanpool operator, two large metropolitan transit agencies, a member of the public, and one who wished to remain anonymous.

One commenter asked that FTA extend the comment period for an additional 45 to 60 days. FTA declined this request, as FTA specified in the Notice of Availability that "[l]ate-filed comments will be considered to the extent practicable," and FTA has considered all comments received after the November 20, 2009, deadline. Several commenters asked that FTA withhold publication of the circular until new surface transportation reauthorization legislation had been enacted. FTA believes that such an approach is not feasible, given uncertainty concerning the reauthorization process and the need to implement changes mandated by the 2005 reauthorization bill.

One commenter objected to the language in section 6 of the title page where FTA reserved the right to update the circular to reflect changes in revised or new guidance or regulation. FTA disagrees with this objection, noting that FTA is already obligated to include an opportunity for notice and comment when revising a circular or regulation, and there is no need to duplicate that effort when updating each circular affected by that revision.

A. Chapter I—Introduction and Background

Chapter I of the revised circular is the introductory chapter containing general information about FTA, including contact information. It briefly addresses the current authorizing legislation for the Urbanized Area Formula program (a.k.a. "Section 5307 program"), provides information about Grants.gov, includes definitions applicable to the program and provides a brief program history. A "Definitions" section has been added to this circular, defining common terms used in the Section 5307 program.

Chapter I contains a number of topics that have been reorganized in the new circular. The former section "Other Funds Available for Transit Projects" is now renamed "Relationship to Other Programs" to be consistent with other FTA circulars, and moved to Chapter II. We have also moved the section titled "Flexible Funds" to the "Relationship to Other Programs" section in Chapter II, and transferred information on apportionments and local and Federal share to Chapter III. In addition, we have incorporated the information in the section titled "Grant Application Process" into other sections of the revised circular.

Several commenters suggested that the term "direct recipient" be deleted in favor of the term "designated recipient." FTA declines to adopt that change, as the two terms are not identical. A "designated recipient" is an entity officially designated by the Governor through the planning process to receive and apportion funds. A direct recipient, in contrast, is any entity that receives funds directly from FTA. In some cases, the designated recipient may also be a direct recipient, although a direct recipient may not necessarily be the designated recipient.

One commenter suggested that content be added to address the National Transit Database (NTD) and the Uniform System of Accounts (USOA). FTA has accepted and incorporated those changes in Chapter I, under the section titled "Definitions." Another suggested that administrative costs be defined and addressed in the Circular, which FTA has done in Chapter III, section 6, "Eligible Capital Projects." One commenter asked FTA to address force account plans, which FTA has done in Appendix E, "Preventive Maintenance."

B. Chapter II—Program Overview

Chapter II of the former circular, "Applicant Eligibility" has been augmented to contain additional detail about the Urbanized Area Formula program. Chapter II addresses the statutory authority for the Urbanized Area Formula program, followed by the goals of the program, recipient designation, the respective roles of the

designated recipient and FTA, a discussion about transportation management areas, FTA oversight, and the relationship of the Urbanized Area Formula Program to other FTA programs. This format conforms to Chapter II in the other circulars FTA has recently updated. In discussions regarding Transportation Management Areas in Chapter II and Apportionments in Chapter III, to conform to revisions of the joint planning regulation issued in February 2007, we deleted references to the expanded planning areas of a Transportation Management Area when referring to the Governor authority to reallocate funds apportioned to the Governor for urbanized areas under 200,000 in population. The Governor's authority is restricted only in the case of small urbanized areas officially designated as Transportation Management Areas.

One commenter, a large metropolitan transportation agency, objected to FTA's attempt to meet GPRA (Government Performance and Results Act) requirements by setting performance targets, using program measures to determine grant funding levels, or using those measures in a punitive manner. The commenter suggested that FTA provide additional clarification in the final circular as to the measurement of fleet condition and specifically recommends that FTA require recipients to report "average fleet age" information. FTA acknowledges the commenter's concerns, but ridership and condition data are long-standing national data measures and submitted to the National Transit Database on a regular basis. With regard to their use as determinants, formulas such as the fixed guideway tier of the 5307 formula are determined by Congress and implemented by FTA. Finally, FTA believes that comprehensive fleet age and condition statistics are necessary for FTA to estimate fleet condition on a national level with a reasonable degree of accuracy.

C. Chapter III—General Program Information

Chapter III continues to address eligible capital, operating and planning activities, as well as advance capital project authority, reflecting changes made by Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for users (SAFETEA–LU). Transportation development credits (formerly referred to as toll revenue credits) have been added to Chapter III to provide a calculation method that is consistent with the method used by the Federal Highway Administration (FHWA). FTA has moved and supplemented information about "Preventive Maintenance" into a new Appendix E due to the length and complexity of the topic. FTA has moved pre-award authority and letters of no prejudice to Chapter IV. Additional information addressed in Chapter III includes apportionments, funds availability, and local and Federal share. All of these sections have been updated to be consistent with the law and with the format of other recently revised FTA circulars.

One commenter asked FTA to support a definition of Mobility Management that included employer-oriented Transportation Management Organizations. FTA has included language in Chapter III, section 6f(5) to implement this request. The same commenter asked that FTA revise Chapter III to address eligibility that takes into account emissions benefits for purposes of compliance with the Clean Air Act. Emissions benefits, while a factor under the Congestion Management and Air Quality (CMAQ) program, are not statutory factors for consideration under the section 5307 program. Finally the same commenter asked that the circular include stronger provisions to include private providers and operators in the local planning and programming process. FTA does not get involved in the details of the local public participation process, and instead defers to the local Metropolitan Planning Organizations (MPOs) to determine their locally-developed processes and procedures.

D. Chapter IV—Program Development

The sections of former Chapter IV, "Apportionments," describing how funds are apportioned under the urbanized area formula program and apportionments are transferred to other eligible programs, are now in the first sections of Chapter III. FTA has added a new Chapter IV, "Program Development," to address the role of the designated recipient and the metropolitan planning organization (MPO), applicants other than designated recipients; pass-through arrangements (formerly found in Chapter II); subarea allocation and transfer of funds for highway projects (formerly found in Chapter IV); planning requirements (formerly in Appendix A); program of projects and public participation requirements; certifications and assurances (formerly found in Chapter V); undertaking projects in advance; a catch-all section for pre-award authority; and letters of no prejudice (formerly found in Chapter III).

FTA has revised each of these sections to reflect changes in statutes, regulations, and FTA policy. We are also streamlining some sections, such as planning, while expanding others, such as certifications and assurances, to provide more detailed guidance to our recipients.

One commenter noted that the draft circular did not account for the various roles of designated recipients vis-à-vis Metropolitan Planning Organizations (MPO) throughout the country. Given the wide variation of these roles among the various urbanized areas (UZA), the commenter stated that the circular must be flexible. The commenter perceived that Chapter IV of the draft assumes a Metropolitan Planning Organization (MPO) is the sole designated recipient for the UZA. This structure is impractical in some communities where the Metropolitan Planning Organization (MPO) is not staffed sufficiently to undertake the duties of a designated recipient or others where the independence of local governments is more pronounced and, as a result, a single Metropolitan Planning Organization (MPO) function is primarily to coordinate the activities of multiple designated recipients. FTA agrees with this commenter and has revised Chapter IV accordingly to clarify the relationship between Metropolitan Planning Organization (MPO), Designated Recipient and other recipients. Chapter IV has also been revised to clarify that the Metropolitan Planning Organization (MPO) and the designated recipient can be two separate entities.

Another commenter, a large metropolitan transportation agency operating across state boundaries, asked that the circular specifically address transit agencies that must work with multi-state Metropolitan Planning Organization (MPO)s, acknowledging them as designated recipients. Consistent with statute, however, designated recipients are determined by local officials, not FTA, and FTA believes language in a circular would have no effect on that process.

One commenter asked why "toll revenue credits" had been renamed "transportation development credits" in the revised circular. FTA is making this change to reflect statutory changes in the 2005 reauthorization law.

Several commenters suggested that the planning justification be removed from the Transportation Electronic Award Management (TEAM) system as redundant, because by virtue of their inclusion in a Statewide Transportation Improvement Plan (STIP), they already have been through the Metropolitan Planning Organization (MPO) planning process. FTA does not agree with this

suggestion, as Transportation Electronic Award and Management (TEAM) is the official administrative record for FTA-funded projects and the data must be included with the Transportation Electronic Award and Management (TEAM) file. The justification to be included with the application is more project-specific.

Finally, one commenter suggested that the discussion of joint development address private investment and provide additional guidance on how retail space can qualify as incidental space. FTA believes that FTA's publication "Final Agency Guidance on the Eligibility of Joint Development Improvements Under Federal Transit Law" (72 FR 5788, Feb. 7, 2007) provides adequate direction, but interested parties may contact FTA's headquarters or regional offices for specific questions not addressed by the Final Agency Guidance document.

E. Chapter V—Coordinated Planning

The revised Chapter V addresses the coordinated planning process required under the Section 5310, Elderly Individuals and Individuals with Disabilities formula program; the Section 5316, Job Access and Reverse Commute (JARC) program; and the Section 5317, New Freedom program. Often the designated recipient for the Urbanized Area Formula program will also be the designated recipient for one or more of these human services transportation programs. The revised Chapter V contains substantially the same information as that found in FTA Circular 9040.1F, Nonurbanized Area Formula Program Guidance and Grant Application Instructions.

The information found in the former Chapter V, "Requirements Associated with Urbanized Area Formula Program Grants" has been reorganized into other chapters. For example, the section, "National Transit Database Reporting System" has been updated and moved to the new Chapter VI. We are also providing a link to the FTA Web site as well as to the TEAM system, where applicants can find the instructions. FTA has moved the section titled "Certification Procedures" to the rewritten Chapter IV. The section titled "FTA Oversight" has been updated and moved to the new Chapter II. The section titled "Certifications Particular to the Urbanized Area Formula Program" has been renamed "Certifications Required by 49 U.S.C. 5307" and moved to Chapter IV. Updated information on program of projects and public participation requirements have also been moved to Chapter IV. Finally, FTA is eliminating the "Alphabetical List of Other Requirements" as the content of that section is already addressed in other chapters. Updated information related to "Associated Capital Maintenance Items," "New Technology Introduction" and "Lease vs. Buy Considerations" can be found in Chapter III under "Capital Projects;" updated information on "Buses," "Bus Facilities," and "Fixed Guideway Rolling Stock," has been consolidated into Chapter IV's section titled, "Requirements Related to Rolling Stock and Equipment." The section on "New Starts" has been removed because information on the relationship between the New Starts program and the Urbanized Area Formula program is already addressed in Chapter II. Other provisions in the former Chapter V can be found in the revised Chapter VII, "Other Provisions."

F. Chapter VI—Program Management and Administrative Requirements

The content of the former Chapter VI, "Application Instructions," has been updated, streamlined, and moved to Appendix A. The revised Chapter VI contains information on the TEAM system, Electronic Clearing House Operation (ECHO) system, and, as previously discussed, information on the National Transit Database, requirements related to vehicles and equipment, and requirements related to facilities. The information in this chapter is consistent with that found in other recently updated FTA circulars.

Several commenters stated that the estimation of useful service life in Chapter VI, section 5, for facilities was impractical, given variations in climate, geography, and usage. They claimed that such an exercise would result in additional investments of time and costs on transit agencies and FTA alike with no practical benefit. FTA does not agree with these commenters—by establishing a standard useful life for facilities, FTA can ensure consistency across projects and regions.

G. Chapter VII—Other Provisions

Chapter VII of the former circular contained instructions for preparing a project budget. This information has been updated and moved to Appendix B, consistent with other recently revised FTA circulars. The revised Chapter VII conforms to the "Other Provisions" chapters in other FTA circulars, and addresses common Federal requirements that FTA grantees are held to in addition to the program-specific requirements. As previously stated, some of the information has been relocated from the former Chapter V's "Alphabetical Listing of Other Requirements." Other sections, such as the Presidential Coin Act, are new to this circular. Recipients should use this chapter, in conjunction with FTA's Master Agreement and the current fiscal year Certifications and Assurances to assure that they have met all requirements. Recipients may contact FTA HQ or Regional Counsel if they have additional questions concerning these requirements.

Once commenter asked FTA to include explicit language excluding vanpool drivers from FTA's drug and alcohol testing requirements. Consistent with prior legal opinions from FTA's Chief Counsel, FTA has included specific language in Chapter VII, section 7 of the revised circular.

H. Appendices

The appendices are intended as tools for developing a grant application. Appendix A specifically addresses steps and instructions for preparing a grant application, including pre-application and application stages. This information is comparable to Chapter VI, "Application Instructions," in the former circular, although it has been updated and reorganized. Appendix A also includes an application checklist. Appendix B provides budgetary information, including a sample budget, replacing the information formerly found in Chapter VII, "Instructions for Preparing a Project Budget." Appendix C consists of the content of the former Appendix D, "Operating Assistance Projects." Appendix D contains the content of the former Appendix F, "Forms and Representative Documents," with the exception of documents we have removed that are now readily available online. Appendix E contains a description of the preventive maintenance program, and is new to this circular. Appendix F contains updated contact information for FTA's regional and metropolitan offices, which was previously contained in Chapter VIII of the former circular.

Several commenters opined that the "Engineering Review" required in the revised Appendix A would unnecessarily add time and costs without likely improvement of project management. One commenter claimed that this proposal raises the bar for new projects and will increase the cost of project development, grant management, and FTA oversight. Another commenter added that state of good repair projects and routine replacement investments should not be subjected to more extensive oversight. FTA responds that this is not a new requirement, but rather, is currently required under Chapter VI, section 9c, of the outgoing FTA Circular 9030.1C,

and remains an effective management tool. The commenter perhaps misunderstood that the "Engineering Review" was performed by FTA in reviewing the grant application and that the grantee simply had to provide sufficient information in the grant application about the proposed project for FTA to review. In the final circular the review has been renamed "Engineering/Technical" review to clarify the nature of the review is relative to the complexity of the project.

Issued in Washington, DC, this 23rd day of March 2010.

Peter Rogoff,

FTA Administrator.

[FR Doc. 2010–7083 Filed 3–30–10; 8:45 am]

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Federal Register

Wednesday,
March 31, 2010

Part II

Department of Justice

Drug Enforcement Administration

21 CFR Parts 1300, 1304, 1306, and 1311
Electronic Prescriptions for Controlled Substances; Final Rule

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1304, 1306, and 1311

[Docket No. DEA–218I]

RIN 1117–AA61

Electronic Prescriptions for Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Interim Final Rule with Request for Comment.

SUMMARY: The Drug Enforcement Administration (DEA) is revising its regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations will also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are in addition to, not a replacement of, the existing rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances dispensing; additionally, the regulations will reduce paperwork for DEA registrants who dispense controlled substances and have the potential to reduce prescription forgery. The regulations will also have the potential to reduce the number of prescription errors caused by illegible handwriting and misunderstood oral prescriptions. Moreover, they will help both pharmacies and hospitals to integrate prescription records into other medical records more directly, which may increase efficiency, and potentially reduce the amount of time patients spend waiting to have their prescriptions filled.

DATES: This rule has been classified as a major rule subject to Congressional review. The effective date is June 1, 2010. However, at the conclusion of the Congressional review, if the effective date has been changed, the Drug Enforcement Administration will publish a document in the **Federal Register** to establish the actual effective date or to terminate the rule.

The incorporation by reference of certain publications listed in the rule is approved by the Director of the Federal Register as of June 1, 2010.

Written comments must be postmarked and electronic comments must be submitted on or before June 1, 2010. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after Midnight Eastern Time on the last day of the comment period.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA–218" on all written and electronic correspondence. Written comments sent via regular or express mail should be sent to the Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 8701 Morrissette Drive, Springfield, VA 22152. Comments may be sent to DEA 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.

Please note that DEA is requesting that electronic comments be submitted before midnight Eastern Time on the day the comment period closes because *http://www.regulations.gov* terminates the public's ability to submit comments at midnight Eastern Time on the day the comment period closes. Commenters in time zones other than Eastern Time may want to consider this so that their electronic comments are received. All comments sent via regular or express mail will be considered timely if postmarked on the day the comment period closes.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Comments: DEA is seeking additional comments on the following issues: Identity proofing, access control, authentication, biometric subsystems and testing of those subsystems, internal audit trails for electronic prescription applications, and third-party auditors and certification organizations.

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. Please note that the Freedom of Information Act applies to all comments received. If you wish to inspect the agency's public docket file in person by appointment, please see the **FOR FURTHER INFORMATION** paragraph.

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I. 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 an adequate 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.

Controlled Substances

Controlled substances are drugs and other substances that have a potential for abuse and psychological and physical dependence; these include opioids, stimulants, depressants, hallucinogens, anabolic steroids, and drugs that are immediate precursors of these classes of substances. DEA lists controlled substances in 21 CFR part 1308. The substances are divided into five schedules: Schedule I substances have a high potential for abuse and have no currently accepted medical use in treatment in the United States. These substances may only be used for research, chemical analysis, or manufacture of other drugs. Schedule II–V substances have currently accepted medical uses in the United States, but also have potential for abuse and psychological and physical dependence that necessitate control of the substances under the CSA. The vast majority of Schedule II, III, IV, and V controlled substances are available only pursuant to a prescription issued by a practitioner licensed by the State and registered with DEA to dispense the substances. Overall, controlled substances constitute between 10 percent and 11 percent of all prescriptions written in the United States.

II. Regulatory History

The Controlled Substances Act and Current Regulations. The CSA and DEA's regulations were originally adopted at a time when most transactions and particularly prescriptions were done on paper.

The CSA provides that a controlled substance in Schedule II may only be dispensed by a pharmacy pursuant to a "written prescription," except in emergency situations (21 U.S.C. 829(a)). In contrast, for controlled substances in Schedules III and IV, the CSA provides that a pharmacy may dispense pursuant to a "written or oral prescription." (21 U.S.C. 829(b)). Where an oral prescription is permitted by the CSA, the DEA regulations further provide that a practitioner may transmit to the pharmacy a facsimile of a written, manually signed prescription in lieu of an oral prescription (21 CFR 1306.21(a)).

Under longstanding Federal law, for a prescription for a controlled substance to be valid, it must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice (*United States* v. *Moore, 423 U.S. 122 (1975);* 21 CFR 1306.04(a)). As the DEA regulations state: "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." (21 CFR 1306.04(a)).

The Controlled Substances Act is unique among criminal laws in that it stipulates acts pertaining to controlled substances that are permissible. That is, if the CSA does not explicitly permit an action pertaining to a controlled substance, then by its lack of explicit permissibility the act is prohibited. Violations of the Act can be civil or criminal in nature, which may result in administrative, civil, or criminal proceedings. Remedies under the Act can range from modification or revocation of DEA registration, to civil monetary penalties or imprisonment, depending on the nature, scope, and extent of the violation.

Specifically, it is unlawful for any person knowingly or intentionally to manufacture, distribute, or dispense, a controlled substance or to possess a controlled substance with the intent of manufacturing, distributing, or dispensing that controlled substance, except as authorized by the Controlled Substances Act (21 U.S.C. 841(a)(1)).

Further, it is unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, issued for a legitimate medical purpose, from a practitioner, while acting in the course of the practitioner's professional practice, or except as otherwise authorized by the CSA (21 U.S.C. 844(a)). It is unlawful for any person to knowingly or intentionally acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge (21 U.S.C. 843(a)(3)).

It is unlawful for any person knowingly or intentionally to use a DEA registration number that is fictitious, revoked, suspended, expired, or issued to another person in the course of dispensing a controlled substance, or for the purpose of acquiring or obtaining a controlled substance (21 U.S.C. 843(a)(2)).

Beyond these possession and dispensing requirements, it is unlawful for any person to refuse or negligently fail to make, keep, or furnish any record (including any record of dispensing) that is required by the CSA (21 U.S.C. 842(a)(5)). It is also unlawful to furnish any false or fraudulent material information in, or omit any information from, any record required to be made or kept (21 U.S.C. 843(a)(4)(A)).

Within the CSA's system of controls, it is the individual practitioner (*e.g.,* physician, dentist, veterinarian, nurse practitioner) who issues the prescription authorizing the dispensing of the controlled substance. This prescription

must be issued for a legitimate medical purpose and must be issued in the usual course of professional practice. The individual practitioner is responsible for ensuring that the prescription conforms to all legal requirements. The pharmacist, acting under the authority of the DEA-registered pharmacy, has a corresponding responsibility to ensure that the prescription is valid and meets all legal requirements. The DEA-registered pharmacy does not order the dispensing. Rather, the pharmacy, and the dispensing pharmacist merely rely on the prescription as written by the DEA-registered individual practitioner to conduct the dispensing.

Thus, a prescription is much more than the mere method of transmitting dispensing information from a practitioner to a pharmacy. The prescription serves both as a record of the practitioner's determination of the legitimate medical need for the drug to be dispensed, and as a record of the dispensing, providing the pharmacy with the legal justification and authority to dispense the medication prescribed by the practitioner. The prescription also provides a record of the actual dispensing of the controlled substance to the ultimate user (the patient) and, therefore, is critical to documenting that controlled substances held by a pharmacy have been dispensed legally. The maintenance by pharmacies of complete and accurate prescription records is an essential part of the overall CSA regulatory scheme established by Congress.

American Recovery and Reinvestment Act. On February 17, 2009, the President signed the American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 111–5, 123 STAT. 115). Among its many provisions, the Recovery Act promotes the "meaningful use" of electronic health records (EHRs) via incentives. The health information technology provisions of the Recovery Act are primarily found in Title XIII, Division A, Health Information Technology, and in Title IV of Division B, Medicare and Medicaid Health Information Technology. These titles together are cited as the Health Information Technology for Economic and Clinical Health Act or the HITECH Act. Under Title IV, the Medicare and Medicaid health information technology provisions in the Recovery Act provide incentives and support for the adoption of certified electronic health record technology. The Recovery Act authorizes incentive payments for eligible professionals and eligible hospitals participating in Medicare or Medicaid if they can demonstrate to the Secretary of HHS that they are "meaningful EHR users" as defined by the Act and its implementing regulations. Such incentive payments to encourage electronic prescribing are allowed, but penalties in any form, by third party payers are prohibited. These incentive payments will begin in 2011.

On January 13, 2010, HHS published two rules to implement the provisions of the HITECH ACT. The Centers for Medicare and Medicaid Services published a notice of proposed rulemaking entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program" (75 FR 1844) [CMS–0033–P, RIN 0938–AP78]. The proposed rule would specify the initial criteria an eligible professional and eligible hospital must meet to qualify for the incentive payment; calculation of the incentive payment amounts; and other payment and program participation issues.

The Office of the National Coordinator for Health Information Technology published an interim final rule entitled "Health Information Technology; Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology" (75 FR 2014) [RIN 0991–AB58]. The interim final rule became effective February 12, 2010. The certification criteria adopted in the interim final rule establish the capabilities and related standards that certified electronic health record technology will need to include in order to, at a minimum, support the achievement of the proposed meaningful use Stage 1 (beginning in 2011) by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR incentive programs. The comment period for both rules ended March 15, 2010.

The Office of the National Coordinator for Health Information Technology also published a notice of proposed rulemaking entitled "Proposed Establishment of Certification Programs for Health Information Technology" (75 FR 11328, March 10, 2010) (RIN 0991–AB59) which proposes the establishment of certification programs for purposes of testing and certifying health information technology. The proposed rule specifies the processes the National Coordinator for Health Information Technology would follow to authorize organizations to perform the certification of health information technology.

Electronic Prescription Applications. Electronic prescription applications [1] and electronic health record (EHR) applications have been available for a number of years and are anticipated by many to improve healthcare and possibly reduce costs by increasing compliance with formularies and the use of generic medications. Electronic prescriptions may reduce medical errors caused by illegible handwriting. Adoption of these applications has been relatively slow, primarily because of their cost, the disruption caused during implementation, and lack of mature standards that allow for interoperability among applications.[2] Some have also expressed a concern about the inability to use electronic prescription applications for all prescriptions.

Electronic prescription applications may be stand-alone applications (*i.e.,* applications that only create prescriptions) or they may be integrated into EHR applications that create and link all medical records and associated information.[3] Either type of application may be installed on a practitioner's computers (installed applications) or may be an Internet-based application, where the practitioner accesses the application through the Internet; for these latter applications, the application service provider (ASP) retains the records on its servers. For most practitioners and pharmacies, the applications are purchased from application providers. Some large healthcare systems and chain pharmacies, however, may develop and maintain the applications themselves, serving as both the practitioner or pharmacy and the application provider.

The existing electronic prescription applications allow practitioners to create a prescription electronically, but accommodate different means of transmitting the prescription to the pharmacy. Practitioners may print the prescription for manual signature; the prescription may then be given to the patient or the practitioner's office may fax it to a pharmacy. Some applications will automatically transmit an image of the prescription as a facsimile. True

[1] "Application" means a software program used to perform a set of functions.

[2] California Healthcare Foundation. "Gauging the Progress of the National Health IT Technology Initiative", January 2008; Congressional Budget Office, Evidence on the Costs and Benefits of Health IT, May 2008.

[3] The National Alliance for Health Information Technology has defined the terms "electronic Medical record (EMR)," "electronic health record (EHR)," and "personal health record (PHR." Both EMRs and EHRs are defined to be maintained by practitioners, whereas a PHR is defined to be maintained by the individual patient. The main distinction between an EMR and an EHR is the EHR's ability to exchange information interoperably. DEA's use of the term EHR in this rule relates to those records maintained by practitioners, as opposed to a PHR maintained by an individual patient, regardless of how those records are maintained.

electronic prescriptions, however, are transmitted as electronic data files to the pharmacy, whose applications import the data file into its database. Virtually all pharmacies maintain prescription records electronically; prescriptions that are not received as electronic data files are manually entered into the pharmacy application.

Because of the large number of electronic prescription and pharmacy applications and the current lack of a mature standard for the formatting of prescription data, most electronic prescriptions are routed from the electronic prescription or EHR application through intermediaries, at least one of which determines whether the prescription file needs to be converted from one software version to another so that the receiving pharmacy application can correctly import the data. There are generally three to five intermediaries that route prescriptions between practitioners and pharmacies. For example, a prescription may be routed to the application provider, then to a hub that converts the prescription from one software version to another to meet the requirements of the receiving pharmacy, then to the pharmacy application provider or chain pharmacy server before reaching the dispensing pharmacy. Some application providers further route prescriptions through aggregators who direct the prescription to a hub or to a pharmacy. For closed healthcare systems, where the practitioners and pharmacies are part of the same system, intermediaries are not needed.

Standards. Any electronic data transfer depends on the ability of the receiving application to open and read the information accurately. To be able to do this, the fields and transactions need to be defined and tagged so that the receiving application knows, for example, that a particular set of characters is a date and that other sets are names, etc. The National Council for Prescription Drug Programs (NCPDP) has developed a standard for prescriptions, called SCRIPT, which is generally used by application providers; hospital-based applications may also use Health Level 7 (HL7) standards. SCRIPT is a data transmission standard "intended to facilitate the communication of prescription information between prescribers, pharmacies, and payers."[4] It defines transactions (*e.g.,* new prescription, refill request, prescription change, cancellation,), segments (*e.g.,* provider, patient), and data fields within segments (*e.g.,* name, date, quantity). Each data field has a number and a defined format (*e.g.,* DEA number is nine characters). The standardization allows the receiving pharmacy to identify and separate the data it receives and import the information into the correct fields in the pharmacy database. SCRIPT does not address other aspects of prescription or pharmacy applications (*e.g.,* what information is displayed and stored at a practice or pharmacy, logical access controls, audit trails). SCRIPT provides for, but does not mandate the use of, some fields (*e.g.,* practitioner first name and patient address) that DEA requires. In addition, although the standard mandates that applications include certain fields, it does not require that those fields be completed before transmission is allowed. The SCRIPT standard is still evolving; the most recent is Version 10 Release 6. The interoperability issues that require intermediaries generally relate to pharmacy and practitioner applications using different versions of the standard as well as varying approaches to providing opening and reading instructions.

One intermediary, SureScripts/RxHub, certifies electronic prescription and pharmacy applications for compliance with the SCRIPT standard; SureScripts/RxHub determines whether the electronic prescription application creates a prescription that conforms to the SCRIPT standard and whether the pharmacy application is able to open and read a SCRIPT prescription correctly.[5] SureScripts/RxHub certification does not address aspects of applications unrelated to their ability to produce or read a prescription in appropriate SCRIPT format.

The Certification Commission for Healthcare Information Technology (CCHIT) is a private, nonprofit organization recognized by the Secretary of HHS as a certification body for EHRs under the exception to the physician self-referral prohibition and safe harbor under the anti-kickback statute, respectively, for certain arrangements involving the donation of interoperable EHR software to physicians and other health care practitioners or entities (71 FR 45140 and 71 FR 45110, respectively, August 8, 2006). CCHIT develops criteria for electronic medical records (EMRs or EHRs) and certifies applications against these criteria. Although electronic prescribing is addressed in the CCHIT ambulatory certification criteria, these criteria do not address all elements with which DEA has concern, such as the particular information required in a prescription. The CCHIT criteria do address security issues, such as access control and audit logs. CCHIT is developing standards for stand-alone electronic prescription applications. DEA has not been able to identify any organization that sets standards for or certifies pharmacy applications for security issues or even for the ability to record and retain information such as dispensing data.

Proposed Rule. On June 27, 2008, DEA published a Notice of Proposed Rulemaking (NPRM) to revise its regulations to allow the creation, signature, transmission, and processing of controlled substance prescriptions electronically (73 FR 36722). The proposed rule followed consultations with the industry and the Department of Health and Human Services, which is responsible for establishing transmission standards for electronic prescriptions and security standards for health information. The proposed rule provided two approaches, one for the private sector and one for Federal healthcare providers. The private sector approach included identity proofing of individual practitioners authorized to sign controlled substances prescriptions prior to granting access to sign such prescriptions, two-factor authentication including a hard token separate from the computer for accessing the signing functions, requirements for the content and review of prescriptions, limited transmission provisions, requirements of pharmacy applications processing controlled substances prescriptions for dispensing, third party audits of the application providers, and internal audit functions for electronic prescription application providers and pharmacy applications. The Federal healthcare providers told DEA that the approach proposed for the private sector was inconsistent with their existing practices and did not meet the security requirements imposed on all Federal systems. The approach proposed for Federal healthcare systems was based, therefore, on the existing Federal systems, which rely on public key infrastructure (PKI) and digital certificates to address basic security issues related to non-repudiation, authentication, and record integrity.

DEA's Concerns. DEA's proposed rule was a response to existing and potential problems that exist when prescriptions are created electronically. It is essential that the rules governing the electronic prescribing of controlled substances do not inadvertently facilitate diversion and abuse and undermine the ability of

[4] National Council for Prescription Drug Programs, Prescriber/Pharmacist Interface SCRIPT Standard Implementation Guide Version 10.0, October 2006.

[5] *http://www.surescripts.com/certification.html,* accessed April 29, 2009.

DEA, State, and local law enforcement to identify and prosecute those who engage in diversion. In this vein, DEA's primary goals were to ensure that nonregistrants did not gain access to electronic prescription applications and generate or alter prescriptions for controlled substances and to ensure that a prescription record, once created, could not be repudiated. In the case of at least some existing electronic prescription application service providers, individuals are allowed to enroll online. ASPs may ask for DEA registration and State authorization numbers, although they are not required to do so; the degree to which these are verified is at the discretion of the application provider. Similarly, application providers that sell installed applications may or may not determine whether the practitioners have valid State and DEA authorizations. Where a medical practice purchases an application or service, providers may or may not obtain this information for all practitioners in the practice.

Most of the applications appear to rely on passwords to identify a user of the application. Passwords are often described as the weakest link in security because they are easily guessed or, in healthcare settings, where multiple people use the same computers, easily observed. Where longer, more complex passwords are required by applications as a means to increase their effectiveness, this can actually be counterproductive, as it often causes users to write down their passwords, which weakens overall security.[6] There are, in general, very limited standards for security of electronic prescription applications and no assurance that even where security capabilities exist, that they are used. For example, applications may be able to set access controls to limit who may sign a prescription, but unless those controls are set properly, anyone in a practice might be able to sign a prescription in a practitioner's name. The Certification Commission for Healthcare Information Technology (CCHIT) requires that an application have logical access controls and audit trails to gain certification, but there is no requirement that these functions be used. More than half the electronic prescription application providers certified with SureScripts/RxHub (for transmission) are not certified with CCHIT.

Even if there are logical access controls, they may not limit who can perform functions such as approving a prescription or signing it. At medical practices and even more so at hospitals and clinics, many staff members may use the same computers. The person who logged onto the application may not be the person entering prescription information later or the person who transmits the prescription. Some applications have internal audit trail functions, but whether these are active and reviewed is at the practitioner's discretion. In addition, with multiple people using computers, it is unclear that the audit trail can accurately identify who is performing actions. Except for those Federal electronic prescription applications that require practitioners to digitally sign prescriptions, none of the applications transmit any indication that a prescription was actually signed.

With multiple intermediaries moving prescriptions between practitioners and pharmacies, there is no assurance that a prescription may not be altered or added during transmission. Some intermediaries have good security, but there is no requirement for them to do so and practitioners and pharmacies have no control over which intermediaries are used. The pharmacy has no way to verify that the prescription was sent by the practitioner whose name is on the prescription or that if it was, that it was not altered after the practitioner issued it. The evidence of forgery and alteration that pharmacies use to identify illegitimate paper prescriptions do not exist in an electronic record—not only because electronic prescriptions contain no handwritten signatures, but also because electronic prescriptions are typically created from drop-down menus, which prevent or reduce the likelihood of misspelled drug names, inappropriate dosage forms and units, and other indicators of possible forgery.

The existing processes used for electronic prescriptions for noncontrolled substances, therefore, make it easy for every party to repudiate the prescription. A practitioner can claim that someone outside the practice issued a prescription in his name, that someone else in the practice used his password to issue a prescription, or that it was altered after he issued it either in transmission or at the pharmacy. Proving or disproving any of these claims would be very difficult with the existing processes. DEA and other law enforcement agencies might not be able to prove a case against someone issuing illegitimate prescriptions; equally important, practitioners might have trouble proving that they were not responsible for illegitimate prescriptions issued in their name.

Because regulations do not currently exist permitting the use of electronic prescriptions for controlled substances, there is naturally no evidence of diversion related to electronic prescriptions of these substances. That there is no evidence that other noncontrolled prescription drugs have been diverted through electronic prescriptions is not relevant for several reasons. First, there is a very limited, if any, black market for other prescription medications. Second, there is no reason for law enforcement to investigate diversion of these medications, if it occurs, because such diversion may not be illegal (this would depend on State law). Finally, the number of electronic prescriptions, including refill requests, has not been great (4 percent in 2008, according to SureScripts/RxHub).

In contrast, prescription controlled substances have always carried a significant inherent risk of diversion, both because they are addictive and because they can be sold for significantly higher prices than their retail price. The recent studies showing increasing levels of abuse of these drugs throughout the United States heightens the cause for concern. Accordingly, with controlled substances there is a considerable incentive for individuals and criminal organizations to exploit any vulnerabilities that exist to obtain these substances illegally.

The National Survey on Drug Use and Health (NSDUH) (formerly the National Household Survey on Drug Abuse) is an annual survey of the civilian, non-institutionalized, population of the United States aged 12 or older. The survey is conducted by the Office of Applied Studies, Substance Abuse and Mental Health Services Administration, of the Department of Health and Human Services. Findings from the 2008 NSDUH are the latest year for which information is currently available. The 2008 NSDUH[7] estimated that 6.2 million persons were current users, i.e., past 30 days, of psychotherapeutic drugs—pain relievers, anti-anxiety medications, stimulants, and sedatives—taken nonmedically. This represents 2.5 percent of the population aged 12 or older. From 2002 to 2008, there was an increase among young adults aged 18 to 25 in the rate of current use of prescription pain

[6] National Institute of Standards and Technology. Special Publication 800–63–1, *Draft Electronic Authentication Guideline,* December 8, 2008. Appendix A.

[7] Substance Abuse and Mental Health Services Administration. (2009). *Results from the 2008 National Survey on Drug Use and Health: National Findings* (Office of Applied Studies, NSDUH Series H–36, DHHS Publication No. SMA 09–4434). Rockville, MD. *http://www.oas.samhsa.gov/nsduh/2k8nsduh/2k8Results.pdf.*

relievers, from 4.1 percent to 4.6 percent. The survey found that about 52 million people 12 and older had used prescription drugs for non-medical reasons in their lifetime; about 35 million of these had used prescription painkillers nonmedically in their lifetime.

The consequences of prescription drug abuse are seen in the data collected by the Substance Abuse and Mental Health Services Administration on emergency room visits. In the latest data, Drug Abuse Warning Network (DAWN), 2006: National Estimates of Drug-Related Emergency Department Visits,[8] SAMHSA estimates that, during that one year, approximately 741,000 emergency department visits involved nonmedical use of prescription or over-the-counter drugs or dietary supplements, a 38 percent increase over 2004. Of the 741,000 visits, 195,000 involved benzodiazepines (Schedule IV) and 248,000 involved opioids (Schedule II and III). Overall, controlled substances represented 65 percent of the estimated emergency department visits involving prescription drugs or over-the-counter drugs or dietary supplements. Between 2004 and 2006, the number of visits involving opioids increased 43 percent and the number involving benzodiazepines increased 36 percent. Of all visits involving nonmedical use of pharmaceuticals, about 224,000 resulted in admission to the hospital; about 65,000 of those individuals were admitted to critical care units; 1,574 of the visits ended with the death of the patient. More than half of the visits involved patients 35 and older.

People dependent on the drugs are willing to pay a high premium to obtain them, creating a black market for these drugs. The problem of illegitimate prescriptions, which exists with paper prescriptions, is exacerbated by the speed of electronic transmissions and the difficulty of identifying an electronic prescription as invalid. A single prescription can be sent to multiple pharmacies; multiple practitioners' identities can be stolen and each identity used to issue a limited number of prescriptions to prevent a pharmacy or a State prescription monitoring program from noticing an unusual pattern. DEA's goal in the proposed rule was to address these vulnerabilities and ensure that before controlled substance prescriptions are issued electronically, the process is adequately secure to protect both DEA registrants and society.

Based on DEA's concerns, certain requirements must exist for any system to be used for the electronic prescribing of controlled substances:

- Only DEA registrants may be granted the authority to sign controlled substance electronic prescriptions. The approach must, to the greatest extent possible, protect against the theft of registrants' identities.
- The method used to authenticate a practitioner to the electronic prescribing system must ensure to the greatest extent possible that the practitioner cannot repudiate the prescription. Authentication methods that can be compromised without the practitioner being aware of the compromise are not acceptable.
- The prescription records must be reliable enough to be used in legal actions (enforcing laws relating to controlled substances) without diminishing the ability to establish the relevant facts and without requiring the calling of excessive numbers of witnesses to verify records.
- The security systems used by any electronic prescription application must, to the greatest extent possible, prevent the possibility of insider creation or alteration of controlled substance prescriptions.

Comments. DEA received 229 comments, 35 of which were copies. Twenty-one practitioner organizations, 24 pharmacy organizations, 18 States (State licensing boards of medicine and pharmacy, and three State health departments), and 19 application providers were among the commenters. Several States supported the rule as proposed, expressing concern about the security of electronic prescriptions and stating that the rule should prevent insider tampering or creation of controlled substance prescriptions. Advocacy groups concerned with drug use similarly supported the proposed rule as did a few other commenters. A number of commenters generally supported electronic prescriptions without addressing the proposed rule.

Most commenters, however, raised a substantial number of issues about various provisions of the proposed rule; their comments are addressed in detail in section IV of this preamble. On a general level, they expressed concern that the proposed requirements would prove too burdensome and would create a barrier to the adoption of electronic prescribing. They also raised two overarching issues that have affected the approach that DEA has adopted in this interim final rule.

First, the commenters noted that DEA's proposed approach addressed primarily one model for electronic prescription applications, application service providers (ASPs). In this model, the practitioner subscribes to a service and accesses, usually over the Internet, an electronic prescription application that is maintained on the ASP's servers. The ASP controls access to the application, has access to all of the records, and maintains security. The practitioner does not need to install the application or maintain servers that archive the records. Many electronic prescription application providers, particularly those that develop EHRs and hospital applications, install their software on the practitioner's computers. Once the application is installed, the electronic prescription application provider's role is limited to providing technical assistance when needed. Access control, records, and security are handled by the practitioners or their staff. Some of the proposed provisions did not work when the electronic prescription application provider is not involved in logical access control.

Second, many commenters pointed out that the technology continues to evolve, the EHR applications are still changing, and that the standards for electronic prescriptions are not mature. A number of commenters indicated that the current transmission system, which relies on a series of intermediaries to provide interoperability, may not be needed when both technology and the standards evolve. These commenters wanted DEA to provide more flexibility to be able to adjust to advancements as they occur.

III. Discussion of the Interim Final Rule

This section provides an overview of the interim final rule. As noted above, commenters raised a number of issues related to specific proposed provisions. DEA has revised the rule to address commenters' concerns and to recognize the variations in how electronic prescription applications are implemented. In arriving at an interim final rule, DEA has balanced a number of considerations. Chief among these is DEA's obligation to ensure that the regulations minimize, to the greatest extent possible, the potential for diversion of controlled substances resulting from nonregistrants gaining access to electronic prescription applications and electronic prescriptions. At the same time, DEA has sought to streamline the rules to reduce the burden on registrants.

[8] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. *Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits.* DAWN Series D–30, DHHS Publication No. (SMA) 08–4339, Rockville, MD, 2007. *http://dawninfo.samhsa.gov/.*

Another of DEA's goals has been to provide flexibility in the rule so that as technologies and standards mature, registrants and application providers will be able to take advantage of advances without having to wait for a revision to the regulations. Finally, DEA has revised the rules to place requirements on either the application or on registrants so that neither DEA nor registrants are dependent on intermediaries for maintenance of information.

In response to commenters' concerns, DEA is adopting an approach to identity proofing (verifying that the user is who he claims to be) and logical access control (verifying that the authenticated user has the authority to perform the requested operation) that is different from the approach that it proposed. The interim final rule provisions related to these two steps are based on the concept of separation of duties: No single individual will have the ability to grant access to an electronic prescription application or pharmacy application. For individual practitioners in private practice (as opposed to practitioners associated with an institutional practitioner registrant), identity proofing will be done by an authorized third party that will, after verifying the identity, issue the authentication credential to a registrant. As some commenters suggested, DEA is requiring registrants to apply to certain Federally approved credential service providers (CSPs) or certification authorities (CAs) to obtain their authentication credentials or digital certificates. These CSPs or CAs will be required to conduct identity proofing at National Institute of Standards and Technology (NIST) SP 800–63–1 Assurance Level 3, which allows either in-person or remote identity proofing. Once a Federally approved CSP or CA has verified the identity of the practitioner, it will issue the necessary authentication credential.

The successful issuance of the authentication credentials will be necessary to sign electronic controlled substance prescriptions, but possession of the credential will not be sufficient to gain access to the signing function. The electronic prescription application must allow the setting of logical access controls to ensure that only DEA registrants or persons exempted from the requirement of registration are allowed to indicate that prescriptions are ready to be signed and sign controlled substance prescriptions. Logical access controls may be by user or role-based; that is, the application may allow permissions to be assigned to individual users or it may associate permissions with particular roles (*e.g.,* physician, nurse), then assign each individual to the appropriate role. Access control will be handled by at least two people within a practice, one of whom must be a registrant. Once the registrant has been issued the authentication credential, the individuals who set the logical access controls will verify that the practitioner's DEA registration is valid and set the application's logical access controls to grant the registrant access to functions that indicate a prescription is ready to be signed and sign controlled substance prescriptions. One person will enter the data; a registrant must approve the entry, using the two-factor authentication protocol, before access becomes operational.

DEA is allowing, but not requiring, institutional practitioners to conduct identity proofing in-house as part of their credentialing process. At least two people within the credentialing office must sign any list of individuals to be granted access control. That list must be sent to a separate department (probably the information technology department), which will use it to issue authentication credentials and enter the logical access control data. As with private practices, two individuals will be required to enter and approve the logical access control information. Institutional practitioners may require registrants and those exempted from registration under § 1301.22 to obtain identity proofing and authentication credentials from the same CSPs or CAs that individual practitioners use. The institutional practitioner may also conduct the identity proofing in-house, then provide the information to these CSPs or CAs to obtain the authentication credentials. In this last case, the institutional practitioners would be acting as trusted agents for the CSPs or CAs, under rules that those organizations set. Because DEA has made extensive changes to the requirements related to identity proofing and logical access control, DEA is seeking further comments on these issues.

As proposed, DEA is requiring in this interim final rule that the authentication credential be two-factor. Two-factor authentication (two of the following—something you know, something you have, something you are) protects the practitioner from misuse of his credential by insiders as well as protecting him from external threats because the practitioner can retain control of a biometric or hard token. Authentication based only on knowledge factors is easily subverted because they can be observed, guessed, or hacked and used without the practitioner's knowledge. In the interim final rule DEA is allowing the use of a biometric as a substitute for a hard token or a password. If a hard token is used, it must meet FIPS 140–2 Security Level 1 for cryptographic devices or one-time-password devices and must be stored on a device that is separate from the computer being used to access the application. The CSPs and CAs may issue a new hard token or register and provide credentials for an existing token. Regardless of whether a new token is provided and activated or an existing token is registered for the signing of controlled substances prescriptions, communications between the CSP or CA and practitioner applicant must occur through two channels (*e.g.,* mail, telephone, e-mail).

However, while DEA is requiring in this interim final rule that the authentication credential be two-factor, DEA is seeking further comments on this issue. Specifically, DEA seeks comments in response to the following question:

- Is there an alternative to two-factor authentication that would provide an equally safe, secure, and closed system for electronic prescribing of controlled substances while better encouraging adoption of electronic prescriptions for controlled substances? If so, please describe the alternative(s) and indicate how, specifically, it would better encourage adoption of electronic prescriptions for controlled substances without diminishing the safety and security of the system.

DEA is establishing standards with which any biometric being used as one factor to sign controlled substance prescriptions must comply; however, DEA is not specifying the types of biometrics that may be used to allow for the greatest flexibility and adaptation to new technologies in the future. DEA consulted extensively with NIST in the development of these standards and has relied on their recommendations for this aspect of the rule. If a biometric is used, it may be stored on a computer, a hard token, or the biometric reader. Storage of biometric data, whether in raw or template format, has implications for data protection and maintenance. These are considerations that should be weighed by application providers and implementers when choosing where and how biometric data may be stored. Additionally, application providers and implementers may wish to consider using open standard biometric data formats when available, to provide interoperability where more than one application provider may be providing biometric capabilities (*e.g.,* a network that spans multiple entities) and to protect their interests. Because the use

of biometrics and the standards related to their use were not discussed in the notice of proposed rulemaking, DEA is seeking further comments on these issues.

DEA is requiring that the application display a list of controlled substance prescriptions for the practitioner's review before the practitioner may authorize the prescriptions. A separate list must be displayed for each patient. All information that the DEA regulations require to be included in a prescription for a controlled substance, except the patient's address, must appear on the review screen along with a notice that completing the two-factor authentication protocol is legally signing the prescription. A separate key stroke will not be required for this statement. Registrants must indicate that each controlled substance prescription shown is ready to be signed. When the registrant indicates that one or more prescriptions are to be signed, the application must prompt him to begin the two-factor authentication protocol. Completion of the two-factor authentication protocol legally signs the prescriptions. When the two-factor authentication protocol is successfully completed, the application must digitally sign and archive at least the DEA-required information. If the practitioner is digitally signing the prescription with his own private key,[9] the application need not digitally sign the record separately, but must archive the digitally signed record. DEA is allowing any practitioner to use the digital signature option proposed for Federal healthcare systems. Unless a practitioner has digitally signed a prescription and is transmitting the prescription with the digital signature, the electronic prescription must include an indication that the prescription was signed.

The electronic prescription application must generate a monthly log of controlled substance prescriptions issued by a registrant, archive a record of those logs, and provide the logs to the practitioner. The practitioner is not required to review the monthly log.

Because the prescription information will be digitally signed when the practitioner completes the two-factor authentication protocol, the prescription need not be transmitted immediately. Information other than the information that must be digitally signed may be added to the file (*e.g.,* pharmacy URLs) or the prescription may be reviewed (*e.g.,* at a long-term care facility) after it is signed and before it is transmitted to the pharmacy. After the practitioner completes the authentication protocol, the information that the DEA regulations require to be included in a prescription for a controlled substance may not be modified before or during transmission.

DEA has clarified that the application may print copies of an electronically transmitted prescription if they are clearly labeled as copies, not valid for dispensing. If a practitioner is notified by an intermediary or pharmacy that a transmission failed, he may print a copy of the transmitted prescription and manually sign it. The prescription must indicate that it was originally transmitted to a specific pharmacy and that the transmission failed. The pharmacy is responsible for checking to ensure that the prescription was not received electronically and no controlled substances were dispensed pursuant to the electronic prescription prior to filling the paper prescription.

DEA has also clarified that the requirement that the DEA-required contents of the prescription not be altered during transmission applies only to changes to the content (not format) by intermediaries, not to changes that may lawfully be made at a pharmacy after receipt. Pharmacy changes to electronic prescriptions for controlled substances are governed by the same statutory and regulatory limitations that apply to paper prescriptions. Intermediaries may not convert an electronic controlled substance prescription into a fax. Once a prescription is created electronically, all records of the prescription must be retained electronically.

Unless the prescription is being transmitted with a digital signature, either the last intermediary or the pharmacy must digitally sign the prescription; the pharmacy must archive the digitally signed prescription. Both the electronic prescription application and the pharmacy application must maintain an internal audit trail that records any modifications, annotations, or deletions of an electronic controlled substance prescription or when a functionality required by the rule is interfered with; the time and date of the action; and the person taking the action. The application provider and the registrants must develop a list of auditable events; auditable events should be occurrences that indicate a potential security problem. For example, an unauthorized person attempting to sign or alter a prescription would be an auditable event; a pharmacist annotating a record to indicate a change to a generic version of a drug would not be. The applications must run the internal audit function daily to identify any auditable events. When one occurs, the application must generate a readable report for the practitioner or pharmacist. If a practitioner or pharmacy determines that there is a potential security problem, they must report it to DEA within one business day.

Application providers must obtain a third-party audit before the application may be used to create, sign, transmit, or process controlled substance prescriptions and whenever a functionality related to controlled substance prescription requirements is altered, or every two years after the initial audit, whichever occurs first. If one or more certification organizations establish procedures to review applications and determine whether they meet the requirements set forth in the DEA regulations, DEA may allow this certification to replace the third-party audit. DEA will notify registrants of any such approvals of organizations to conduct these third-party certifications through its Web site. At this time, no such certification exists for either electronic prescription or pharmacy applications, but the Certification Commission for Healthcare Information Technology (CCHIT) has developed a program for electronic prescription applications.

All records must be maintained for two years from the date on which they were created or received. Pharmacy records must be backed up daily; DEA is not specifying where back-up files must be stored.

Because DEA is allowing any registrant to use the public key infrastructure (PKI) option proposed for Federal healthcare systems, the interim final rule does not include separate requirements for these systems.

When a prescription is transmitted (outside of a closed system), it moves through three to five intermediaries between practitioners and pharmacies. Although prescriptions could be altered, added, or deleted during transmission, DEA is not regulating transmission. Registrants have no control over the string of intermediaries. A practitioner might be able to determine from his

[9] For technical accuracy, DEA is describing the method of digitally signing as "applying the private key." The private key is a secret quantity stored on the user's token that is used in the computation of digital signatures. Digital certificates contain a related quantity called the public key, which is used to verify signatures generated by the corresponding private key. The user is not required to know, and does not enter either key. A message digest is computed by the signing software on the user's computer, and the portion of the signing function that involves the private key is automatically performed by the user's token, once the user has provided the token and a second authentication factor such as a password or PIN. From the user's perspective, the experience is similar to using an ATM card.

application provider which intermediaries it uses to move the prescription from the practitioner to SureScripts/RxHub or a similar service, but neither the practitioner nor the application provider would find it easy to determine which intermediaries serve each of the pharmacies a practitioner's patients may choose. Pharmacies have the problem in reverse; they may know which intermediaries send them prescriptions, but have no way to determine the intermediaries used to route prescriptions from perhaps hundreds of practitioners using different applications to SureScripts/RxHub or a similar service. DEA believes the involvement of intermediaries will not compromise the integrity of electronic prescribing of controlled substances, provided the requirements of the interim final rule are satisfied. Among these requirements is that the prescription record be digitally signed before and after transmission to avoid the need to address the security of intermediaries. DEA realizes that this approach will not prevent problems during the transmission, but it will at least identify that the problem occurred during transmission and protect practitioners and pharmacies from being held responsible for problems that may arise during transmission that are not attributable to them.

Some commenters on the NPRM claimed that the security practices of intermediaries were sufficient to protect electronic prescriptions. These practices, which are voluntary, do not address the principal threats of diversion, which occur before and after transmission. Maintaining the integrity of the record during transmission is of little value if there is no assurance that a registrant created and transmitted the prescription or that pharmacy staff did not alter it after receipt.

DEA wishes to emphasize that the electronic prescribing of controlled substances is in addition to, not a replacement of, existing requirements for written and oral prescriptions for controlled substances. This rule provides a new option to prescribing practitioners and pharmacies. It does not change existing regulatory requirements for written and oral prescriptions for controlled substances. Prescribing practitioners will still be able to write, and manually sign, prescriptions for Schedule II, III, IV, and V controlled substances, and pharmacies will still be able to dispense controlled substances based on those written prescriptions and archive those records of dispensing. Further, nothing in this rule prevents a practitioner or a practitioner's agent from using an existing electronic prescription application that does not comply with the interim final rule to prepare a controlled substance prescription, so that EHR and other electronic prescribing functionality may be used, and print the prescription for manual signature by the practitioner. Such prescriptions are paper prescriptions and subject to the existing requirements for paper prescriptions.

IV. Discussion of Comments

A. Introduction

This section summarizes the 194 comments received to the NPRM by issue and provides DEA's responses. For each issue, DEA first summarizes the proposed rule, then presents the comments and DEA's responses. The subjects are presented in an order that tracks the process of issuing and dispensing a prescription from practitioner to pharmacy. Issues that apply to both types of applications (*e.g.,* third-party audits, recordkeeping) are presented once. General comments and ancillary issues are discussed at the end of this section.

B. Identity Proofing and Logical Access Control

DEA proposed that practitioners would be required to undergo in-person identity proofing, with DEA-registered hospitals, State licensing boards, or law enforcement agencies checking the identification documents. The record of the identity proofing would then have been sent to the electronic prescription application provider, which would use the information to set access controls to ensure that only practitioners eligible to issue controlled substance prescriptions were allowed to sign these prescriptions.

1. Identity Proofing

Comments. Some commenters, including electronic prescription application providers and practitioner organizations, supported identity proofing, but recommended changes to the proposed rule. One physician noted that identity proofing was particularly important to prevent online enrollment without any checks on the veracity of the information submitted. Other commenters, including insurance organizations, some practitioner organizations, and some pharmacy organizations, opposed the requirement for identity proofing, stating that it would be burdensome to practitioners and a barrier to adoption of electronic prescribing. One electronic prescription application provider noted that DEA does not conduct identity proofing for issuing paper prescriptions. Several practitioner organizations and a State Board of Pharmacy stated that there was no assurance that identity proofing would reduce diversion, citing the vulnerabilities of paper prescriptions. One pharmacy chain stated that DEA should restrict access to the database of DEA registration numbers.

DEA Response. DEA continues to believe that it is critical to the security of electronic prescribing of controlled substances that authentication credentials used to sign controlled substance prescriptions be issued only to individuals whose identities have been confirmed based on information presented in, and consistent with, the application (except for institutional practitioners; see discussion below). Without this step, nonregistrants—at a practitioner's office, at an application provider, or elsewhere—could obtain an authentication credential in a registrant's name and use it to issue illegal prescriptions. As DEA discussed in the NPRM, some existing electronic prescription application providers allow people to enroll online, with no checks on whether the person is who he claims to be. Although it is true that DEA does not require in-person identity proofing for registration and allows applications to be filed online, DEA conducts a number of checks on registration applications before issuing a registration. In addition, filing a false registration application is a Federal crime punishable by up to four years in prison under 21 U.S.C. 843. Moreover, electronic prescriptions, unlike written or oral prescriptions, lack the human elements of handwriting or the spoken voice, which a pharmacist can take into account in ascertaining whether the prescription was issued by the actual practitioner or an impostor; identity proofing serves to some degree to fill this void.

In response to comments on whether this requirement will reduce diversion, DEA is well aware of the vulnerabilities of the paper-based prescription system, but that such vulnerabilities exist does not mean that DEA should allow similar or greater vulnerabilities with electronic prescriptions for controlled substances. A forged paper prescription provides forensic evidence of who committed the forgery and can exonerate a practitioner based on that evidence; an electronic prescription issued in a practitioner's name provides no such evidence, making it difficult for law enforcement to identify the person who issued it and difficult for the practitioner to prove that he did not. Restricting access to the CSA database would not solve the problem of patients, medical office staff,

and pharmacy staff, all of whom have routine access to DEA numbers, issuing fraudulent prescriptions.

DEA recognizes that identity proofing and logical access controls (discussed below) will not stop all misuse of electronic prescription applications. Identity proofing will not prevent a registrant from issuing invalid prescriptions or allowing a staff member to issue prescriptions in his name, and it is not intended to prevent such activity. The purpose of identity proofing is to limit to as great an extent as possible the ability of nonregistrants to obtain an authentication credential and issue electronic controlled substance prescriptions under a practitioner's name.

Comments. A substantial number of commenters raised issues related to who would conduct the identity proofing. The State Boards generally objected to being asked to conduct identity proofing, asserting that they did not have the staff or resources to do so. They noted that they would need to train staff and perhaps seek legislative authority and funding to carry out this function. Other commenters doubted that hospitals or law enforcement agencies would be willing to conduct the checks or thought that DEA intended to charge for the process. Some practitioners objected to the idea of having law enforcement agencies involved. Many commenters objected to the cost of trips to a third party and stated that it would be a barrier to adoption, particularly for practitioners who are not affiliated with a hospital, such as mid-level practitioners and dentists. Some commenters, including electronic prescription application providers, asked that other entities be allowed to conduct identity proofing (*e.g.,* notaries, application providers, passport processing agencies, the American Association of Medical Colleges).

A long-term care facility (LTCF) organization, several information technology organizations, and an application provider suggested that DEA use existing certification authorities (CAs) that issue digital certificates and routinely conduct identity proofing as part of the enrollment process. An information technology firm suggested that DEA establish a set of common criteria under which credential issuers can become accredited, citing the Department of Defense External Certification Authority program as an example. The commenter also suggested that DEA specify that firms qualified as shared service providers by the Federal Bridge Certification Authority (FBCA) could serve as CSPs. A few commenters associated with application providers or information technology organizations asked DEA to consider remote identity proofing systems.

DEA Response. In view of the comments, DEA has revised the requirements for identity proofing to adopt an approach that does not involve parties discussed in the proposed rule. As suggested by some commenters, for individual practitioners in private practice (*i.e.,* those practitioners not seeking access to an institutional practitioner's applications), DEA will use existing certification authorities (CAs) and similar credential service providers (CSPs) that have been approved by a Federal authority. These organizations conduct identity proofing and issue digital certificates and other identity credentials as part of their existing businesses. The standards they use to conduct identity proofing and issue credentials are established in documents (*e.g.,* Certificate Policies, Certificate Practice Statements, and Assurance Frameworks) that are reviewed and approved by Federal authorities and subject to third-party audits for their implementation. DEA is specifying that the identity proofing must meet NIST SP 800–63–1 Assurance Level 3 although a CA or CSP may impose higher standards.

DEA's objective is to ensure that identity proofing and the provision of two-factor authentication credentials will be done by a third party that is not involved in any other part of the electronic prescribing process. This approach is based on the concept of separation of duties, to ensure that the ability to sign controlled substance prescriptions will not depend on the action of a single entity or person. A registrant will need the two-factor authentication credential before he will be able to sign electronic prescriptions for controlled substances, but the possession of the token or tokens associated with the credential will not, itself, authorize a registrant to access the application to sign controlled substances prescriptions. Logical access control will be granted separately. Without the two-factor authentication credential, a practitioner will not be able to sign controlled substance prescriptions even if granted access.

For practitioners who are obtaining a two-factor authentication credential that does not include a digital certificate, DEA is requiring that they obtain their authentication credential from a credential service provider (CSP) that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets NIST Sp 800–63–1 Assurance Level 3 or above. For practitioners obtaining a digital certificate, DEA is requiring that they obtain the digital certificate from a certification authority that is cross-certified with the Federal Bridge Certification Authority (FBCA) at a basic assurance level or higher and that conducts identity proofing at NIST SP 800–63–1 Assurance Level 3 or above. DEA believes that shared service providers would be too restrictive and believes that the approach it is implementing provides greater flexibility for the regulated industry.

DEA is not dictating how a CSP or CA conducts identity proofing. The standards for identity proofing are set by the Federal Bridge Certification Authority (FBCA) or the General Services Administration in their certificate policies and frameworks and in NIST SP 800–63–1. Level 3 requires either in-person identity proofing based on checking government-issued photographic identification or remote identity proofing. For in-person identity proofing, Level 3 requires the examination of a government-issued photographic identification, which must be verified with either the issuing agency, credit bureaus, or other similar databases. The verification must confirm that the name, date of birth, and address listed in the application for the credential are consistent with the information in other records checked. The person checking the identification must compare the person with the photograph, record the identification number, address (if listed), and date of birth. If the identification is valid, the issuing organization may authorize or issue the credential and send notice to the address of record; if the identification or other records checked do not confirm the address listed in the application (as may happen if the person has recently moved), the organization must issue credentials in a manner that confirms the address of record (the address of record is the address listed in the application).

For remote identity proofing, Level 3 requires a valid government-issued identification number and a financial account number. These numbers must be confirmed via record checks with either the issuing agency or institution or through credit bureaus or similar databases. The check must confirm that the name, address, date of birth, and other personal information in the records are consistent with the application and sufficient to identify a unique individual. The address or telephone number must be confirmed by issuing the credential in a manner that

confirms the ability of the applicant to receive communications at the listed address or number. DEA notes that CAs and CSPs may conduct more extensive remote identity proofing and may require additional information from applicants. DEA believes that the ability to conduct remote identity proofing allowed for in Level 3 will ensure that practitioners in rural areas will be able to obtain an authentication credential without the need for travel. DEA expects that application providers will work with CSPs or CAs to direct practitioners to one or more sources of two-factor authentication credentials that will be interoperable with their applications. DEA is seeking comment on this approach to identity proofing.

DEA is not requiring the CSP or CA to check DEA registrations or State authorizations to practice or dispense controlled substances as part of the identity-proofing process; these will be checked as part of logical access control, as discussed in the next section. DEA decided to have checks for the DEA registration, authorization to practice, and authorization to dispense controlled substances for individual practitioners handled separately from identity proofing for three reasons. First, the information that is used to verify identity may not be the information associated with a DEA registration. Government-issued photographic identifications and credit cards usually are associated with home addresses and, perhaps, Social Security numbers; DEA registrations are usually associated with business locations and, in some cases, taxpayer identification numbers. In addition, the registration database that DEA makes available through the National Technical Information Service does not include this personal information, so that a CA or CSP would have to contact DEA for each applicant. Second, some practices or application providers may want some or all of the nonregistrants on the staff to obtain authentication credentials so that there will be only one method of authenticating to the application. The possession of a two-factor authentication credential would not, in these cases, distinguish between those who can sign controlled substance prescriptions and those who cannot. Third, the decision to grant access to the functions that allow a practitioner to indicate that a prescription is ready for signing and to sign controlled substance prescriptions is based on whether the person is a DEA registrant, not on the possession of a two-factor authentication credential. The two-factor authentication credential is a necessary, but not a sufficient, condition for signing a controlled substance prescription. It is logical, therefore, to require the people who set logical access controls, rather than those who conduct identity proofing, to check the DEA and State authorizations to practice and, where applicable, authorizations to dispense controlled substances of prescribing practitioners.

Comments. One medical group association and a healthcare system recommended that the larger practices be allowed to conduct the identity proofing themselves as they already conduct Level 4 identity proofing when they issue credentials.

DEA Response. In view of the comments, DEA has expanded upon the proposed rule to allow institutional practitioners, which are themselves DEA registrants, to conduct the identity proofing for any individual practitioner whom the institutional practitioner is granting access to issue prescriptions using the institution's electronic prescribing application. Because institutional practitioners have credentialing offices, the interim final rule allows those offices to conduct in-person identity proofing, which they can do as part of their credentialing process. DEA is not requiring institutional practitioners to meet the requirements of NIST SP 800–63–1 for identity proofing. As some commenters stated, these institutions already conduct extensive checks before they credential a practitioner. The interim final rule simply requires that before they issue the authentication credential they check the person's government-issued photographic identification against the person presenting it. They must also check State licensure and DEA registrations, where applicable, but they do this as part of credentialing and do not need to repeat the checks for practitioners whom they have already credentialed.

The rule only allows institutional practitioners to conduct in-person identity proofing, not remote identity proofing. There are two reasons for this limitation. First, the practitioners will be visiting the institution on a regular basis so the burden should be relatively low. Second, most institutional practitioners may not have the ability or desire to conduct the credit and other background checks that are part of remote identity proofing at NIST Levels 2 and 3. DEA recognizes that in some large systems, the credentialing office may be at a central location and many staff may work at other locations. In those cases, the institutional practitioner can decide whether to have the staff visit the central location or send someone from the credentialing office to the other locations to conduct the identity proofing. DEA notes that this issue will arise only during the initial enrollment of previously credentialed practitioners. After that, practitioners being newly credentialed by an institution can undergo identity proofing when and where they are credentialed. The rule also requires that the credentialing office check the DEA and State authorizations to practice and, where applicable, authorizations to dispense controlled substances because this check should be part of their standard credentialing process.

Under the rule, the institutional practitioner may issue the two-factor authentication credentials itself or obtain them from a third party, which will have to be a CSP or CA that meets the criteria specified above. In the latter case, the institutional practitioner could have each practitioner apply for the two-factor credential himself, which would entail undergoing identity proofing by the CSP or CA. Alternatively, the institutional practitioner can serve as a trusted agent for the third party. Trusted agents conduct part of the identity proofing on behalf of the CSP or CA and submit the information for each person along with a signed agreement that specifies the trusted agent's responsibilities. DEA emphasizes that institutional practitioners are allowed, but not required, to conduct identity proofing. If an institutional practitioner (*e.g.,* a small hospital or clinic) decides to have each practitioner obtain identity proofing and the two-factor authentication credential on his own, as other individual practitioners do, that is permissible under the rule. DEA is seeking comment on this approach to identity proofing by institutional practitioners.

Comments. An intermediary, a pharmacist organization, and a State asked whether practitioners would need to undergo identity proofing more than once if they used multiple electronic prescription applications. An application provider and a practitioner organization asked if the identity proofing needed to be revalidated every year. Several commenters asked about the need to obtain separate authentication credentials if the practitioner holds multiple DEA numbers.

DEA Response. Identity proofing is required to obtain a two-factor authentication credential. If a practitioner uses multiple applications (*e.g.,* at his practice and at a hospital), he may need to obtain separate authentication credentials, based on the

following considerations. A practitioner will need to undergo identity proofing for each such credential that he needs unless the applications he wishes to use require authentication credentials from the same CSP or CA; in that case, the CSP or CA will determine whether a single application for identity proofing and issuance of the authentication credential can serve as a basis for issuing multiple credentials. It may also be possible that multiple applications will accept the same two-factor authentication credential. For example, if a practitioner obtains a digital certificate from an approved CA, he may be able to use it to digitally sign prescriptions on multiple applications, if they accept digital signatures. For those practitioners who use more than one DEA registration to issue controlled substance prescriptions, DEA is not requiring a practitioner to have a separate authentication credential based solely on the fact that he uses more than one DEA registration. As for the need for revalidation of identity proofing, those periods will be set by the CSP or CA.

Comments. Practitioner organizations asked if practitioners will be charged for the identity proofing.

DEA Response. DEA expects that the CSP or CA will charge for the issuance of a two-factor authentication credential, which will generally include the cost of identity proofing. Whether practitioners will pay directly or through the application provider will be a business decision on the part of application providers.

Comments. A practitioner organization expressed concern with the proposed rule language that referenced "State licenses" because some States do not issue licenses to mid-level practitioners.

DEA Response. DEA agrees with this commenter and has revised the language in the interim final rule to refer to State authorization to practice and State authorization to dispense controlled substances.[10]

2. Access Control

In the NPRM, DEA proposed that the identity proofing document had to be submitted to the application provider, which would then check the DEA registration and State authorizations to practice, and set access controls. DEA also proposed that the application providers check DEA registration status weekly and revoke authentication credentials if practitioners' registrations had been terminated, revoked, or suspended.

Comments. A LTCF organization stated that any electronic prescribing application must have, at its core, control over access rights. A practitioner organization also emphasized the need to limit access to signing authority within an application. An electronic prescription application provider stated that it did not set access controls for the applications it sells and installs at medical practices. Although its applications have logical access controls, the practice administrator is responsible for setting the controls. The application provider is not involved in the process.

DEA Response. In its proposed rule, DEA did not adequately differentiate between authentication, authorization, and access. NIST, in its special publication SP 800–12, provides the following description of these three steps:

> Access is the ability to do something with a computer resource. This usually refers to a technical ability (*e.g.,* read, create, modify, or delete a file, execute a program, or use an external connection). Authorization is the permission to use a computer resource. Permission is granted, directly or indirectly, by the application or system owner. Authentication is proving (to some reasonable degree) that users are who they claim to be.

NIST SP 800–12 further states:

> Access control is the means by which the ability is explicitly enabled or restricted in some way (usually through physical and system-based controls). Computer-based access controls are called logical access controls. Logical access controls can prescribe not only who or what (*e.g.,* in the case of a process) is to have access to a specific system resource but also the type of access that is permitted. These controls may be built into the operating system, may be incorporated into applications programs or major utilities (*e.g.,* database management systems or communications systems), or may be implemented through add-on security packages.[11]

DEA has revised its approach to access control to remove the application provider and its staff from direct involvement in the process. Instead, the interim final rule will require that the application must have the capability to set logical access controls that limit access to the functions for indicating a prescription is ready for signing and for signing the prescription to DEA registrants. The interim final rule will also limit access to setting these logical access controls. The application may set logical access controls on an individual basis or on roles. If the logical access controls are role-based, one or more roles will have to be limited to individuals authorized to prescribe controlled substances. This role may be labeled "DEA registrant" or physician, dentist, nurse practitioner, etc., provided the role is limited to those authorized to issue controlled substance prescriptions. For an individual practitioner who is an agent or employee of an institutional practitioner, and who has been authorized to prescribe controlled substances under the registration of the institutional practitioner pursuant to 21 CFR 1301.22(c), if logical access controls are role-based, one role will have to be "authorized to sign controlled substance prescriptions." (Other methods of setting logical access controls that NIST cites—location or time—do not appear to be relevant, although applications or users may add such limits based on their own concerns.)

The application logical access control capability must require that data entry of authorizations for setting logical access controls and the functions limited to registrants (indicating that a controlled substance prescription is ready for signing and signing a controlled substance prescription) involve two people. The requirement for two people to be involved in such data entry is frequently used to protect applications from internal security threats. If a person is able, through the use of false identity documents, to obtain a two-factor authentication credential in a registrant's name, he will still not be able to sign controlled substance prescriptions unless he is granted access, by two people (one of whom is a registrant). The interim final rule does not specify in detail how the application must be structured to ensure that two people concur with the data entry; rather, the rule simply requires that the application must not accept these logical access controls without the action of two parties. For example, a small practice with two registrants neither of whom is expecting to leave may decide that only the registrants will perform this function, which may occur only at the initial installation or upgrade of an electronic prescription application to comply with controlled substance

[10] Under the CSA, every person who dispenses a controlled substance must have a DEA registration, and may only dispense controlled substances to the extent authorized by his registration, unless DEA has by regulation, waived the requirement of registration as to such person. 21 U.S.C. 822(a)(2), 822(b), 822(d). To be eligible to obtain a DEA registration, a practitioner must be licensed or otherwise authorized by the State or jurisdiction in which he practices to dispense controlled substances. 21 U.S.C. 802(21), 823(f), 824(a)(3).

[11] National Institute of Standards and Technology. Special Publication 800–12 *An Introduction to Computer Security—The NIST Handbook,* Chapter 17; October, 1995. *http://csrc.nist.gov/publications/nistpubs/800-12/800-12-html/chapter17-printable.html.*

prescription requirements. In large practices, the registrants might find it beneficial to allow nonregistrants, such as a practice information technology administrator, to administer logical access controls in conjunction with a registrant.

The interim final rule requires that at least one of the people assigned the role of administering logical access control must verify that any registrant granted authorization to indicate that a prescription is ready for signing and to sign controlled substance prescriptions has a valid DEA registration, a State authorization to practice and, where applicable, a State controlled substance authorization. In small practices, this verification may require nothing more than checking expiration dates on the practitioners' DEA Certificate of Registration and State authorization(s), unless there is reason to question the current validity. In larger practices, verification may take more time. Individual registrations can be checked online at DEA's Web site at *http://www.deadiversion.usdoj.gov/* by clicking on the Registration Validation button on the left side of the Web page.

Once DEA registration and State authorization to practice and State authorization to dispense controlled substances have been verified, two people must be involved in entering the data to the application to identify those people authorized to indicate that a prescription is ready for signing and to sign controlled substance prescriptions; those two people are also involved in entering data to the application to identify people whose authorization has been revoked. The first person must enter the data. A registrant must then use his two-factor authentication credential to provide the second approval. The application must ensure that until the second approval occurs, logical access controls for controlled substance prescription functions cannot be activated or altered. DEA recognizes that some solo practitioners may not have other employees although it seems unlikely that they do not have at least part-time help for office management and back office functions. DEA is not requiring that the second person be an employee, simply that there be two people involved and that the persons involved be specifically designated by the practitioner(s). For such solo practitioners and for many small practices, logical access controls may need to be set only once because they will usually be set or changed only with staff turnover.

All entries and changes to the logical access controls for setting the controls and for the controlled substance prescription functions must be defined as auditable events and a record of the changes retained as part of the internal audit trail. DEA is seeking comment on this approach to logical access control for individual practitioners.

Logical access must be revoked whenever any of the following occurs: A DEA registration expires without renewal, or is terminated, revoked, or suspended; the registrant reports that a token associated with the two-factor authentication credential has been lost or compromised; or the registrant is no longer authorized to use the practice's application. DEA anticipates that for most practices, logical access controls will be set and changed infrequently, usually when a new registrant joins the practice or a registrant leaves. Even in larger practices, changes to authorizations are likely to occur relatively infrequently.

DEA recognizes that application service providers (ASPs) may currently set access controls, to the extent that they do, at the ASP level and that the interim final rule may require them to reprogram some of their security controls. DEA believes these steps are necessary to ensure that a registrant is involved in the process of setting logical access controls and that these cannot be set or changed without the concurrence of a registrant. If registrants submitted a list of people to be authorized to perform the controlled substance prescription functions to an ASP, there would need to be a process to ensure that the list was from a legitimate source (*e.g.,* notarization), which could be cumbersome, particularly for larger practices where the list may change more frequently than is the case for small practices. In addition, the responsibility for data entry would then rest with ASP staff, who will not have the same degree of interest in protecting registrants from the misuse of the applications as the registrants themselves have.

For institutional practitioners, the setting of logical access controls will necessarily be somewhat different because the registrant is not an individual. The principle, however, is the same. Identity proofing must be separate from setting logical access controls; two individuals must be involved in each step. The interim final rule therefore requires that two individuals from the credentialing office provide the part of the institution that controls the computer applications with the names of practitioners authorized to issue controlled substance prescriptions. The entry of the data will also require the involvement of two individuals. The institutional registrant is responsible for designating and documenting individuals or roles that can perform these functions. Logical access must be revoked whenever any of the following occurs: The institutional practitioner's or, where applicable, individual practitioner's DEA registration expires without renewal, or is terminated, revoked, or suspended; the practitioner reports that a token associated with the two-factor authentication credential has been lost or compromised; or the individual practitioner is no longer authorized to use the institutional practitioner's application. DEA is seeking comment on this approach to logical access control for institutional practitioners.

Comments. An application provider to a major healthcare system agreed that access controls were needed, but noted that in a large healthcare system this is complex because of the variety of practitioners involved and will take time to implement.

DEA Response. The interim final rule does not require applications to distinguish which schedules of controlled substances a registrant is authorized to prescribe. Practitioners are responsible for knowing which schedules they may prescribe; if a practitioner prescribes beyond the extent authorized by his registration, he is dispensing in violation of the CSA.[12] In addition, asking applications to distinguish among all the variations of prescribing authority may add unnecessary complication to applications that will mostly be used by practitioners who are authorized to prescribe all Schedule II, III, IV, and V substances. This approach should reduce some of the complexity in programming logical access controls because the application providers will not need to distinguish among DEA registrants. DEA also notes that the 2009 security survey of the Health Information and Management Systems Society (HIMSS) indicated that all of the 196 healthcare systems surveyed have established user access controls.[13]

Comments. Several application providers objected to the proposed requirement that they check DEA registration status weekly.

DEA Response. Because application providers are no longer responsible for controlling access, DEA has removed this requirement in the interim final rule. People within a practitioner's office or an institutional practitioner

[12] 21 U.S.C. 822(b), 841(a)(1).

[13] Healthcare Information and Management Systems Society. *2009 HIMSS Security Survey,* November 3, 2009. *http://www.himss.org/content/files/HIMSS2009SecuritySurveyReport.pdf.*

will be familiar with any issues related to the status of a DEA registration. They will have access to the expiration date of the DEA registration and State authorization(s) to practice and, where applicable, to dispense controlled substances and be able to check with the practitioner to ensure that the registration has been renewed. If a practitioner is subject to suspension or revocation, other registrants in the practice or the institutional practitioner are likely to be aware of the legal problems and can revoke access control.

DEA recognizes that this approach will not prevent a registrant in solo practice from continuing to issue controlled substances prescriptions under an expired, terminated, suspended, or revoked registration. However, it is already clear under existing law and regulations that a practitioner who prescribes or otherwise dispenses controlled substances beyond the scope of his registration is committing a violation of the CSA and subject to potential criminal prosecution, civil fine, and loss of registration. Any practitioner who would use his two-factor authentication credential to issue prescriptions after he is legally barred from doing so would be creating evidence of such criminal activity. As discussed above, the purpose of identity proofing and access control is to prevent nonregistrants from gaining the ability to issue controlled substance prescriptions.

C. Authentication Protocols

Authentication protocols are classified by the number of factors they require. NIST and others recognize three factors: something you know, something you have, and something you are. Combinations of user IDs and passwords are one-factor because they require only information that you know. A standard ATM uses two-factor—something you know (a personal identification number (PIN)) and something you have (bank card). DEA proposed that practitioners be required to use a two-factor authentication protocol to access the electronic prescription application to sign controlled substance prescriptions. DEA proposed that one factor would have to be a hard token that met NIST SP 800–63 Level 4 and that the cryptographic module would have to be validated at Federal Information Processing Standard (FIPS) 140–2 Security Level 2 overall and Level 3 security.

Comments. Three information technology firms asserted that two-factor authentication is not common. They suggested that a clear 'audit log' be generated upon the provider authentication, prescription approval, transmission of prescription, and successful prescription transmittal. They suggested that this audit log should be in the form defined by Healthcare Information Technology Standards Panel (HITSP) T15 "Collect and Communicate Security Audit Trail Transaction." Other commenters noted that the Certification Commission for Healthcare Information Technology (CCHIT) does not require two-factor authentication and has only listed it as a possibility for its 2010 standard. A State Board of Pharmacy supported two-factor authentication, stating that concerns expressed by some members of industry about the added time to complete two-factor authentication are misplaced. It said that the two-factor authentication will take a minimal amount of time compared to the time it takes to move through the multiple screens used to create a prescription in most applications.

DEA Response. DEA agrees that CCHIT does not yet require two-factor authentication. Two-factor authentication is roadmapped by CCHIT in 2010 and beyond. DEA emphasizes, however, that an audit log will not provide any assurance of who issued a prescription. The commenters appear to have confused logical access control with authentication. The problem DEA is addressing with the requirement for two-factor authentication credentials is not that someone may use their own authentication credential to alter or create a prescription, but that a nonregistrant will use a registrant's authentication credential to create and sign a prescription. If a nonregistrant has been able to use a registrant's authentication credential, the audit trail will incorrectly indicate that the registrant was responsible for the prescription. DEA believes that use of two-factor authentication limits this possibility.

As commenters indicated, single-factor authentication usually means passwords alone or in combination with user IDs. NIST states in its special publication SP 800–63–1: "* * * the ability of humans to remember long, arbitrary passwords is limited, so passwords are often vulnerable to a variety of attacks including guessing, use of dictionaries of common passwords, and brute force attacks of all possible password combinations. * * * all password authentication mechanisms are vulnerable to keyboard loggers and observation of the password when it is entered." NIST also states that "* * * many users, left to choose their own passwords will choose passwords that are easily guessed and even fairly short[.]" [14] This problem is exacerbated in healthcare settings where multiple people may use the same computers and work in close proximity to each other. Even if other staff cannot guess the password, they may have many opportunities to observe a practitioner entering the password. Strong passwords (combinations of 8 or more letters, numbers, and special characters) are hard to remember and are often written down. None of these strategies alters the ability of others in a healthcare setting to observe the password. NIST, in its draft guidance on enterprise password management (SP 800–118) states the following:

> Organizations should be aware of the drawbacks of using password-based authentication. There are many types of threats against passwords, and most of these threats can only be partially mitigated. Also, users are burdened with memorizing and managing an ever-increasing number of passwords. However, although the existing mechanisms for enterprise password management can somewhat alleviate this burden, they each have significant usability disadvantages and can also cause more serious security incidents because they permit access to many systems through a single authenticator. Therefore, organizations should make long-term plans for replacing or supplementing password-based authentication with stronger forms of authentication for resources with higher security needs.[15]

DEA remains convinced that single-factor authentication is insufficient to ensure that a practitioner will not be able to repudiate a prescription he signed.

Comments. Although only a few commenters opposed two-factor authentication, believing that passwords were sufficient, most comments DEA received on the issue raised substantial concerns about the details of the proposed rule on this subject. These concerns focused on the requirement for a hard token and the security levels proposed.

A practitioner organization, a hospital organization, a pharmacy association, a health information technology organization, a healthcare system, other medical associations, and a number of application providers asked DEA to allow the use of biometrics as an alternative to a hard token. The practitioner organization stated that a

[14] National Institute of Standards and Technology. Special Publication 800–63–1, *Draft Electronic Authentication Guideline,* December 8, 2008, Appendix A. *http://csrc.nist.gov/Publications/PubsSPs.html.*

[15] National Institute of Standards and Technology. Special Publication 800–118, *Guide to Enterprise Password Management* (draft), April 2009; *http://csrc.nist.gov/publications/drafts/800-118/draft-sp800-118.pdf.*

second authentication at the time of transmission is reasonable given the potential for unintentional or intentional failure to have only authorized prescribers actually transmit the prescription. That commenter asserted that the key is to view authentication as having many highly acceptable approaches and requiring that a certain strength of authentication be the outcome, but not prescribe the exact method by which that authentication is generated. A health information technology organization asserted that the Association of American Medical Colleges uses a fingerprint biometric strategy to permanently identity proof all future physicians at the time they take their Medical College Admission Test (MCAT). An application provider noted that biometric identifiers will limit unauthorized access to electronic prescription applications and ensure non-repudiation with absolute certainty; the commenter asserted that these applications cannot be compromised without the practitioner's knowledge. The commenter noted that biometric identifiers cannot be misplaced, loaned to others or stored in a central location for use by other persons. The commenter noted, however, that the technology may not be ready to deploy in a scalable, cost-effective way at this time.

DEA Response. DEA agrees with these commenters and has revised the interim final rule to allow the use of a biometric as a second factor; thus, two of the three factors must be used: a biometric, a knowledge factor (*e.g.,* password), or a hard token. While DEA is uncertain about the extent to which existing biometric readers will be used in healthcare settings, DEA believes it is reasonable to allow for such technology because the technology is likely to improve. The HIMSS 2009 security survey indicated that 19 percent of the 196 healthcare systems surveyed use biometric technologies as a tool to provide security for electronic patient data; the HIMSS 2009 leadership survey of larger healthcare systems found that 18 percent used biometrics as a tool to provide security for electronic patient data, but 36 percent indicated that they intended to do so.[16] The 2009 security survey also found that 33 percent of the systems already use two-factor authentication for security.

DEA is establishing several requirements for the use of biometrics, and for the testing of the software used to read the biometrics. DEA is establishing these standards after extensive consultation with NIST, and based on NIST recommendations. A discussion of these requirements follows.

• The biometric subsystem must operate at a false match rate of 0.001 or lower.

The term "false match rate" is similar to the term "false accept rate"—it is the rate at which an impostor's biometric is falsely accepted as being that of an authorized user. DEA is not establishing a false non-match (rejection) rate; while users may be interested in this criterion, DEA does not have an interest in setting a requirement for a tolerance level for false rejections for electronic prescription applications.

• The biometric subsystem must use matching software that has demonstrated performance at the operating point corresponding with the required false match rate specified (0.001) or a lower false match rate. This testing must be performed by the National Institute of Standards and Technology (NIST) or another DEA-approved (government or non-government) laboratory.

This criterion is designed to ensure that an independent third-party has tested the software and has determined its effectiveness on a sequestered data set that is large enough for high confidence in the results, which will be made publicly available for consumers. DEA believes that the requirement to have the biometric software tested by an independent third party, as discussed further below, will provide greater assurance to electronic prescription application providers and practitioners that the biometric subsystem being used, in fact, meets DEA's requirements. NIST currently lists technologies which it has tested and their rates of performance at the following URLs: *http://fingerprint.nist.gov* for fingerprint testing, *http://face.nist.gov* for facial testing, and *http://iris.nist.gov* for iris testing.

• The biometric subsystem must conform to Personal Identity Verification authentication biometric acquisition specifications, pursuant to NIST Special Publication 800–76–1, if they exist for the biometric modality of choice.

This requirement specifies minimum requirements for the performance of the device that is used to acquire biometric data (usually an image), whereas the prior requirements relate to the software used to compare biometric samples to determine if a user is who he claims to be. NIST Special Publication 800–76–1[17] describes technical acquisition and formatting specifications for the biometric credentials of the PIV system. Section 4.2 covers sensor specifications for fingerprint acquisition for the purpose of authentication; Section 8.6 covers conformance to this specification. Section 5.2 covers both format and acquisition specifications for facial images. While the format requirements for PIV will not be required by DEA here, the normative requirements for facial image acquisition establish minimum criteria for automated face recognition, specifically the "Normative Notes," numbers 4 through 8 under Table 6. DEA also recommends using the normative values for PIV conformance in Table 6 rows 36 through 58 for frontal facial image acquisition. Currently, specifications exist only for fingerprint and face acquisitions.

DEA wishes to emphasize that the use of SP 800–76–1 does not imply that all requirements related to Federally mandated Personal Identity Verification cards apply in this context, only those specified for biometric acquisition for the purposes of authentication. PIV goes beyond this application, in that it has additional requirements for fingerprint registration (or enrollment) suitable for a Federal Bureau of Investigation background check, and the PIV credential has interoperability requirements that will not necessarily apply to users of controlled substance electronic prescription applications.

• The biometric subsystem must either be co-located with a computer or PDA that the practitioner uses to issue electronic prescriptions for controlled substances, where the computer or PDA is located in a known, controlled location, or be built directly into the practitioner's computer or PDA that he uses to issue electronic prescriptions for controlled substances.

This criterion is intended to add to the security of the biometric factor by physically controlling access to the biometric device to reduce the potential for spoofing.

• The biometric subsystem must store device ID data at enrollment (i.e., biometric registration) with the biometric data and verify the device ID at the time of authentication.

Within this context, enrollment is the process of collecting a biometric sample from a new user and storing it (in some format) locally, on a network, and/or on a token. These enrolled data are stored

[16] Healthcare Information and Management Systems Society. *2008 HIMSS Security Survey,* October 28, 2008. HIMSS, 20th Annual 2009 HIMSS Leadership Survey, April 6, 2009. *http://www.himss.org.*

[17] National Institute of Standards and Technology. Special publication 800–76–1, *Biometric Data Specification for Personal Identity Verification,* January 2007. *http://csrc.nist.gov/publications/PubsSPs.html.*

for the purpose of future comparisons when someone (whether the genuine user or an impostor) attempts to log in. To help ensure that log-in attempts are being initiated by the genuine user (as opposed to a spoofed biometric), this requirement in combination with the above requirement increase the difficulty for an impostor to spoof a biometric and remotely issue an unlawful prescription.

- The biometric subsystem must protect the biometric data (raw data or templates), match results, and/or non-match results when authentication is not local.
- If sent over an open network, biometric data (raw data or templates), match results, and/or non-match results must be:
  - Cryptographically source authenticated;
  - Combined with a random challenge, a nonce, or a timestamp to prevent replay;
  - Cryptographically protected for integrity and confidentiality;
  - Sent only to authorized systems.

The above requirements are to ensure the security and integrity for this authentication factor (a biometric), ensuring any data related to the biometric subsystem (biometric patterns and results of comparisons) are sent from an authorized source to an authorized destination and that the message was not tampered with in transit. Additionally, cryptographic protection of the biometric data addresses an aspect of the user's interests in confidentiality of personal data.

The easiest way to meet the above requirements when authentication is not local is to run a client authenticated TLS connection or a similar protocol between the endpoints of any remote communication carrying data subject to the above requirements. Another possible solution that may be used is server authenticated TLS in combination with a secure HTTP cookie at the client that contains at least 64 bits of entropy.

DEA also recognizes that biometrics application providers have a vested interest in either selling their applications directly to practitioners or electronic prescription application providers, or partnering with those electronic prescription application providers to market their applications. Therefore, as discussed above, to provide practitioners and electronic prescription application providers with an objective appraisal of the biometrics applications they may purchase and use, DEA is requiring independent testing of those applications. This testing is similar to the third-party audits or certifications of the electronic prescription and pharmacy applications DEA is also requiring. Testing of the biometric subsystem must have the following characteristics:

- The test is conducted by a laboratory that does not have an interest in the outcome (positive or negative) of performance of a submission or biometric.

DEA wishes to ensure that the testing body is independent and neutral. As noted previously, tests may be conducted by NIST, or DEA may approve other government or nongovernment laboratories to conduct these tests.

- Test data are sequestered.
- Algorithms are provided to the testing laboratory (as opposed to scores).

To the extent possible, independent testing should provide an unbiased evaluation of its object of study, which should yield repeatable, generalizable results. The above two requirements reflect the principle behind independent testing. If test participants had access to the test data used in an evaluation, they would have the opportunity to tune or augment their algorithms to maximize accuracy on that data set, but would likely fail to give a fair assessment of the algorithm's performance. Therefore, test data should not be made public before the testing period closes, and if test data are sequestered, algorithms must be provided to the independent testing laboratory for the experiment(s) to be conducted. Additionally, the latter requirement permits the independent testing laboratory to produce the results itself that are ultimately used to characterize performance.

- The operating point(s) corresponding with the false match rate specified (0.001), or a lower false match rate, is tested so that there is at least 95% confidence that the false match and non-match rates are equal to or less than the observed value.

As discussed above, testing should yield results that are repeatable. The resulting measurements of an evaluation should have a reasonably high degree of reliability. A confidence level of 95% or greater will characterize the values from an evaluation as reliable for this context.

- Results are made publicly available.

The provision of testing results to the public, either through a Web site or other means, will help to ensure transparency of the testing process and of the results. Such transparency will provide greater opportunity for interested electronic prescription application providers and others to compare results between biometrics application providers to find the biometric application that best meets their needs.

DEA recognizes the need for assurance that a captured biometric sample is obtained from a genuine user—and not a spoofed copy, particularly in unattended applications such as electronic prescriptions for controlled substances, where many users may have access to computers that contain electronic prescription applications. Liveness detection is a tool that some biometric vendors have developed to address this issue. However, since this is an active area of research that has not been standardized, DEA is not setting a specific requirement for liveness detection at this time, but will reconsider this tool in the future as industry standards and specifications are developed.

DEA emphasizes that the use of biometrics as one factor in the two-factor authentication protocol is strictly voluntary, as is all electronic prescribing of controlled substances. As noted previously, DEA wishes to emphasize that these standards do not specify the types of biometrics that may be acceptable. Any biometric that meets the criteria specified above may be used as the biometric factor in a two-factor authentication credential used to indicate that prescriptions are ready to be signed and sign controlled substance prescriptions. DEA, after extensive consultation with NIST, has written these criteria to be as flexible as possible to emerging technologies, allowing new biometrics systems to develop in the future that meet these criteria.

Because the use of biometrics and the standards related to their use were not discussed in the notice of proposed rulemaking, DEA is seeking further comment on these issues. Specifically, DEA is seeking comments in response to the following questions:

- What effect will the inclusion of biometrics as an option for meeting the two-factor authentication requirement have on the adoption rate of electronic prescriptions for controlled substances, using the proposed requirements of a password and hard token as a baseline? Do you expect the adoption rate to significantly increase, slightly increase, or be about the same? Please also indicate why.
- Is there an alternative to the option of biometrics which could result in greater adoption by medical practitioners of electronic prescriptions for controlled substances while also providing a safe, secure, and closed system for prescribing controlled substances electronically? If so, please describe the alternative(s) and indicate

how, specifically, it would be an improvement on the authentication requirements in this interim rule.

Also, based on the comments received, it appears that a number of commenters may have already implemented biometrics as an authentication credential to electronic applications. DEA is seeking information from commenters on their experiences implementing biometric authentication. DEA seeks the following information:

- Why was the decision made to adopt biometrics as an authentication credential? Why was the decision made to adopt biometrics as opposed to another option? What other options were considered?
- What are biometrics as an authentication credential used for (*e.g.,* access to a computer, access to particular records, such as patient records, or applications)?
- How many people in the practice/institution use biometric authentication (number and percentage, type of employee—practitioners, nurses, office staff, etc.)?
- What types of biometric authentication credentials are used (*e.g.,* fingerprint, iris scan, hand print)?
- How are the biometrics read, and what hardware is necessary (*e.g.,* fingerprint readers built into keyboards or mouses, on-screen biometric readers, external readers attached to computers)?
- Is biometric authentication used by itself or in combination with a user ID or password?
- How are biometric readers distributed (*e.g.,* at every computer workstation, at certain workstations based on location, allocated based on number of staff)?
- Was the adoption of biometrics part of installation of a new system or an addition to existing applications?
- How long did the implementation process take? Was the time related to implementing biometrics or other application installation issues?
- Which parts of the biometric implementation were completed without difficulty?
- What challenges were encountered and how were they overcome?
- Were workflows affected during or after implementation and, if so, how were they affected and for how long?
- How do the users feel about the use of biometrics as an authentication credential?
- Has the use of biometric authentication improved or slowed workflows? If so, how?
- Has the use of biometric authentication improved data and/or network security?
- What other benefits have been realized?

Comments. A practitioner organization recommended that the second factor be eliminated when a biometric authentication device is used.

DEA Response. DEA believes that any authentication protocol that uses only one factor entails greater risk than a two-factor authentication protocol. While DEA recognizes the strength that biometrics provide, biometric readers themselves are not infallible. They can falsely accept a biometric, or purported biometric, that does not correspond to the biometric associated with a particular user. Requiring two-factor authentication, regardless of the factors used (Something you know, something you have, and something you are), ensures a strong authentication method, which DEA believes is necessary to sign electronic prescriptions for controlled substances.

Comments. Some physician and pharmacy organizations objected to hard tokens, asserting that they are inconvenient, impractical, easily lost or shared, and generally not secure enough. They suggested tap-and-go proximity cards because, they asserted, such cards would be more cost effective. These physician organizations further noted that hospital security systems may bar the use of certain hard tokens. One application provider indicated that it had tried one-time-password devices in an application used for electronically prescribing noncontrolled substances and found they discouraged use of the application. Two large healthcare systems suggested alternative challenge-response methods as well as biometrics as another approach for closed systems.

Other commenters objected to the requirement for Level 4 security for the hard token. They noted that relatively few devices that are validated by Federal Information Processing Standards (FIPS) meet Level 4. One application provider stated that DEA's description in the proposed rule is more like Level 3 with a hard token. It asserted that Level 4 would mean that any user of the application, not just practitioners signing controlled substance prescriptions, would need Level 4 tokens. Some commenters further asserted that few devices meet FIPS 140–2 Security Level 3 for physical security. An intermediary stated the current NIST SP 800–63–1 draft definition is different from the original SP 800–63 definition; the commenter indicated that SP 800–63–1 does not require that approved cryptographic algorithms must be implemented in a cryptographic module validated under FIPS 140–2. Thus, the commenter believed, the requirements according to this new draft SP 800–63–1 could be implemented more easily.

DEA Response. DEA has revised this rule to allow the use of a hard token that is separate from the computer being accessed and that meets FIPS 140–2 Security Level 1 security or higher. Proximity cards that are smart cards with cryptographic modules could serve as hard tokens. The FIPS 140–2 requirements for higher security levels generally relate to the packaging of the token (tamper-evident coatings and seals, tamper-resistant circuitry). DEA does not consider this level of physical security necessary for a hard token.

Contrary to the intermediary's statement, NIST SP 800–63–1 does require that cryptographic modules be FIPS 140–2 validated. NIST SP 800–63–1 requires the following for one-time-password devices: "Must use approved block cipher or hash function to combine a symmetric key stored on device with a nonce to generate a one-time password. The cryptographic module performing this operation shall be validated at FIPS 140–2 Level 1 or higher." For single-factor and multi-factor cryptographic tokens at Assurance Level 2 or 3, NIST SP 800–63–1 requires: "The cryptographic module shall be validated at FIPS 140–2 Level 1 or higher."

DEA believes that NIST 800–63–1 Assurance Level 3 as described will meet its security concerns. As discussed above, DEA continues to believe that reliance on passwords alone, as a few commenters suggested, would not provide sufficient security in healthcare settings where computers are accessed and shared by staff. Many staff may be able to watch passwords being entered, and computers may be accessible to patients or other outsiders. In addition, DEA notes that practitioners might find strong passwords more burdensome than a biometric or token over the long run. Strong passwords generally need to be long (*e.g.,* 8–12 characters) with a mix of characters, to maintain security. They also need to be changed frequently (*e.g.,* every 60 to 90 days). However, imposing these password requirements would make it more likely that practitioners would simply write down passwords, thereby rendering them useless for purposes of security. In contrast to the time limits typically required for strong passwords, a token and biometrics can last for years. Although initially simpler to implement, passwords impose a burden on the user, who has to remember and key in the password, and on the application, which has to reset passwords when the user forgets them.

DEA is not allowing the use of some two-factor combinations. For example, look-up secret tokens or out-of-band tokens are not acceptable. Look-up secret tokens, which are something you have, are often printed on paper or plastic; the user is asked to provide a subset of characters printed on the card. Unlike a hard token, these tokens can be copied and used without the practitioner's knowledge, undermining non-repudiation. Out-of-band tokens send the user a message over a separate channel (*e.g.,* to a cell phone); the message is then entered with the password. Although DEA recognizes that these tokens might work, DEA doubts if they are practical because they require more time for each authentication than the other options.

Based on the comments received, it appears that a number of commenters have already implemented a variety of hard tokens (*e.g.,* proximity cards, USB devices) as an authentication credential to electronic applications. DEA is seeking information from commenters on their experiences implementing hard tokens as authentication credentials. DEA seeks the following information:

- Why was the decision made to adopt hard token(s) as an authentication credential? Why was the decision made to adopt hard tokens as opposed to another option? What other options were considered?
- What are hard token(s) as an authentication credential used for (*e.g.,* access to a computer, access to particular records, such as patient records, or applications)?
- How many people in the practice/institution use hard tokens for authentication (number and percentage, type of employee—practitioners, nurses, office staff, etc.)?
- What types of hard tokens are used (*e.g.,* proximity cards, USB drives, OTP devices, smart cards)?
- Are the hard tokens used by themselves or in combination with user IDs or passwords?
- How are the hard tokens read (where applicable), and what hardware is necessary (*e.g.,* card readers built into keyboards, external readers attached to computers)?
- How are hard token readers distributed (*e.g.,* at every computer workstation, at certain workstations based on location, allocated based on number of staff)?
- Was the adoption of hard tokens part of installation of a new system or an addition to existing applications?
- How long did the implementation process take? Was the time related to implementing hard tokens or other application installation issues?
- Which parts of the implementation were completed without difficulty?
- What challenges were encountered and how were they overcome?
- Were workflows affected during or after implementation and, if so, how were they affected and for how long?
- How do the users feel about the use of hard tokens as an authentication credential?
- Has the use of hard tokens as an authentication credential improved or slowed workflows? If so, how?
- Has the use of hard tokens as an authentication credential improved data and/or network security?
- What other benefits have been realized?

Comments. Practitioner organizations asked who will create and distribute hard tokens, and how losses, malfunctions, and application downtime will be handled. A physician stated that tokens should be able to create keys on the token immediately under user control to speed distribution and replacement that has been such a barrier in pilot work.

DEA Response. Who distributes the hard tokens will depend on the application being used. In some cases, the credential service provider, working in conjunction with the electronic prescription application provider, may distribute the hard tokens; in other cases, the credential service provider, working in conjunction with the electronic prescription application provider, may tell the practitioners what type of token is required (*e.g.,* a smart card, thumb drive, PDA), then securely register or activate the token. DEA agrees with the commenter that the latter scenario would make replacement easier because the practitioner could purchase a new token locally and obtain a new credential without having to wait for the application provider to send a new token. DEA, however, believes it is better to provide flexibility and allow credential service providers, electronic prescription application providers, and practitioners to determine how to provide and replace tokens when they are lost or malfunction.

Electronic prescription application downtime is not specific to tokens; any electronic prescription application may experience downtime regardless of the authentication method used. Practitioners will always have the option of writing controlled substance prescriptions manually.

Comments. A physician stated that there are special problems for physicians in small practices who do not normally wear institutional identification badges and have tighter time and budget constraints than large organizations. He stated that consideration should be given to allowing some exemptions for small practices or physicians who are willing to accept some risk from less than ideal authentication such as the use of biometrics as a substitute for cryptographic two-factor authentication or use of private keys or other cryptographic secrets protected by software installed on computers in a limited controlled office environment that would allow operation with only the PIN from a defined set of computers that were shared in a small practice. The commenter asserted that the cost of cryptographic tokens is not large, but a potential barrier nonetheless.

DEA Response. As discussed above, DEA is allowing the use of biometrics as an alternative to hard tokens, as one factor in the two-factor authentication protocol. DEA disagrees, however, with allowing an exception from two-factor authentication for small practices. DEA recognizes the constraints on small practices, but believes that the interim final rule, which allows Level 3 tokens and biometrics, will make it easier for small practices. One-factor authentication, such as a PIN, will not provide adequate security, particularly in a small practice where passwords may be more easily guessed than in a large practice because the office staff will be familiar with the words a practitioner is most likely to use (*e.g.,* nickname, favorite team, child's or pet's name).

Comments. A State agency reported on a vendor that uses a security matrix card; prescribers log on using a password and user ID and then have to respond to a challenge that corresponds to three interstices on the card. The commenter asserted that the challenge is unique to the provider, different every time, and only the card will provide the correct response. The commenter asserted that although there are some vulnerabilities, it is simple and inexpensive.

DEA Response. DEA believes that such devices can be vulnerable as they may be physically reproduced and provided to others, or reproduced and used by others without the practitioner's knowledge. For that reason, DEA does not believe that these types of authentication tokens address DEA's concerns. Hard tokens are tangible, physical, objects, possessed by a practitioner. Giving this tangible, physical object to another person takes a specific physical act on the part of the practitioner. That act is difficult for the practitioner to deny, and thus strengthens the value of hard tokens as a method of security.

Comments. A pharmacy association and an application provider asked whether practitioners would need multiple tokens if they used multiple applications.

DEA Response. The number of tokens that a practitioner will need will depend on the applications and their requirements. It is possible that multiple authentication credentials could be stored on a single token (*e.g.,* on a smart card or thumb drive). If a practitioner accesses two applications that require him to have a digital certificate, it is possible that a single digital certificate could be used for both.

D. Creating and Signing Electronic Controlled Substance Prescriptions

DEA proposed that controlled substance prescriptions must contain the same data elements required for paper prescriptions. DEA proposed that, as with paper prescriptions, practitioners or their agents would be able to create a prescription. When the prescription was complete, DEA proposed that the application require the practitioner to complete the two-factor authentication protocol. The application would then present at least the DEA-required elements for review for each controlled substance prescription and the practitioner would have to positively indicate his approval of each prescription. Prior to signing, the proposed rule would have required the practitioner to indicate, with another keystroke, agreement with an attestation that he had reviewed the prescription information and understood that he was signing the prescription. The practitioner would then have signed the prescription for immediate transmission. If there was no activity for more than two minutes after two-factor authentication, the application would have been required to lock out the practitioner and require reauthentication to the signing function. The first intermediary that received the prescription would have been required to digitally sign and archive the prescription.

1. Reviewing Prescriptions

DEA proposed that the application present to the practitioner certain prescription information including the patient's name and address, the drug name, strength, dosage form, quantity prescribed, directions for use, and the DEA registration number under which the prescription would be authorized. DEA further proposed to require the practitioner to indicate those prescriptions that were ready to be signed.

DEA proposed allowing practitioners to indicate that prescriptions for multiple patients were ready for signing and allow a single signing to cover all approved prescriptions.

Comments. A number of commenters were concerned about the data elements that must be presented to practitioners for review. Two application providers stated that the data elements should be limited because too much data will be confusing. They asserted that the patient's address is unlikely to be useful to practitioners as patients are usually identified by name and date of birth; it is unlikely that most practitioners would recognize an address as incorrect. They also expressed their view that the practitioner did not need to see the DEA registration number associated with the prescription.

A practitioner organization expressed agreement with the requirement in the proposed rule that prior to the transmission of the electronic prescription, the application should show a summary of the prescription. It noted that while National Council for Prescription Drug Programs (NCPDP) SCRIPT provides fields and codes for all required data, not all are mandatory. In addition, this commenter indicated some applications do not show all of the DEA-required prescription information. The commenter asked how applications will be updated and/or modified to meet the specifications required in the proposed rule. Another commenter, an application provider, stated that developers will have to redesign the applications at the screen level and at the user permission level, which will add costs. An insurance organization stated that the current NCPDP standards do not accommodate the described process and will have to be revised to conform next generation electronic prescribing software to the DEA requirements. The commenter believed that this would create another delay in the eventual use of electronic prescribing for controlled substances.

DEA Response. DEA has revised the rule to limit the required data displayed for the practitioner on the screen where the practitioner signs the controlled substance prescription to the patient's name, drug information, refill/fill information, and the practitioner information. If there are multiple prescriptions for a particular patient, the practitioner information and the patient name could appear only once on the screen. The refill information, if applicable, will be a single number. For Schedule II substances, if a practitioner is writing prescriptions indicating the earliest date on which a pharmacy may fill each prescription under § 1306.12(b), these dates will also have to appear, consistent with the current requirement for paper prescriptions. DEA emphasizes that although this rule allows for one element of the required controlled substance prescription information (the patient's address) not to appear on the review screen, the controlled substance prescription that is digitally signed by either the application or the practitioner and that is transmitted must include all of the information that has always been required under 21 CFR part 1306.

DEA realizes that many application providers will have to update their applications, but it notes that most perform regular updates and upgrades. They may choose to incorporate the changes required by these regulations as part of a regular revision cycle.

Comments. A few application providers objected to requiring a review of the prescription information by the practitioner prior to signing, stating that this is not required for paper prescriptions.

DEA Response. DEA recognizes that it is possible that some applications currently in use for the prescribing of noncontrolled substances might not require the practitioner to review prescription data prior to signing. Nonetheless, with respect to the prescribing of controlled substances, a practitioner has the same responsibility when issuing an electronic prescription as when issuing a paper prescription to ensure that the prescription conforms in all respects with the requirements of the CSA and DEA regulations. This responsibility applies with equal force regardless of whether the prescription information is entered by the practitioner himself or a member of his staff. Whether the prescription for a controlled substance is on paper or in electronic format, it would be irresponsible for a practitioner to sign the prescription without carefully reviewing it, particularly where the prescription information has been entered by someone other than the practitioner. Careful review by the practitioner of the prescription information ensures that staff or the practitioner himself has entered the data correctly. Doing so is therefore in the interest of both the practitioner and patient. Electronic prescriptions are expected to reduce prescription errors that result from poor handwriting, but as reports by Rand Health have stated, the applications create the potential for new errors that result from keystroke

mistakes.[18] Rand Health reported many electronic prescribing applications are designed to create a prescription using a series of drop down menus; some of the applications do not display the information after it is selected so that keystroke errors (*e.g.,* selecting the wrong patient or drug) may be difficult to catch. Comments on the proposed rule from a State Pharmacy Board indicate that such keystroke errors do occur in electronic prescriptions. Recent research on electronic prescribing in the United States and Sweden also found that electronic prescriptions have problems with missing and incorrect information, which indicates that the applications allow prescriptions to be transmitted without information in the standard prescription fields.[19] A review screen should alert practitioners to these problems. DEA notes that a number of electronic prescription application providers indicated that their applications already meet this practitioner review requirement.

Comments. Practitioner organizations expressed the view that checking an "all" box should be sufficient if a practitioner approves all of the prescriptions displayed, as opposed to indicating each prescription approved individually. Two State agencies, an information technology organization, and application providers objected to DEA's proposal to allow signing of prescriptions for multiple patients at one time. Some commenters believed that allowing practitioners to sign prescriptions for multiple patients at one time posed health and safety risks for the patients. Others stated that the prescriber might not notice fraudulent prescriptions in a long list.

DEA Response. DEA agrees that allowing practitioners to simultaneously issue multiple prescriptions for multiple patients with a single signature increases the likelihood of the potential detrimental consequences listed by the commenters. Accordingly, DEA has revised the rule to allow signing of multiple prescriptions for only a single patient at one time. Each controlled substance prescription will have to be indicated as ready for signing, but a single two-factor authentication can then sign all prescriptions for a given patient that the practitioner has indicated as being ready to be signed. DEA notes that many patients who are prescribed controlled substances receive only one controlled substance prescription at a time.

2. Timing of Authentication, Lockout, and Attestation

DEA proposed that the practitioner would use his two-factor authentication credential to access the review screen. The practitioner would indicate those prescriptions ready to be signed. Prior to signing, DEA proposed that the practitioner indicate agreement with the following statement: "I, the prescribing practitioner whose name and DEA registration number appear on the controlled substance prescription(s) being transmitted, have reviewed all of the prescription information listed above and have confirmed that the information for each prescription is accurate. I further declare that by transmitting the prescription(s) information, I am indicating my intent to sign and legally authorize the prescription(s)." If there was no activity for two or more minutes, the application would have to lock him out; he would have to reauthenticate to the application before being able to continue reviewing or signing prescriptions.

Comments. DEA received a substantial number of comments on the timing of authentication and signing, lockout, and attestation. An application provider organization stated that delegating prescription-related tasks (*e.g.,* adding pharmacy information) to practitioner staff is a vital step in the prescribing process. The commenter believed that requiring all such tasks to occur before the practitioner approves and signs the prescription would change the workflow in practitioners' offices. The application provider recommended that DEA allow for variable workflows in which ancillary information regarding the prescription, such as which destination pharmacy to send to, may be completed by the nurse after signing, but all other data specific to the medication dispensed be locked down and only editable by the prescribing practitioner. Another application provider suggested revising the requirement for reviewing and indicating that a prescription is ready to sign to read: "* * * where more than one prescription has been prepared at any one time[,] * * * prior to the time the practitioner authenticates to the application, the application must make it clear which prescriptions are to be signed and transmitted." This commenter expressed the view that although this may seem like a subtle distinction, the user interface design of electronic prescribing applications is variable, and many applications already clearly show the user which prescriptions are awaiting signature and transmittal (for instance, by displaying them in a different frame on the screen or in a different color). The commenter asserted that a requirement that the user take further action to specify the prescriptions he/she will sign would be superfluous.

Commenters generally expressed concern about the additional keystrokes required to take these steps, stating that each new keystroke adds to the burden of creating an electronic prescription and discourages use of electronic prescriptions. An insurance organization stated that the process DEA proposed would require at least three practitioner confirmations of the electronic prescription. The commenter asserted that the more steps in the process, the less the workflow integration with current electronic prescribing workflow, and the increased potential for the reversion to written prescriptions. Another insurance organization stated the process of reviewing and signing should be streamlined. The commenter believed the process proposed by DEA seemed to have five steps with three confirmations.

Commenters were particularly concerned about the 2-minute lockout period. They were unsure whether it applied to the initial access to the application or to access to the signing function. A number of application providers stated that requiring two-factor authentication to sign the prescription would be more effective and eliminate the need for a lockout; that is, they advocated making the use of the two-factor authentication synonymous with signing a controlled substance prescription. One practitioner organization stated that the authentication and lockout could interrupt work flows; access to other functions of the electronic medical record must be available with the authentication. The application providers also noted that lockouts are easy to implement.

Those commenters who addressed the attestation statement expressed opposition to it. They emphasized that a practitioner must comply with the Controlled Substances Act and its implementing regulations in the prescribing of any controlled substance. Some were of the view that the statement did not serve any new purpose or address any new requirement. They emphasized that such a statement is not required for written prescriptions. Commenters

[18] Bell, D.S., *et al.,* "A Conceptual Framework for Electronic Prescribing," *J Am Med Inform Assoc.* 2004; 11:60–70.

[19] Warholak, T.L. and M.T. Mudd. "Analysis of community chain pharmacists' interventions on electronic prescriptions." *J. Am. Pharm. Assoc.* 2009 Jan–Feb; 49(1): 59–64.

Astrand, B. *et al.* "Assessment of ePrescription Quality: an observational study at three mail-order pharmacies." *BMC Med Inform Decis Mak.* 2009 Jan 26; 9:8.

further stated that they believed it would be an annoyance, and that practitioners would not read it, but would simply click it and move on. They also asserted that each additional step DEA added to the creation of an electronic prescription made it more likely that practitioners would decide to revert to paper prescriptions. Many individual practitioners indicated they found the statement unnecessary and demeaning. A few commenters stated that if DEA believed this was essential, it should be a one-time notice, similar to licensing agreements that appear on first use of a new application.

A number of organizations stated that they believed a better approach would be to present a simple dialog box with a clear and short warning that a prescription for a controlled substance is about to be signed. Some suggested this dialog could have three buttons: Agree, Cancel, and Check Record. Some commenters also noted that when prescribers get prescription renewal requests (for noncontrolled substances) in their electronic medical record applications now they have to minimize or temporarily "cancel" the request, check the chart for appropriateness, and then click yes or no. Commenters believed that the proposed rule does not seem to include this necessary capability.

DEA Response. DEA has revised the rule to limit the number of steps necessary to sign an electronic controlled substance prescription to two. Practitioners will not have to use two-factor authentication to access the list of prescriptions prior to signing. When they review prescriptions, they will have to indicate that each controlled substance prescription is ready for signing, then, as some commenters recommended, use their two-factor authentication credential to sign the prescriptions. If the information required by part 1306 is altered after the practitioner indicated the prescription was ready for signing, a second indication of readiness for signing will be required before the prescription can be signed.

As discussed previously, DEA has revised the rule to limit the required data displayed for the practitioner on the screen where the practitioner signs the controlled substance prescription to the patient's name, drug information, refill/fill information, and the practitioner information. The requirement in the proposed rule that the patient's address be displayed on the screen at this step of the process has been eliminated. (However, consistent with longstanding requirements for controlled substance prescriptions, the patient's address must be included in the prescription data transmitted to the pharmacy.) Because DEA is requiring that the application digitally sign the information required by the DEA regulations at the time the practitioner signs the prescription, additional non-DEA-required information (*e.g.,* pharmacy URL) could also be added after signing. (See discussion below.) Using two-factor authentication as the signing function eliminates the need for the lockout requirement and, therefore, this rule contains no such requirement.

DEA has revised the rule to eliminate a separate keystroke for an attestation statement and adopted the suggestion of some of the commenters that the statement be included on the screen with the prescription review list. Further, DEA has revised the statement displayed. The statement will read: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above." The practitioner will not be required to take any action with regard to the statement. Rather, the statement is meant to be informative and thereby eliminate the possibility of any uncertainty as to the significance of completing the two-factor authentication protocol at that time and the limitation on who may do so. The only keystrokes that the practitioner will have to take will be to indicate approval of the prescription and affix a legal signature to the prescription by execution of the two-factor authentication protocol. DEA notes that some applications already present practitioners with a list of prescriptions ready to be signed and require their approval. For these applications, only the two-factor authentication will be a new step.

3. Indication That the Prescription Was Signed

Because the National Council for Prescription Drug Programs SCRIPT standard does not currently contain a field for the signature of a prescription, DEA proposed that the prescription record transmitted to the pharmacy must include an indication that the practitioner signed the prescription. This indication could be a single character.

Comments. An application provider organization stated that existing logic in audit trails should cover the requirement for an indication that the prescription was signed. When a practitioner sends the prescription, the prescription is associated with the practitioner. One electronic prescription application provider objected to the addition of a field indicating that the prescription has been signed and asked whether the pharmacy could fill the prescription if the field was not completed. A standards development organization stated that DEA would have to request the addition of the field to NCPDP SCRIPT. Two application providers stated that without a prescription and signature format, there is no way to verify the signature.

DEA Response. DEA is not specifying by regulation how the field indicating that a prescription has been signed could be formatted, only that such a field must exist and that electronic prescription applications must indicate that the prescription has been signed using that particular field. As DEA noted in the NPRM, the field indicating that the prescription was signed could be a single character field that populates automatically when the practitioner "signs" the prescription. DEA is not requiring that a signature be transmitted. The field is needed to provide the pharmacy assurance that the practitioner in fact authorized the prescription. Although most existing applications may not transmit the prescription unless the prescription is approved or signed, and DEA is making that an application requirement, the pharmacy has no way to determine whether the electronic prescription application the practitioner used to write the prescription meets the requirement absent an indication that the prescription was signed. The prescription application's internal audit trail is not available to the pharmacist who has to determine whether he can legally dispense the medication. If a pharmacy receives an electronic prescription for a controlled substance in which the field indicates that the prescription has not been signed, the pharmacy must treat this as it would any written prescription that does not contain a manual signature as required by DEA regulations.

The required contents for an electronic prescription for a controlled substance set forth in the interim final rule are the same contents that have long been required under the DEA regulations for all paper and oral prescriptions for controlled substances. As with all regulations issued by any agency, the DEA regulations are publicly available, every standards organization and application provider has access to them, and all persons subject to the regulations are legally

obligated to abide by them. If any organization or application provider wants its standard or application to be compliant with the regulations and, therefore, usable for controlled substance prescriptions, they need only read the regulations and make any necessary changes.

Comments. A standards organization asked how the signature field affected nurses that act as agents for practitioners and nurses at LTCFs who are given oral prescription orders.

DEA Response. Longstanding DEA regulations allow agents of a practitioner to enter information on a prescription for a practitioner's manual signature and also permit practitioners to provide oral prescriptions to pharmacies for Schedule III, IV, and V controlled substances. Nurses, who are not DEA registrants, are not allowed to sign controlled substances prescriptions on behalf of practitioners regardless of whether the prescription is on paper or electronic. Accordingly, whether in the LTCF setting or otherwise, nurses may not be given access to, or use, the practitioner's two-factor authentication credential to sign electronic prescriptions for controlled substances.

4. Other Prescription Content Issues

DEA proposed that only one DEA number should be associated with a controlled substance prescription.

Comments. A number of commenters associated with mid-level practitioners stated that some State laws require that a controlled substance prescription from a mid-level practitioner must contain the practitioner's supervisor's DEA registration number as well as the mid-level practitioner's DEA registration number. Other commenters noted that under § 1301.28 a DEA identification number is required in addition to the DEA registration number on prescriptions written by practitioners prescribing approved narcotic controlled substances in Schedules III, IV, or V for maintenance or detoxification treatment. Other commenters stated that the DEA requirements for paper prescriptions include, for practitioners prescribing under an institutional practitioner's registration, the special internal code assigned by the institutional practitioner under §§ 1301.22 and 1306.05. These commenters stated that NCPDP SCRIPT does not accommodate the special internal codes, which do not have a standard format, nor do most pharmacy computer applications. They also noted that a pharmacy has no way to validate the special internal codes.

DEA Response. DEA's concern with multiple DEA numbers on a single prescription is based on a need to be able to identify the prescribing practitioner. The interim final rule allows multiple DEA numbers to appear on a single prescription, if required by State law or regulations, provided that the electronic prescription application clearly identifies which practitioner is the prescriber and which is the supervisor. NCPDP SCRIPT already provides such differentiation.

DEA is aware of the issue of internal code numbers held by individual practitioners prescribing controlled substances as agents or employees of hospitals or other institutions under those institutions' registrations pursuant to § 1301.22(c). DEA published an Advance Notice of Proposed Rulemaking (74 FR 46396, September 9, 2009) to seek information that can be used to standardize these data and to require institutions to provide their lists of practitioners eligible to prescribe controlled substances under the registration of the hospital or other institution to pharmacies on request.

The problem with special codes for individual practitioners prescribing controlled substances using the institutional practitioner's registration and the DEA-issued identification number for certain substances used for detoxification and maintenance treatment is that SCRIPT does not currently have a code to identify them. Codes exist that identify DEA numbers and State authorization numbers; the fields are then defined to limit them to the acceptable number of characters. The general standard for the identification number field, however, is 35 characters. It should, therefore, be possible for NCPDP to add a code for an institution-based DEA number that allows up to 35 characters, with the first nine characters in the standard DEA format; the remaining characters should be sufficient to accommodate most institutional coding systems until DEA and the industry can standardize the format. Similarly, NCPDP should be able to add a code for the identification number for maintenance of detoxification treatment. Free text fields may also need to be used to incorporate other information required on certain prescriptions; for example, part 1306 requires that prescriptions for gamma hydroxybutyric acid the practitioner must indicate the medical need for the prescription; for certain medications being used for maintenance or detoxification treatment, the practitioner must include an identification number in addition to his DEA number.

On the issue of the inability of pharmacies to validate the special code assigned by an institutional practitioner to individual practitioners permitted to prescribe controlled substances using the institution's DEA registration, DEA notes that the "validation" that some pharmacy applications conduct simply confirms that the DEA number is in the standard format and conforms to the formula used to generate the DEA registration numbers. The validation does not confirm that the number is associated with the prescriber listed on the prescription or that the registration is current and in good standing. To confirm the actual validity of the DEA number, the pharmacy would have to check the DEA registration database using the Registration Validation tool available at the Office of Diversion Control Web site (*http://www.DEAdiversion.usdoj.gov*). If a pharmacy has reason to question any prescription containing special identification codes for individual practitioners, it must contact the institutional practitioner.

DEA recognizes that revisions to the SCRIPT standard to accommodate identification codes for individual practitioners prescribing controlled substances using the institutional practitioner's registration, identification numbers for maintenance or detoxification treatment, and dates before which a Schedule II prescription may not be filled may not occur immediately as they have to be incorporated into a revision to the standard that is subject to the standards development process. Application providers will then have to incorporate the new codes into their applications.

Because DEA does not want to delay implementation of electronic prescribing of controlled substances for any longer than is necessary to accommodate the main provisions of the rule, DEA has added provisions to §§ 1311.102 ("Practitioner responsibilities."), 1311.200 ("Pharmacy responsibilities."), and 1311.300 ("Third-party audits.") to address the short-term inability of applications to handle information such as this accurately and consistently. DEA is requiring that third-party auditors or certification organizations determine whether the application being tested can record, store, and transmit (for an electronic prescription application) or import, store, and display (for a pharmacy application) the basic information required under § 1306.05(a) for every controlled substance prescription, the indication that the prescription was signed, and the number of refills. Any application that cannot perform these functions must not be approved, certified, or used for

controlled substance prescriptions. The third-party auditors or certification organizations must also determine whether the applications can perform these functions for the additional information required for a subset of prescriptions; currently this information includes the extension data, the special DEA identification number, the dates before which a prescription may not be filled, and notes required for certain prescriptions. If a third-party auditor or certification organization reports that an application cannot record, store, and transmit, or import, store, and display one or more of these data fields, the practitioner or pharmacy must not use the application to create, sign and transmit or accept and process electronic prescriptions for controlled substances that require this information.

Comments. Some commenters stated that the requirement that the prescription be dated would remove the ability to create several Schedule II prescriptions for future filling.

DEA Response. DEA does not allow practitioners to post-date paper prescriptions as some commenters seemed to think. Under § 1306.05(a), all prescriptions for controlled substances must be dated as of, and signed on, the day when issued. Under § 1306.12(b), practitioners are allowed to issue multiple prescriptions authorizing the patient to receive up to a 90-day supply of a Schedule II controlled substance provided, among other things, the practitioner indicates the earliest date on which a pharmacy may fill each prescription. These prescriptions must be dated on the day they are signed and marked to indicate the earliest date on which they may be filled. All of these requirements can (and must) be satisfied when a practitioner elects to issue multiple prescriptions for Schedule II controlled substances by means of electronic prescriptions. At present, it is not clear that the SCRIPT standard accommodates the inclusion of these dates or that pharmacy applications can accurately import the data. As noted in the previous response, until applications accurately and consistently record and import these data, applications must not be used to handle these prescriptions.

Comments. One application provider stated that DEA should not include the practitioner's name, address, and DEA number on the review screen because, in some cases, prescriptions are written for one of several practitioners in a practice to sign. This commenter stated that with paper prescriptions, there is no indication other than the signature as to which practitioner signed the prescription. A State pharmacist association asked DEA to require that the prescription include the practitioner's phone number and authorized schedules.

DEA Response. Only a practitioner who has issued the prescription to the patient for a legitimate medical purpose in the usual course of professional practice may sign a prescription. As stated above, the requirements for the information on an electronic prescription are the same as those for a paper prescription. DEA notes that the NCPDP SCRIPT standard includes a field for telephone number, but DEA is not requiring its use. If a pharmacist has questions about a practitioner's registration and schedules, the pharmacist can check the registration through DEA's Web site.

Comments. One company recommended registering actual written signatures and associating them with electronic prescriptions. A State asked that digital ink signatures be recognized and be allowed on faxes; this would allow people to avoid using SureScripts/RxHub, which the commenter indicated is expensive.

DEA Response. DEA does not believe there is any way to allow the foregoing signature methods while providing an adequate level of assurance of non-repudiation. Verification of a manually written signature depends on more than the image of the signature.

5. Transmission on Signing/Digitally Signing the Record

DEA proposed that the electronic prescription would have to be transmitted immediately upon signing. DEA proposed that the first recipient of the electronic prescription would have to digitally sign the record as received and archive the digitally signed copy. The digital signature would not be transmitted to the other intermediaries or the pharmacy.

Comments. Some commenters disagreed with the requirement that prescriptions be transmitted on signing. A practitioner organization and a health information technology group supported the requirement, but stated that DEA should word this so the intent is clear that the electronic prescription application is to be configured to electronically transmit the prescription as soon as it has been signed by the prescriber. They stated that DEA must make it clear that an electronic prescription is not considered to be "transmitted" unless it has been successfully received by the pharmacist who will fill the prescription, and an acknowledgment has been returned to the prescriber's application. An application provider stated that DEA should remove the requirement for instant transmission of prescription data: Many electronic prescribing applications use processes where pending messages are stored and, with a fixed periodicity of 10 seconds, transmitted to electronic prescribing networks. The commenter believed that this requirement might require complete re-architecting of these processes, which would create a substantial burden on electronic prescribing application developers. A chain pharmacy stated that DEA should allow the prescriber the option to put the prescription in a queue or to immediately transmit. The commenter suggested that if opting to hold in a queue, the prescriber would have to approve prior to sending. If, however, the prescription is automatically held in a queue due to connectivity problems, the prescriber should not be required to re-approve the prescription.

A standards organization recommended extending to long-term care facilities (LTCFs) the option allowed to Federal health care agencies where the prescription may be digitally signed and "locked" after being signed by the practitioner, while allowing other facility-determined information, such as resident unit/room/bed, times of administration, and pharmacy routing information to be added prior to transmission. The commenter noted that these additional data elements are distinct from the prescription data required by § 1306.05(a). The commenter explained that this digitally signed version would be archived and available for audit. The organization stated that its recommended process matches a key aspect of the accepted LTCF order workflow, where the nursing facility reviews each physician order in the context of the resident's full treatment regimen and adds related nursing and administration notes. The commenter explained that after review and nursing annotation, the prescription is forwarded to the appropriate LTC pharmacy. By requiring that the prescription be digitally signed immediately after the physician's signature (or upon receipt if the facility system is the first recipient of the electronic prescription), this rule could appropriately be extended to non-Federal nursing facilities, enabling them to meet existing regulations requiring review of resident medication orders by facility nursing staff prior to transmission to the pharmacy. A pharmacist organization, whose members work in LTCFs and similar facilities, stated that the rule may be impossible to put into operation without

fundamental changes to pharmacy practice and workflow. Other commenters also stated that the workflow at LTCFs mean that nurses generally enter information about prescriptions into records and transmit them to pharmacies. The standards organization recommended a modification to allow nursing staff at LTCFs to review, but not change, the prescription before transmission. The commenter asserted that this modification would enable consultation with the prescriber regarding potential conflicts in the care of the resident, and could prevent dispensing of duplicate or unnecessary controlled medications. Further, the commenter asserted that this change would resolve a conflict between the proposed rule and existing nursing home regulations, which call for review of resident medication orders by facility nursing staff prior to their transmission to the pharmacy.

On the issue of having the first recipient digitally sign the DEA-required information, some commenters asked about the identity of the first recipient. One application provider expressed the view that unless the application provider is the first recipient, it cannot be held responsible for the digital signing and archiving. Where the first processor is a third-party aggregator, this commenter asserted, it should be responsible for complying. An application provider organization stated that adding a digital signature will greatly increase the storage cost of transaction data.

One application provider stated that if the prescription is created on an Internet-based application, such as one on which the prescriber uses an Internet browser to access the application, the prescription would actually be digitally signed on the Internet-based application provider's servers by the prescriber. Therefore, the initial digital signature archived on the Internet-based prescribing application would be that of the prescriber, created using the hardware cryptographic key, rather than that of the application provider. The commenter indicated that in this case, the application network provider, rather than the electronic prescription application provider, should digitally sign the prescription with its own digital signature and archive the digitally signed version of the prescription as received. The commenter asserted that for true ASP applications (Web-based applications), the prescriber is actually digitally signing the prescription at the server. It is not necessary, this commenter indicated, for the Web-based electronic prescription application provider to sign also. Some commenters thought that every intermediary would be required to digitally sign and archive a copy. A State board of pharmacy said the first recipient should not have to digitally sign the prescription unless the first recipient is the pharmacy. The responsible pharmacist should have to digitally sign the prescription.

An application provider stated that the combination of authentication mechanisms, combined with reasonable security measures by the practice (*e.g.,* at a minimum, not sharing or writing down passwords), is sufficient to prevent abuse. Additionally, this commenter indicated, the audit logs should be sufficient to recognize and document fraud or forgery. The commenter stated that the requirement for digitally signing the record should be dropped.

DEA Response. DEA has revised the rule to eliminate the need for signing and transmission to occur at the same time. Under the proposed rule, the application of the digital signature to the information required under part 1306 would have occurred after transmission. Hence, under the proposed rule, it was critical that the information be transmitted immediately so that the DEA-required information could not be altered after signature but before transmission. Under the interim final rule, however, the application will apply a digital signature to and archive the controlled substance prescription information required under part 1306 when the practitioner completes the two-factor authentication protocol. Alternatively, the practitioner may sign the controlled substance prescription with his own private key. Because of the digital signature at the time of signing, the timing of transmission is less critical. DEA expects that most prescriptions will be transmitted as soon as possible after signing, but recognizes that practitioners may prefer to sign prescriptions before office staff add pharmacy or insurance information. In long-term care facilities, nurses may need to transfer information to their records before transmitting. By having the application digitally sign and archive at the point of two-factor authentication, practitioners and applications will have more flexibility in issuing and transmitting electronic prescriptions.

DEA does not believe that the security mechanisms that the application provider cited at a practitioner's office would sufficiently provide for non-repudiation. DEA disagrees with the State Board of Pharmacy that the first recipient or the electronic prescription application need not digitally sign the record. Unless the record is digitally signed before it moves through the transmission system, practitioners would be able to repudiate prescriptions by claiming that they had been altered during transmission (inadvertently or purposefully). The only way to prove otherwise would be to obtain (by subpoena or otherwise) all of the audit log trails from the intermediaries, assuming that they retained them. As DEA is not requiring the intermediaries to retain records or audit trails, it might not be possible to obtain them. In addition, unless a practitioner was transmitting prescriptions to a single pharmacy, the number of intermediaries involved could be substantial; although the practitioner's application might use the same routers to reach SureScripts/RxHub or its equivalent, each of the recipient pharmacies may rely on different intermediaries.

6. PKI and Digital Signatures

DEA proposed an alternative approach, limited to Federal healthcare facilities, that would be based on public key infrastructure (PKI) and digital signature technology. Under this approach, practitioners would obtain a digital certificate from a certification authority (CA) cross-certified with the Federal Bridge CA (FBCA) and use the associated private key to digitally sign prescriptions for controlled substances. DEA proposed this approach based on requests from Federal health care agencies that have implemented PKI systems. Those agencies noted that the option DEA proposed for all health care practitioners did not meet the security needs of Federal health care agencies.

Comments. A number of commenters, including practitioner associations, one large chain drug store, several electronic prescription application providers, and organizations representing computer security interests asked DEA to allow any practitioner or provider to use the digital signature approach, as an option. A pharmacist organization and a standards development organization stated that long-term care facilities should be able to use this approach. A practitioner organization and a healthcare management organization stated that the system would be more secure, and prescribers' liability would be reduced, if prescribers could digitally sign prescriptions. Three application providers preferred applying a practitioner's digital signature rather than a provider's. They stated that the added burden to the electronic health record is authentication using smart-cards (of a well known format), and that it can wrap the NCPDP SCRIPT prescription in XML-Digital signature

envelop with a signature using the identity of the authenticated user. The commenters stated that the added burden to the healthcare provider is the issuance of a digital certificate that chains to the Federal PKI, possibly SAFE Biopharma or possibly extending the Federal PIV card. A State pharmacist organization asked why DEA is in favor of a system that is less secure than the one Federal health agencies use.

Some commenters noted that although the current system, based on intermediaries, makes use of digital signatures difficult, changes in technology may make it feasible in the future. In addition, for healthcare systems with their own pharmacies, a PKI-based approach would be feasible now. An intermediary stated that NCPDP SCRIPT could not accommodate a digital signature, but other IT organizations argued that this is not necessarily true. One information technology security firm stated that companion standards to NCPDP SCRIPT standard in XML and HL7, which ought to be considered, include the W3C's XML digital signature standard (XML–DSig) and the Document Digital Signature (DSG) Profile. Several application providers stated:

> The prescription should be digitally signed using encapsulated XML Digital Signature with XADES profile. The specific profile is recognized for optional use by CCHIT [the Certification Commission for Healthcare Information Technology] in S28. This is fully specified in HITSP C26 for documents, which points at the IHE DSG profile. HITSP C26 and IHE DSG profile uses detached signatures on managed documents. This might be preferred as it would have the least impact on the existing data flow, or further profiling could support encapsulation if necessary. CCHIT S28 is not fully clear and has not yet been tested.

An information technology organization stated that DEA should require PKI. The government has a highly secure, interoperable digital identity system for Federal agencies and cross-certified entities through FBCA. The commenter asserted that this system should provide the framework for DEA's rule for electronic prescribing of controlled substances. The commenter believed that it is a widely available and supported system that provides the level of security, non-repudiability, interoperability, and auditability required by legislation covering the prescribing of controlled substances. The commenter stated that such a system would provide strong evidence that the original prescription was signed by a DEA-registered practitioner, that it was not altered after it was signed and transmitted, and that it was not altered after receipt by the pharmacist.

An information technology provider suggested the application allow the end users to choose credential types, including PKI and/or One Time Password (OTP) credentials, and recommended end users be permitted to use their existing PKI credentials if their digital certificates met Federal Medium Assurance requirements and are issued from a CA that is cross-certified with the Federal Bridge. The commenter asserted that it is expected that there will be a number of service providers who will offer a turnkey PKI service to issue digital certificates for non-Federal entities that meet these requirements. This would lower costs for the overall system and would foster a stronger adoption curve for end users because they may be able to use a device they already possess to secure online accounts.

A PKI system designer noted that digital signatures can be used for any data. Once prescription and pharmacy applications are using the same version of SCRIPT the commenter believed there will be no need for conversion of prescriptions from one software version to another. The commenter further asserted that:

> * * * prescriptions need not be sent in a format that can be immediately interpreted by a pharmacy computer. It would be efficient, but it is not necessary. Free text messages can be digitally signed, too. * * * Free text messages may not be as efficient as NCPDP SCRIPT messages, but they do the job, just as the scores of faxes or paper-based prescriptions do, only better and faster.

Another information technology firm noted that digital signatures work for systems as simple as email and PDF. The commenter stated that Adobe Acrobat is capable of performing signature validation and checking for certificate revocation using either a Certificate Revocation List (CRL) or an Online Certificate Status Protocol (OCSP) request.

An intermediary further stated that the FIPS 186–2 Digital Signature Standard published in January 2000 has some shortcomings that are addressed in the current draft version FIPS 186–3 of the standard. The commenter believed these shortcomings relate to the signature schemas. The commenter asserted that FIPS 186–2 does not support RSA signature schemes according to Public Key Cryptography Standard (PKCS) #1 version 2.1, which is a widely used industry standard. The commenter indicated that PKCS#1 is added to the FIPS 186–3 draft for the Digital Signature Standard. Therefore, the commenter asserted, signatures according to PKCS#1 version 2.1 (RSASSA–PKCS1-v1_5 and RSASSA–PSS) should also be considered as appropriate for electronic prescriptions for controlled substances. This same commenter asserted that the minimum key sizes for digital signatures should meet the requirements specified in NIST SP 800–57 Part 1.

DEA Response. DEA agrees with the practitioner organizations and other commenters that the digital signature option should be available to any practitioner or group that wants to adopt it and has revised the interim final rule to provide this option to any group. DEA believes it is important to provide as much flexibility as possible in the regulation and accommodate alternative approaches even if they are unlikely to be widely used in the short-term. DEA notes that a number of commenters, including a major pharmacy chain, anticipate that once the SCRIPT standard is mature, the intermediaries will no longer be needed and prescriptions will then move directly from practitioner to pharmacy as they do in closed systems. At that point, the PKI/digital signature approach may be more efficient and provide security benefits. In the short-term, some closed systems may find this approach advantageous. DEA emphasizes that the use of a practitioner digital signature is optional. DEA is including the option to accommodate the requirements of existing Federal systems and to provide flexibility for other systems to adopt the approach in the future if they decide that it would provide benefits for them.

Under the interim final rule, using a private key to sign controlled substance prescriptions will be an option provided that the associated digital certificate is obtained from a certification authority that is cross-certified with the Federal PKI Policy Authority at a basic assurance level or above. The electronic prescription application will have to support the use of digital signatures, applying the same criteria as proposed for Federal systems. The private key associated with the digital certificate will have to be stored on a hard token (separate from the computer being accessed) that meets the requirements for FIPS 140–2 Security Level 1 or higher. If a practitioner digitally signs a prescription with his own private key and transmits the prescription with the digital signature attached, the pharmacy will have to validate the prescription, but no other digital signatures will need to be applied. (If the practitioner uses his own private key to sign a prescription, the electronic prescribing application will not have to apply an application digital signature.) If the

digital signature is not transmitted, the pharmacy or last intermediary will have to digitally sign the prescription. DEA emphasizes that Federal systems will be free to impose more stringent requirements on their users, as they have indicated that they do.

As noted in other parts of this rulemaking, DEA has updated the incorporation by reference to FIPS 186–3, June 2009.

E. Internal Audit Trails

DEA proposed that an application provider must audit its records and applications daily to identify if any security incidents had occurred and report such incidents to DEA.

Comments. One application provider stated that daily audit log checks would not be feasible and objected to reporting incidents as no parallel requirement exists for paper prescriptions. The application provider stated that SureScripts/RxHub transmission standards should address all security concerns.

DEA Response. DEA disagrees with this commenter. At the July 2006 public hearing,[20] application providers stated that their applications had internal audit trails and they suggested that the audit function provided security and documentation. In the HIMSS 2009 Security Survey 83 percent of respondents reported having audit logs for access to patient records. The requirement for an internal audit trail should, therefore, not impose any additional burden on most application providers. DEA is requiring the application provider to define auditable events and run a daily check for such events. DEA does not expect that many such auditable events should occur. When they do occur, the application must generate a report for the practitioner, who must determine whether the event represented a security problem. DEA notes that only one application provider who commented on the NPRM had concerns regarding this requirement. The SureScripts/RxHub transmission standards provide no protection for attempts to access a practitioner's application.

Although practitioners are not expressly required under the DEA regulations to report suspected diversion of controlled substances to DEA, all DEA registrants have a duty to provide effective controls and procedures to guard against theft and diversion of controlled substances.[21] Accordingly, there is a certain level of responsibility that comes with holding a DEA registration. With that responsibility comes an expectation of due diligence on the part of the practitioner to ensure that information regarding potential diversion is provided to law enforcement authorities, where circumstances so warrant. This requirement is no less applicable in the electronic prescribing context than in the paper or oral prescribing context. In fact, this concern might be heightened in the electronic context, due to the potential for large-scale diversion of controlled substances that might occur when a practitioner's electronic prescribing authority has fallen into unauthorized hands or is otherwise being used inappropriately.

Comments. An application provider organization and two application providers asked how security incidents should be reported. A healthcare system had concerns about reporting an incident before it could be investigated. Another healthcare system requested further clarification and detail surrounding the documentation requirements for findings and reporting of suspicious activity. A number of commenters recommended differing reporting periods from the end of the business day to 72 hours.

DEA Response. At this time, DEA is not specifying by rule how a security incident should be reported. Accordingly, practitioners have several options, including providing the information to DEA by telephone or email. If DEA finds over time that enough of these reports are being submitted to merit a standard format, DEA may develop a reporting form in the future. As DEA and registrants gain experience with these incidents, DEA will be able to provide guidance on the specific information that must be included in the reports. In general, the security incidents that should be reported are those that represent successful attacks on the application or other incidents in which someone gains unauthorized access. These should be reported to both DEA and the application provider because a successful attack may indicate a problem with the application.

DEA recognizes the concern about reporting incidents before the practitioner or application provider has had a chance to investigate. DEA's experience with theft and loss reporting, however, indicates that waiting for investigation may delay reporting for long periods and make it difficult to collect evidence. DEA believes that one business day is sufficient. DEA notes that this is the same length of time required under the regulations for reporting of thefts or significant losses of controlled substances.[22]

F. Recordkeeping, Monthly Logs

1. Recordkeeping

DEA proposed that all records related to controlled substance electronic prescriptions be maintained for five years. DEA also proposed that the electronic records must be easily readable or easily rendered into a format that a person can read.

Comments. Pharmacy commenters generally objected to the five-year record retention requirement, noting that they are required to retain paper prescriptions for only two years. Commenters believed that the added retention time conflicted with many State pharmacy laws and regulations. They also believed there would be additional costs for purchase of added storage capacity. Some electronic prescription application providers expressed their view that 21 U.S.C. 827 limits the applicability of DEA recordkeeping requirements solely to registrants. Accordingly, they believed that DEA has no statutory authority to impose recordkeeping requirements on application providers or intermediaries. Some of the commenters also stated they believed that 21 U.S.C. 827(b) does not give DEA statutory authority to require registrants to maintain records for more than two years. Finally, with respect to the statutory recordkeeping requirements for practitioners, some commenters stated they believed that the recordkeeping provisions are limited to the two sets of circumstances set forth at 21 U.S.C. 827(c)(1)(A) and (B). They stated that if they were required to electronically store other data, such as that relating to identity proofing and transmissions with the digital signature and the monthly reports, this would result in overhead costs that application providers might not find relevant to the delivery of patient care and thus spending time developing such databases would have no value to the delivery of patient care. Commenters noted that these requirements are not part of the paper process and questioned why DEA would introduce it here. Commenters indicated that if five years of transactional data must be stored electronically for immediate retrieval, the cost to the application provider will be prohibitive. If offline or slower

[20] Transcripts, written comments, and other information regarding DEA's public meeting to discuss electronic prescriptions for controlled substances, held in conjunction with the Department of Health and Human Services, may be found at *http://www.DEAdiversion.usdoj.gov/ecomm/e_rx/mtgs/july2006/index.html.*

[21] 21 CFR 1301.71(a).

[22] 21 CFR 1301.76(b).

means of data storage retrieval are required, the cost to the application provider will be drastically reduced while still providing data to the Administration in a timely manner. Finally, a State health care agency asked that all records handled by intermediaries should be easily sorted, should provide a clear audit trail, and should be available to law enforcement.

DEA Response. In response to the comments, DEA has in the interim final rule changed the record retention period from that set forth in the proposed rule to two years, which is parallel to the requirement for paper prescriptions. Although DEA has revised the requirement, it should be noted that if the State in which the activity occurs requires a longer retention period, the State law must be complied with in addition to, and not in lieu of, the requirements of the Controlled Substances Act.

With respect to the issue of placing certain recordkeeping responsibilities on application providers, which are nonregistrants, the following considerations should be noted. While the express recordkeeping requirements of the CSA (set forth in 21 U.S.C. 827) apply only to registrants, DEA has authority under the Act to promulgate "any rules, regulations, and procedures [that the agency] may deem necessary and appropriate for the efficient execution of [the Act]." (21 U.S.C. 871(b)). DEA also has authority under the Act "to promulgate rules and regulations * * * relating to the * * * control of the * * * dispensing of controlled substances." (21 U.S.C. 821). The requirements set forth in the interim final rule relating to recordkeeping by nonregistrant application providers are being issued pursuant to this statutory authority. As stated in the interim final rule, for the purpose of electronic prescribing of controlled substances, DEA registrants may only use those applications that comply fully with the requirements of the interim final rule.

It should also be noted that DEA is not requiring practitioners to create a copy of a prescription or a new record; it is requiring the practitioner to use an application that stores a copy of the digitally signed record and retains the record for two years. These records will be stored on an application service provider's servers if the practitioner is using an application service provider to prescribe or on the practitioner's computers for installed applications. DEA further notes that the electronic prescribing of controlled substances is voluntary; no practitioner is required to issue controlled substance prescriptions electronically.

Although DEA had proposed having the first intermediary store the record, after taking into consideration the comments received to the NPRM, DEA decided that this approach risked losing the records. The practitioner can determine, through audit or certification reports, whether an electronic prescribing application meets DEA's requirements, but it may be difficult for the prescribing practitioner to ensure that an intermediary meets DEA's requirements if the first intermediary is a different firm, as it often is. Intermediaries may change or go out of business, destroying any records stored; intermediaries may also subcontract out some of the functions, further attenuating controls.

2. Monthly Logs

DEA proposed that the electronic prescription application would have to generate, on a monthly basis, a log of all controlled substance prescriptions issued by a practitioner and provide the log to the practitioner for his review. DEA further proposed that the practitioner would be required to review the log, but would not be expected to cross-check it with other records. As DEA explained in the NPRM, the purpose of the log review was to provide a chance for the practitioner to spot obvious anomalies, such as prescriptions for patients he did not see, for controlled substances he did not prescribe, unusual numbers of prescriptions, or high quantity of drugs. The practitioner would have to indicate that he had reviewed the log.

Comments. Commenters were divided on the viability and necessity of the log provision. Several practitioner organizations and one application provider stated that logs should be available for review, but opposed the requirement that practitioners confirm the monthly logs. A long-term care facility organization stated the log would be useful for detecting increased prescribing patterns. It, however, said the brief review proposed was too short and that the review should be reimbursable under Medicare. Other commenters stated that without checking the patients' records, it is unclear how this would increase the likelihood of identifying diversion. The State agency said the rule did not definitively state the mechanism for the review. A healthcare system stated that it would be helpful if DEA would provide further clarification surrounding the type of information that would need to be maintained. This commenter further asserted that DEA should allow noncontrolled prescription drug activity to be reviewed and archived in the same manner so as not to duplicate work for the physician.

Other practitioner groups and application providers opposed the requirement that the practitioner review the monthly log check because such review is not required for paper prescriptions and because, these commenters asserted, it would be difficult to do without cross-checking patient records. An application provider stated that DEA does not have the authority to require the monthly log as 21 U.S.C. 827(c)(1) exempts practitioners from keeping prescription records. Some commenters mistakenly assumed that pharmacies would be generating the logs and that practitioners would have to review multiple logs each month; they opposed the requirement on that basis. An application provider and a State agency expressed doubt about the benefits of the requirement given the number of prescriptions that might be in an individual practitioner's monthly log. A few commenters suggested that DEA should enhance the log requirement to require the electronic prescription application to generate the logs every week (rather than every month, as was proposed). One application provider said that any log requirement would discourage electronic prescribing. Several commenters stated that the check would not enhance non-repudiation. A practitioner organization and a practitioner said that many providers would be worried about their liability if they fail to detect fraud. These commenters suggested that the regulations should protect unintentional failure to detect fraud and the purpose of the logs should be exclusively to help physicians recognize fraud if they are able to do so, but without penalty for failures to catch errors if a good faith review and signature were performed. Another practitioner organization stated that DEA did not detail the practitioner's ultimate responsibility to review and approve the information in the logs, the manner and timeframe in which the review must be completed, or the practitioner's liability for failing to review the log. The commenter asserted that this obligation, as well as the other requirements, seems to create a new practice standard that places more responsibility, and thus increased liability, for proper implementation of the law on practitioners. In addition, this commenter expressed the view that there is a need to specify the confidentiality of all such records,

including who has access and under what circumstances.

A State board of pharmacy said that a review of prescription monitoring records should be accepted as a substitute. Several commenters asked that the review be done electronically. A State agency stated that DEA should prohibit the practitioner from delegating the review to members of his staff.

DEA Response. DEA continues to believe that the monthly log requirement serves an important function in preventing diversion of controlled substances. In view of the comments, however, DEA has modified the requirement to lessen the burden on practitioners. Specifically, under the interim final rule, as in the proposed rule, the electronic prescription application will be required to generate, on a monthly basis, a log of all controlled substance prescriptions issued by a practitioner and automatically provide the log to the practitioner for his review. However, DEA has eliminated from the interim final rule the requirement that the practitioner mandatorily review each of the monthly logs. DEA believes this strikes a fair balance in the following respects. Maintaining in the rule the requirement that the application supply the practitioner with the monthly log will ensure that all practitioners receive the logs on a regular basis without requiring practitioners to expend extra time and effort to request the logs. As a practical matter, this will result in more practitioners actually receiving the logs and, in all likelihood, more practitioners actually reviewing logs than would be the case if practitioners had to affirmatively request each time that the application send the log. The more practitioners review the logs, the more likely it will be that they will detect, without excessive delay, any instances of fraud or misappropriation of their two-factor authentication credentials. Such early detection will allow for earlier reporting by the practitioner of these transgressions and thereby more quickly cut off the unauthorized user's access to electronic prescribing of controlled substances. Ultimately, this is likely to result in fewer instances of diversion of controlled substances and less resulting harm to the public health and safety.

DEA is also maintaining in the interim final rule the requirement that the application be able to generate a log, upon request by the practitioner, of all electronic prescriptions for controlled substances the practitioner issued using the application over at least the preceding two years. As was proposed, the interim final rule requires that this log, as well as the monthly logs, be sortable at least by patient name, drug name, and date of issuance.

With respect to 21 U.S.C. 827, it is true that this provision sets forth the statutorily mandated recordkeeping requirements for DEA registrants. However, this provision does not preclude DEA from requiring that practitioners who elect to prescribe controlled substances electronically use applications that meet certain standards designed to reduce the likelihood of diversion. In this same vein, nothing in 21 U.S.C. 827 precludes DEA from requiring that practitioners, when electronically prescribing controlled substances, use applications that, among other things, maintain records that the agency reasonably concludes are necessary to ensure proper accountability. As stated at the outset of this preamble, DEA has broad statutory authority to promulgate any rules and regulations that the agency deems necessary and appropriate to controlled against diversion of controlled substances or to otherwise efficiently execute the agency's functions under the CSA.[23]

G. Transmission Issues

DEA proposed that the information required under part 1306 including the full name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner must not be altered during transmission; it could be reformatted.

1. Alteration During Transmission

Comments. Many commenters misinterpreted this requirement to mean pharmacies would not be able to substitute generic versions for brand name versions as is allowed under many State laws. One application provider organization suggested that the rule state that no changes are allowed on the medication segment and an application provider could only augment the segments of the prescription pertaining to transaction, transaction source, patient, or physician. Further, this commenter suggested, the application provider would not be able to edit any existing data. A healthcare organization asked how alteration of content is identified (*e.g.,* according to FIPS 180–2).

DEA Response. DEA has revised the rule to clarify that the content of the required information must not be altered "during transmission between the practitioner and pharmacy." The requirement not to alter prescription information during transmission applies to actions by intermediaries. It does not apply to changes that occur after receipt at the pharmacy. Changes made by the pharmacy are governed by the same laws and regulations that apply to paper prescriptions. Again, any applicable State laws must also be complied with. As for changes by intermediaries during transmission, DEA is limiting only changes to the DEA-required elements (those set forth in 21 CFR part 1306). An intermediary could add information about the practitioner other than his name, address, and DEA registration number or about the patient, other than name and address. Alteration during transmission would be identified by comparing the digitally signed prescription retained by the electronic prescription application and the digitally signed prescription retained by the pharmacy.

2. Printing After Transmission and Transmitting After Printing

DEA proposed that if a prescription is transmitted electronically, it could not be printed. If it was printed, it could not be transmitted electronically.

Comments. A number of commenters raised issues related to this requirement. A standards development organization noted that in some cases electronic prescriptions may be cancelled, for example when a transmission fails. In such cases, the commenter believed retransmission should be allowed. Pharmacies and pharmacy organizations stated that if transmission fails, the practitioner should be able to print the prescription. Practitioner organizations suggested the following language: "If electronic transmission is prevented by weather, power loss, or equipment failure, or other similar system failure, prescriptions may be faxed to the pharmacy or printed." A healthcare organization stated that the rule does not define processes for transmission failures. The commenter asked if a second prescription is issued because the first was not received, how it would be clear that the first was cancelled. Many commenters, including pharmacy organizations, practitioner organizations, and electronic prescription application providers, stated that DEA should allow printing of a copy of the electronically transmitted prescription if it is clearly labeled as a copy. They noted that copies are often needed for insurance files and medical records; patients may be given a receipt listing all prescriptions written. Long-term care organizations also stated that these printed prescriptions were

[23] 21 U.S.C. 821, 871(b).

necessary for medication administration records.

DEA Response. DEA had noted in the preamble of the NPRM that transmitted prescriptions could be printed for medical records and other similar needs. DEA agrees with the commenters that such a statement should appear in the regulatory text and has revised the interim final rule to allow printing of a copy of a transmitted prescription, receipt, or other record, provided that the copy is clearly labeled as a copy that is not valid for dispensing. The copy should state, as recommended by commenters, that the original prescription was sent to [pharmacy name] on [date/time] and that the copy may not be used for dispensing. Printed copies of transmitted prescriptions may not be signed.

DEA has also added a provision that the application may print a prescription for signing and dispensing if transmission fails. DEA will require that these original prescriptions include a note to the pharmacy that the prescription was originally transmitted to a specific pharmacy, but that the transmission failed. DEA considers this warning necessary because it is possible that the practitioner will be notified of a failure while the application is still attempting to transmit the prescription. The warning will alert the pharmacy to check its records to be certain a later transmission attempt had not succeeded. If the printed prescription is to be used for dispensing, it must be manually signed by the prescribing practitioner pursuant to § 1306.05(a). As the printed prescription contains information regarding the prior transmission, this information will be retained by the pharmacy.

Comments. A commenter recommended retaining the proposed language, but allowing the use of the SCRIPT CANCEL transaction. The commenter believed this would allow the application to either print the prescription or transmit it to another pharmacy. It noted that most vendors have not implemented support of this transaction. The commenter recommended that intermediaries that certify electronic prescription applications and pharmacy applications for interoperability should have to test and verify that vendors support the message before they are certified to accept controlled substances prescriptions.

DEA Response. DEA agrees that if a transmission fails or is canceled, the practitioner will be able to print the prescription or transmit it to another pharmacy. DEA, however, does not believe it is appropriate to attempt through these regulations to dictate to intermediaries that certify electronic prescription applications and pharmacy applications for interoperability what to cover in their certification requirements. DEA does not consider it advisable to include, as part of its regulations, references to particular functions in the SCRIPT standard, or any other standard, as these standards are constantly evolving.

Comments. A healthcare organization suggested a requirement for the receiving pharmacy to provide confirmation back to the prescriber's application. The commenter suggested that the confirmation may then be printed and given to the patient, thereby providing documentation to demonstrate that the patient's prescription has been successfully transmitted to the patient's pharmacy.

DEA Response. Based on the comments, DEA does not believe that a requirement for a return receipt that would be provided to the patient would be reasonable because it would reduce the flexibility of the system. It would force the practitioner to write and transmit the prescription while the patient was still in the office. DEA does not have a similar requirement for oral or facsimile transmissions of paper Schedule III, IV, and V prescriptions and does not believe that this is warranted or necessary. In addition, as commenters made clear, it is not always possible to access a transmission system at a particular point in time.

3. Facsimile Transmission of Prescriptions by Intermediaries

DEA proposed that intermediaries could not convert an electronic prescription into a fax if transmission failed. They would be required to notify the practitioner, who would then have to print and manually sign the prescription.

Comments. A standards development organization, several electronic prescription application providers, and a pharmacy chain stated that intermediaries should be able to convert electronic prescriptions to faxes if the intermediaries cannot complete the transmission. One electronic prescription application provider stated that 20 percent of its transmissions need to be converted to facsimile because of pharmacy technology problems. An application provider organization stated that DEA is requiring that the prescription be digitally signed, so the prescription would have been signed. In the case of a temporary communication outage between physician and pharmacy, the commenter suggested that the pharmacy could receive a fax containing the ID tags of the script message. Those ID tags could then be later confirmed against the SCRIPT transaction when connectivity is resumed. The commenter believed that if DEA does not allow faxing by the intermediary, a unique workflow will be necessary for controlled substance transaction errors not required for legend drugs.

One State Board of Pharmacy stated that it had found many problems with electronic prescriptions. Among the problems this State Board reported was that even when pharmacies are able to receive electronic prescriptions, their applications do not necessarily read electronic prescriptions accurately. Data entered by a practitioner may be truncated in the pharmacy application or moved to another field. These statements were echoed by a State pharmacist association.

One application provider asked if faxed electronic prescriptions can continue to be treated as oral prescriptions.

DEA Response. A faxed prescription is a paper prescription and, therefore, must be manually signed by the prescribing practitioner registered with DEA to prescribe controlled substances. If an intermediary cannot complete a transmission of a controlled substance prescription, it must notify the practitioner in the manner discussed above. Under such circumstances, if the prescription is for a Schedule III, IV, or V controlled substance, the practitioner can print the prescription, manually sign it, and fax the prescription directly to the pharmacy. DEA recognizes that not all pharmacies are currently capable of receiving fully electronic prescriptions and that there may be other transmission issues; however, it would be incompatible with effective controls against diversion to allow unsigned faxes of controlled substance prescriptions to be generated by intermediaries. As the commenters indicated, most of the reported transmission problems have to do with the lack of a mature standard for electronic prescriptions and the number of pharmacies that are not accepting electronic prescriptions. A number of commenters indicated that they anticipate that the need for intermediaries will disappear once the standard is mature. At that point, the issue of faxes will also be eliminated. As for the comment about treating faxed electronic prescriptions as oral prescriptions, this practice is not allowed under DEA's regulations as the commenter seemed to believe. To reiterate, the regulations have always required that a facsimile of a Schedule

III, IV, or V prescription be manually signed by the prescribing practitioner.

Comments. A State Board of Pharmacy and a healthcare organization stated that under New Mexico and California law it was permissible to electronically generate a prescription and fax it. One commenter indicated that New Mexico allows electronic prescriptions to be sent "by electronic means including, but not limited to, telephone, fax machine, routers, computer, computer modem or any other electronic device or authorized means." A commenter noted that California, among others, allows for the faxing of controlled substances prescriptions with the text "electronically signed by" on the fax.

DEA Response. As discussed above, under DEA's regulations, a faxed prescription is a paper prescription and must be manually signed. It is not permissible to electronically generate and fax a controlled substance prescription without the practitioner manually signing it.

4. Other Issues

Comments. Several electronic prescription application providers stated that DEA had not specified the characteristics of the transmission system between the practitioner and the pharmacy, which could be insecure. They recommended that a clear "secured" communication be used between the electronic prescription application and the pharmacy. Commenters recommended that the communications should meet HITSP T17 "Secured Communications Channel" requirements. They stated that this is already required, though not tested, by the Certification Commission for Healthcare Information Technology today (S28, S29). One State agency recommended requiring end-to-end encryption. An electronic prescription and pharmacy application provider and an intermediary described their network security. A practitioner organization stated that DEA should not over-specify requirements because other specifications exist with which DEA's requirements must coexist.

DEA Response. DEA has not addressed the security of the transmission systems used to transmit electronic prescriptions from practitioners to pharmacies, although some commenters asked DEA to do so and others claimed that the security of these systems provided sufficient protection against misuse of electronic prescriptions. As noted previously, the existing transmission system routes prescriptions through three to five intermediaries between a practitioner and the dispensing pharmacy. Practitioners and pharmacies have no way to determine which intermediaries will be used and, therefore, no way to avoid intermediaries that do not employ good security practices. As a practical matter, once a practitioner purchases an electronic prescription application, the practitioner must accept whatever transmission routing the application provider employs. Neither the practitioner nor electronic prescription application provider has any way of knowing which intermediaries are used by each of the pharmacies that patients' may designate.

None of the security measures that are used for transmission address the threat of someone stealing a practitioner's identity to issue prescriptions or of office staff being able to issue prescriptions in a practitioner's name because of inadequate access controls or authentication protocols. None of the measures address the threat of pharmacy staff altering records to hide diversion. Some commenters indicated that they anticipate the elimination of intermediaries once the SCRIPT standard is mature and interoperability exists without the need for converting a data file from one software version to another so that it can be read correctly.

Although DEA is concerned about the possibility that controlled substances prescriptions could be altered or created during transmission, it has chosen to address those issues by requiring that the controlled substance prescription is digitally signed when the practitioner executes the two-factor authentication protocol and when the pharmacy receives the prescription. The only transmission issues that DEA is addressing in the interim final rule concern one common practice—the conversion of prescriptions from one software version to another—and one possible practice—the facsimile transmission of prescriptions by intermediaries to pharmacies. As discussed above, DEA will permit intermediaries to convert controlled substances prescriptions from one software version to another; DEA will not allow intermediaries to transform an electronic prescription for a controlled substance into a facsimile as many of them do. DEA is also explicitly stating that any DEA-required information may not be altered during transmission.

H. Pharmacy Issues

1. Digital Signature

DEA proposed that either the pharmacy or the last intermediary routing an electronic prescription should digitally sign the prescription and the pharmacy would archive the digitally signed record as proof of the prescription as received.

Comments. State pharmacist associations and some pharmacy application providers asked DEA to analyze the cost of this requirement. One retail association stated that DEA had not considered that the software used to create the prescription might not be compatible with digital signatures. A number of pharmacy chains and pharmacy associations asked DEA to explain what regulatory requirements would apply to those electronic prescriptions that occur through direct exchanges between practitioners and pharmacies (*i.e.,* transmission without intermediaries). A chain pharmacy noted that the intermediaries may be phased out, leaving pharmacies with no choice but to add digital signature functionality. A State Board of Pharmacy stated that the digital signature should be validated to ensure that the record had not been altered. An electronic prescription application provider stated that it will be very difficult for the pharmacies to digitally sign prescriptions in the short run and will require more time. It suggested that the rule include the following statement: "Until 1/1/2011 pharmacies can print out and wet sign controlled drug prescriptions as they arrive, and archive those paper records for an acceptable period." A standards organization stated that the requirement would require a major revision of its standard. A healthcare system recommended that DEA include reasonable alternatives to proposed requirements to address record integrity. This commenter asserted that DEA should allow flexibility regarding the use of digital signatures in systems with no intermediate processing.

DEA Response. DEA did analyze the cost of this requirement in the Initial Economic Impact Analysis associated with the notice of proposed rulemaking [24] and included estimates for the time and costs required to add digital signature functionality to existing applications. DEA disagrees with the commenters that asserted that electronic prescribing applications or the SCRIPT standard are incompatible with digital signatures. As a number of commenters noted, any data file can be digitally signed and can be digitally signed without affecting the formatting of the file.

The interim final rule requires the pharmacy or the last intermediary to digitally sign the prescription and the

[24] *http://www.deadiversion.usdoj.gov/fed_regs/2008/index.gtml.*

pharmacy to archive the digitally signed record. These steps do not alter the data record that the pharmacy application will read. If the last intermediary digitally signs the record, the digital signature will be attached to the data record. Digital signatures, which under current NIST standards range from 160 to 512 bits (which generally equates to 20 to 64 bytes), would fit within the free-text fields that the SCRIPT standard provides (70 characters), or the digital signature could be linked to the prescription record rather than incorporated into the record. If the pharmacy digitally signs the prescription record, the issue of potential problems with the format will not apply. The digitally signed prescription-as-received record ensures that DEA can determine whether a prescription was altered during transmission or after receipt at the pharmacy. If the contents of the digitally signed record at the pharmacy do not match the contents of the digitally signed record held by the practitioner's electronic prescription application, the prescription was altered during transmission. If the record of the prescription in the pharmacy database does not match the digitally signed record of the prescription as received, the prescription was altered after receipt.

About a third of registered pharmacies already have the ability to digitally sign electronic controlled substance orders through DEA's Controlled Substances Ordering System; the private key used for these electronic orders could be used to sign prescriptions upon receipt. Similarly, most applications that move files through virtual private networks or that conduct business over the Internet have digital signature capabilities. DEA has not imposed any requirements for the source of the digital signatures because pharmacies and intermediaries may already have signing modules that can be used. Pharmacies that have a Controlled Substance Ordering System digital certificate obtained it from DEA. In response to the comment on validating the digital signature, the pharmacy or intermediary will be signing the record; DEA sees no need to ask them to validate their own certificate. DEA does not believe that it is necessary to provide an alternative to the digital signature because it should be possible for either the intermediary or pharmacy to apply a digital signature within a reasonable time.

On the issue of direct exchanges between a practitioner and a pharmacy, two digital signatures (the electronic prescription application's or practitioner's and the pharmacy's) would be required unless the practitioner's digital signature is transmitted to the pharmacy and validated. Even when intermediaries are not involved, there is the possibility that an electronic prescription could be intercepted and altered during transmission. When it becomes feasible for practitioners to transmit electronic prescriptions directly to pharmacies, without conversion from one software version to another, the PKI option that DEA is making available under the interim final rule may be an alternative that more applications and practitioners choose to use. The primary barrier to this option is the current need to convert prescription information from one software version to another during transmission because of interoperability issues; conversion of the prescription information from one software version to another makes it impossible to validate the digital signature on receipt. When interoperability issues have been resolved, transmitting a digital signature and validating the digital signature may be more cost-effective for some pharmacies. Because of the alternatives DEA is providing for practitioner issuance of electronic prescriptions for controlled substances, DEA does not believe it is necessary to develop alternative approaches that would apply only to those few truly closed systems. DEA notes that it has also made a number of changes to the proposed rule that are consistent with the practices described by the commenters from closed systems; for example, DEA is allowing institutional practitioners to conduct identity proofing in-house.

2. Checking the CSA Database

DEA proposed that pharmacies would be required to check the CSA database to confirm that the DEA registration of the prescriber was valid at the time of signing.

Comments. Several commenters objected to this requirement, stating that pharmacies are not required to check DEA registrations for paper prescriptions unless they suspect something is wrong with a prescription. They also stated that the requirement would be costly and probably not feasible because the CSA database must be purchased and is not up-to-date. Some commenters expressed the view that since DEA proposed to have electronic prescription application providers check the registration, requiring the pharmacy to do so would be redundant.

DEA Response. DEA agrees with those commenters that expressed the view that, when filling a paper prescription, it is not necessary for a pharmacist who receives an electronic prescription for a controlled substance to check the CSA database in every instance to confirm that the prescribing practitioner is properly registered with DEA. Accordingly, DEA has removed this requirement from the interim final rule. It should be made clear that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of the Controlled Substances Act and DEA regulations, including the requirement that the prescribing practitioner be properly registered. Pharmacists also have an obligation to ensure that controlled substance prescriptions contain all requisite elements, including (but not limited to) the valid DEA registration of the prescribing practitioner. If a pharmacy has doubts about a particular DEA registration, it can now check the registration through DEA's Registration Validation Tool on its Web site rather than having to purchase the CSA database.[25]

3. Audit Trails

DEA proposed that pharmacy applications have an internal electronic audit trail that recorded each time a controlled substance prescription was opened, annotated, altered, or deleted and the identity of the person taking the action. The pharmacy or the application provider would establish and implement a list of auditable events that, at a minimum, would include attempted or successful unauthorized access, use, disclosure, modification, or destruction of information or interference with application operations in the pharmacy application. The application would have to analyze the audit logs at least once every 24 hours and generate an incident report that identifies each auditable event. Security incidents would need to be reported within one business day.

Comments. A substantial number of commenters representing pharmacies and pharmacy associations objected to the requirement that the audit trail document any time a prescription record was viewed, asserting that current applications do not have the capability to track this as opposed to tracking annotations, modifications, and deletions.

[25] DEA provides a "Registration Validation" tool on its Web site, through which DEA registrants may query DEA's registration database regarding another DEA registrant to gather specific information about that registrant. Information available includes: The registrant's name, address, and DEA registration number; the date of expiration of the registration; business activity; and the schedules of controlled substances the registrant is authorized to handle.

DEA Response. In view of the comments, DEA agrees that the audit function does not need to document every instance in which a prescription record is opened or viewed and has revised the rule accordingly. The pharmacy application will only be required to document those instances in which a controlled substance prescription is received, annotated, modified, or deleted. In such circumstances, the application must record when the annotation, modification, or deletion occurred and who took the action.

Comments. Several commenters stated that standards for the automation of capturing auditable events and interpretation of the resulting reports have not been published. Commenters asserted that many pharmacy applications have the ability to track auditable events, but not all have the ability to generate the reports desired by DEA. A number of commenters asked DEA to define auditable event and explain what level of security incident would need to be reported. A chain pharmacy asked DEA to define what constituted an alteration of the record and to clarify that a generic substitution is not an auditable event. An application provider asked if auditable events are limited to information changed at the order level (*e.g.,* administration instructions) or at dispensing (*e.g.,* NDC changed due to insufficient quantity). A number of commenters suggested that reporting of security incidents should be within 2 to 3 business days.

DEA Response. The audit trail and the internal auditing of auditable events serve somewhat different purposes. The audit trail provides a record of all modifications to the prescription record. For example, the audit trail will note when the prescription was dispensed and by whom; it will indicate modifications (*e.g.,* partial dispensing when the full amount is not available, changes to generic version). The auditable events, in contrast, are intended to identify potential security concerns, such as attempts to alter the record by someone not authorized to do so or significant increases in the dosage unit or quantity dispensed without an additional annotation (*e.g.,* indicating practitioner authorization). DEA points out that during hearings on electronic prescriptions, representatives of the pharmacy and electronic prescription application industries uniformly stressed the audit trails as the basis for the security of their applications.

DEA does not believe it is feasible to define or list every conceivable event that would constitute an auditable event for all pharmacies. The extent to which a particular event might raise concern at one pharmacy is not necessarily the same at other pharmacies. For example, a community pharmacy may want to set different triggers for changes to opioid prescriptions than a pharmacy that serves a large cancer center or a pharmacy that services LTCFs would. A community pharmacy that is closed overnight may want to identify any change that occurs during the hours when it is closed—an event that is not a consideration for a pharmacy that is open 24 hours a day. The auditable events must, at a minimum, include attempted or successful unauthorized access, modification, or destruction of information or interference with application operations in the pharmacy application. DEA has dropped the unauthorized "use or disclosure" from its list of auditable events. These events are included in the CCHIT standards for electronic health records and may be important to pharmacies, but are not directly relevant to DEA's concerns.

DEA expects that application providers and developers will work with pharmacies to identify other auditable events. DEA emphasizes that application providers should define auditable events to capture potential security threats or diversion. Changes from brand name drug to a generic version of the same drug, for example, do not represent potential security issues.

Comments. One State recommended that audit trails and event logs should be in a standard format.

DEA Response. DEA understands the State's desire for a uniform format for audit trails and event logs, but in the absence of a single industry-wide standard being utilized by pharmacies, DEA does not believe it would be appropriate at this time to mandate one particular format over others.

Comments. A pharmacy organization and pharmacist associations asked if audit trails and daily audits could be automated. One commenter asked DEA to clarify that the records could be kept on existing systems. Another asked if a pharmacy had to document that the record had been reviewed.

DEA Response. Audit trails and daily audits are automated functions that occur on the pharmacy's computers and that should not require actions on the part of pharmacists or other pharmacy employees except when a security threat is identified, which DEA expects to occur relatively rarely. The internal audit trail records must be maintained for two years, but DEA is not requiring that the pharmacy retain a record of its review of reports of auditable events unless they result in a report to DEA of a potential security incident.

Comments. A chain pharmacy asserted that as the record as received will be digitally signed, only a compromise of the encryption key should be an auditable event.

DEA Response. The digital signature on a record as received does not address the concerns that the audit trail and review are intended to document. The digitally signed prescription as received documents the information content of the prescription on receipt. It does not help identify later alterations of the record; it can show that the record was altered later, but not who did it or when.

Comments. A State asked if pharmacies should discontinue accepting electronic prescriptions if a security incident occurs.

DEA Response. In general, it would be advisable to discontinue accepting electronic prescriptions for controlled substances until the security concerns were resolved. However, if, despite the security concerns associated with the application, the pharmacy is able to verify that a prescription has been issued lawfully, the pharmacy may fill the prescription.

4. Offsite Storage

DEA proposed that back-up records be stored at a separate offsite location. DEA proposed that the electronic record be easily readable or easily rendered into a format that a person could read and must be readily retrievable.

Comments. Most pharmacy commenters objected to offsite storage as costly and not required for paper prescriptions. A pharmacy organization stated that back-up copies should be transferred off-site weekly, not daily.

DEA Response. DEA has removed the requirement for storage of back-up records at another location. DEA, however, recommends as a best practice that pharmacies store their back-up copies at another location to prevent the loss of the records in the event of natural disasters, fires, or system failures.

DEA believes that daily backup of prescription records is an acceptable length of time to ensure the integrity of pharmacy records.

Comments. Several pharmacy chains asked that the functionality for retrieving records be at the headquarters rather than the pharmacy level; they supported the standard of "readily retrievable," as DEA proposed, which is the same standard that applies to paper prescriptions. One State board of pharmacy stated that the provision for making the data available in a readable

format may require extensive reprogramming. A pharmacist association asked DEA to define readily retrievable. One commenter objected to storing information at pharmacies because it could be exposed.

DEA Response. Under the interim final rule, it is permissible for a pharmacy to have records stored on headquarters' computers, but the dispensing pharmacy must be able to retrieve them if requested as they do for computerized refill records allowed under § 1306.22. DEA does not believe that the requirement for readable records will impose significant burdens. Similar requirements exist for computerized refill records. In addition, it is unlikely that pharmacy applications would be useable by pharmacists unless the data can be provided in an easily readable form. "Readily retrievable" is already defined in § 1300.01. Finally, requirements currently exist for pharmacies to retain and store prescription records in compliance with HIPAA requirements to protect individuals' personal information.

5. Transfers

In the NPRM, DEA confirmed existing regulations regarding the transfer of prescriptions for Schedule III, IV, and V controlled substances. Specifically, under § 1306.25(a) a pharmacy is allowed to transfer an original unfilled electronic prescription to another pharmacy if the first pharmacy is unable to or chooses not to fill the prescription. Further, a pharmacy is also allowed to transfer an electronic prescription for a Schedule III, IV, or V controlled substance with remaining refills to another pharmacy for filling provided the transfer is communicated between two licensed pharmacists. The pharmacy transferring the prescription would have to void the remaining refills in its records and note in its records to which pharmacy the prescription was transferred. The notations may occur electronically. The pharmacy receiving the transferred prescription would have to note from whom the prescription was received and the number of remaining refills.

Comments. Several commenters, including three pharmacy chains and an association representing chain drug stores, all indicated their belief that if a prescription transfer occurs within the same pharmacy chain, only one licensed pharmacist is necessary to complete the transfer if that pharmacy chain uses a common database among its pharmacies. One pharmacy chain noted that in many cases, pharmacists do not call each other to effectuate the transfer of the prescription from one pharmacy to another. Commenters requested that DEA revise the rule to address this industry practice.

DEA Response. DEA has never permitted the transfer of a controlled substance prescription without the involvement of two licensed pharmacists, regardless of whether the two pharmacies share a common database. DEA emphasizes that this has been a longstanding requirement, one which was not proposed to be changed as part of this rulemaking. DEA believes that it is important that two licensed pharmacists be involved in the transfer of controlled substances prescriptions between pharmacies so that the pharmacists are aware that the prescription is actually being transferred. As the dispensing of the prescription is the responsibility of the pharmacist, DEA believes that it is critical that those pharmacists have knowledge of prescriptions entering their pharmacy for dispensing. Without this requirement, it would be quite feasible for other pharmacy employees to move prescriptions between pharmacies, thereby increasing the potential for diversion by pharmacy employees.

Comments. One commenter, a large pharmacy, believed that while the NPRM addressed the transfer of prescription refill information for Schedule III, IV, and V controlled substance prescriptions, it did not address the transfer of original prescriptions that have not been filled.

DEA Response. As DEA explained in the NPRM, the existing requirements for transfers of Schedule III, IV, and V controlled substances prescriptions remain unchanged. DEA currently permits the transfer of original prescription information for a prescription in Schedules III, IV, and V on a one-time basis. This allowance does not change. DEA wishes to emphasize that the only changes made to § 1306.25 as part of the NPRM were to revise the text to include separate requirements for transfers of electronic prescriptions. These revisions were needed because an electronic prescription could be transferred without a telephone call between pharmacists. Consequently, the transferring pharmacist must provide, with the electronic transfer, the information that the recipient transcribes when accepting an oral transfer.

6. Other Pharmacy Issues

Comments. An advocacy group stated that although it expects the chain drug stores to be able to handle the administrative burden and expense of security measures demanded by DEA, it was concerned about the ability of independent pharmacies, especially those that rely almost exclusively on prescription revenues and not "front-of-the-store" revenues, to cope with the proposed rule's added requirements.

DEA Response. DEA has revised some of the requirements to reduce the burden imposed by this rulemaking, where DEA believes that doing so does not compromise effective controls against diversion. DEA has also clarified that the third-party audit applies to the application provider, not to the individual pharmacy unless the pharmacy has developed and implemented its own application, a circumstance which, at the present time, is likely limited to chain pharmacies. The audit trail is something that members of industry stated, prior to the proposed rule, was the basis for their security controls. The pharmacy applications should, therefore, have the capability to implement this requirement. DEA is simply requiring that the application identify security incidents, which should be infrequent, and that the pharmacy be notified and take action to determine if the application's security was compromised. This should not be an insurmountable burden for a small pharmacy. The other functions required are automated and do not require action on the part of the pharmacy staff. Most of the burden of the pharmacy requirements fall on the pharmacy application provider, not on the pharmacy.

Comments. Some commenters stated that the requirements for paper prescriptions include, for practitioners prescribing under an institutional practitioner's registration, the specific internal code number assigned by the institutional practitioner under § 1301.22. These commenters stated that NCPDP SCRIPT does not accommodate the extensions, which do not have a standard format, nor do most pharmacy computer applications. They also noted that a pharmacy has no way to validate the extension numbers.

DEA Response. DEA is aware of the issue with extension data and published an Advance Notice of Proposed Rulemaking (74 FR 46396, September 9, 2009) to seek information that can be used to standardize these data and to require institutional practitioners to provide their lists to pharmacies on request. As discussed above, DEA believes that SCRIPT can be modified to accept extensions by adding a code that indicates that the DEA number is for an institutional practitioner and allowing the field to accept up to 35 characters.

Pharmacy applications will need to be revised to accept the longer numbers; without the extension data, there is no way to determine who issued the prescription if individual practitioners with the same name are associated with the institutional practitioner. DEA is not requiring pharmacies to validate the extension numbers unless the pharmacist has reason to suspect that the prescription or prescribing practitioner are not legitimate.

Comments. A pharmacy organization asked if a pharmacy that services a Federal healthcare facility would need to operate separate systems, one for Federal facilities and one for other facilities it serves. It also asked what facilities were considered Federal healthcare facilities.

DEA Response. As discussed above, DEA is allowing any application to use the digital certificate option proposed for Federal healthcare systems. DEA is not, therefore, imposing any different requirements on Federal facilities. Pharmacies may decide whether they will accept and verify digital signatures transmitted with a prescription, whether it was signed by a practitioner at a Federal facility or in private practice. If a pharmacy does not accept controlled substance prescriptions digitally signed with the individual practitioner's private key, it will have to ensure that it has a digitally signed record of the prescription as received. The rest of the requirements for annotating and dispensing a controlled substance prescription are the same for all electronic prescriptions for controlled substances. The determination of whether a particular facility is a Federal facility is not affected by this rulemaking.

I. Third Party Audits

DEA proposed that both electronic prescription applications and the prescription processing module in pharmacy applications should be subject to a third-party audit that met the requirements of SysTrust or WebTrust audits (or for pharmacies, SAS 70). The standards for these audits are established and maintained by the American Institute of Certified Public Accountants.[26] [27] The audits are conducted by CPAs. DEA proposed that the application provider would have to have the third-party audit for processing integrity and physical security before the initial use of the application for electronic controlled substance prescriptions and annually thereafter to ensure that the application met the requirements of the rule. DEA sought comments on whether alternative audit types were available and appropriate.

Comments. An application provider organization stated annual security audits are unrealistic and will not be performed or enforced. The commenter asserted that a better use of both DEA and application provider resources would be to write and enforce a set of standards around systems writing.

DEA Response. Even if DEA had the technical expertise to develop standards, DEA does not believe that imposing an inflexible regulatory standard on applications is a reasonable approach. Security technologies are evolving. Locking applications into a specific format that would then have to be used until the regulation was revised, a time-consuming process, could delay implementation of more user-friendly and efficient applications that may be developed. In addition, most pharmacy applications have been in use for years; forcing them to reprogram in a specified way could be more costly and disruptive than letting each application provider tailor a solution that works for a particular application. DEA is interested in the end result (a secure system that can reasonably be implemented and is consistent with maintenance of effective controls against diversion of controlled substances), not in the details of how they are achieved.

DEA proposed third-party audits as a way to provide registrants with an objective appraisal of the applications they purchase and use. As a number of commenters stated, except for registrants associated with very large practices, large healthcare systems, or chain pharmacies, any of which may have their own information technology departments, the majority of registrants cannot be expected to determine, on their own, whether an application meets DEA's requirements. If they are to have assurance that the application they are using is in compliance with DEA regulatory requirements, that assurance must come from another source.

As commenters noted, DEA essentially had to choose among four possibilities for determining whether an application meets the requirements of part 1311: The application provider could self-certify the application; DEA could review and certify applications; an independent certification organization could take on that role; or the application provider could obtain a third-party audit from a qualified independent auditor. DEA believes that self-certification would not provide any assurance to registrants as non-compliant application providers would have an incentive to misrepresent their compliance with DEA regulatory requirements, and registrants would have few ways to determine the truth. For example, an application provider could claim that its application required the setting of logical access controls when the application, in fact, allowed anyone access regardless of the logical access controls. Until a practitioner or pharmacy discovered that prescriptions were being written or altered by unauthorized persons there would be no reason to suspect a problem with the application.

DEA does not have the expertise or the resources to conduct technical reviews of electronic prescription or pharmacy applications. Even if DEA elected to obtain such expertise, the time required for it to do so and then to review all of the existing applications would delay adoption.

DEA believes that a third-party audit approach allows application providers to seek a review as soon as their applications are compliant, which should make applications available for electronic prescribing of controlled substances sooner than relying on DEA. Third-party audits, while perhaps new to some prescription and pharmacy application providers, are a common approach used by the private sector to ensure compliance with both government regulations and private sector standards. For example, the International Standards Organization (ISO) frequently requires companies to obtain a third-party audit to gain certification for compliance with its standards (*e.g.,* ISO 9001, ISO 14001).[28]

The fourth approach would be to rely on an independent certification organization, such as CCHIT, to test and certify electronic prescription and pharmacy applications. Under the interim final rule, DEA will allow the certifications of such independent organizations to substitute for a third-party audit if the certification process clearly determines that the application being tested is compliant with DEA regulatory requirements and clearly distinguishes between applications that are compliant with part 1311 and those that are not. DEA notes, for example, that CCHIT currently tests and certifies EHRs against a set of published standards and plans to test and certify stand-alone electronic prescribing applications. However, at this time, CCHIT does not evaluate pharmacy applications. Once any certification

[26] *http://www.ffiec.gov/ffiecinfobase/booklets/audit/audit_06_3_party.html.*

[27] *http://www.ffiec.gov/ffiecinfobase/booklets/audit/audit_06_3_party.html.*

[28] *http://www.iso.org/iso/iso_catalogue/management_standards/certification.htm.*

organization has incorporated tests for part 1311 compliance, DEA will work with the organization to determine whether the process and certification are sufficient so that a registrant purchasing an application can rely on the certification to ensure that the application is compliant. Because many application providers seek certification, this approach will reduce costs. DEA notes, however, that it has not been able to identify any independent organization that certifies pharmacy applications or any that certifies prescription modules at the level of detail DEA requires.

Comments. Two commenters asserted that third-party audits are not a common practice and not required for paper prescriptions.

DEA Response. Third-party audits, in this context, address the ability of the electronic prescription application or pharmacy application to handle controlled substance prescriptions securely. It is difficult to understand how that concept could be applied to paper prescriptions, where the only issues are whether they are written in compliance with the law and regulations, properly filed, and whether they have been altered. On a paper prescription, the alteration creates forensic evidence of the change, which is not necessarily the case with a prescription generated using an electronic application, where the lack of an audit trail or an audit function that has been disabled may eliminate any evidence of alterations.

Comments. Many of the commenters on this issue focused on the costs associated with third-party audits. One electronic prescription application provider that currently obtains a SysTrust audit stated that the cost of the audit for the proposed requirements would be considerably less than DEA had estimated. This commenter estimated the cost to be "in the lower tens of thousands of dollars range" rather than the range of $100,000 to $125,000 that DEA mentioned in the NPRM. Another electronic prescription application provider asserted that the cost was underestimated and said the requirement would place a burden on application providers.

A pharmacy organization stated application vulnerabilities should be addressed through technology and that they should not create extra paperwork. It also stated that DEA should ensure that the cost of these audits is reasonable for small practices and pharmacies. A pharmacy organization and an information technology organization stated that the audit requirement is a burden financially and logistically. These commenters noted that some clinics that serve as both practitioners and pharmacies will bear the costs of both sides of the transaction.

DEA Response. DEA emphasizes that the requirement for a third-party audit applies to the application provider, not to the practitioner or pharmacy that uses the application. Unless a healthcare system or a pharmacy has developed its own application, it would not be subject to the requirement. Healthcare systems that serve as both practitioner and pharmacy may obtain a single third-party audit that addresses part 1311 compliance of the integrated system.

DEA has taken a number of steps to reduce the cost of the third-party audit. First, recognizing that the electronic prescribing and prescription processing functions DEA is requiring may not change every year, DEA has revised the rule to require an audit whenever an application is altered in a way that could affect the functionalities within the electronic prescription or pharmacy application related to controlled substance prescription requirements or every two years, whichever occurs first. Second, DEA has clarified that the purpose of the third-party audit is to determine whether the application meets DEA's requirements, that is, that the application is capable of performing the functions DEA requires and does so consistently. Where the application is installed on practice or pharmacy computers, the audit will not need to address the application provider's physical security nor will it need to address physical security at the practice or pharmacy because that will vary with each installation and is beyond the control of the application provider. For application service providers, the physical security of the ASP will need to be audited.

Third, as discussed above, if independent certification organizations develop programs that certify applications for part 1311 compliance, DEA will review their processes to determine whether such certifications can substitute for a third-party audit.

Finally, DEA has expanded the kinds of third-party auditors beyond those who perform SysTrust, WebTrust, or SAS 70 audits to include certified information system auditors (CISA) who perform compliance audits as a regular ongoing business activity. The CISA certification is sponsored by the Information Systems Audit and Control Association (ISACA) [29] and is recognized by the American National Standards Institute under ISO/IEC 17024. The certification is required by the FBCA for third-party auditors and by the Federal Reserve Bank for its examiners and is approved by the Department of Defense. DEA believes that allowing other certified IT auditors will provide application providers with more options and potentially reduce the cost of the audit. DEA is seeking comments on the addition of CISA to the list of permissible auditors.

Comments. A mail-order pharmacy said the rule should state that the annual SysTrust or SAS 70 audit meets DEA's regulatory requirements so that pharmacies passing their most recent audit can begin accepting electronic controlled substance prescriptions.

DEA Response. The SysTrust or SAS 70 audit will be sufficient if the audit has determined that the application meets the applicable requirements of part 1311. Because the pharmacy requirements address internal audit trails, logical access controls, and the ability to annotate and retain prescription records, which may be standard functions in existing pharmacy applications, it is possible that the existing audit has covered these functions. The pharmacy and the auditor should review the requirements of part 1311 and determine whether compliance has been addressed by the existing audit.

Comments. An intermediary suggested that certifying organizations such as itself and CCHIT could make the presentation of the audit a condition of certification. An information technology organization suggested that DEA might consider the North American Security Products Organization (NASPO) certification as a recognized standard for security products since, the commenter asserted, NASPO certification is sponsored by the FBI and Secret Service through the Document Security Alliance.

DEA Response. DEA notes that the commenter's existing certification process does not address the functions that DEA is requiring, but rather focuses on compliance with the SCRIPT standard. The commenter, as it stated, would rely on third-party audits to determine whether the applications meet DEA's requirements. Although the commenter may choose to impose this requirement on entities it certifies, making the third-party audit a condition of certification by this intermediary would not reduce the cost for the application providers because they would still need to obtain a third-party audit. Further, DEA cannot rely on one third party's certification of another third party's audit or certification of a particular application's compliance with DEA regulatory requirements. In

[29] *http://www.isaca.org.*

this regard, DEA must look to its own regulatory authority and regulatory requirements, not those of other entities. This is particularly true as DEA is not mandating the use of intermediaries.

As discussed above, if a certification organization decides to incorporate, as part of its certification, a determination that the application meets the requirements of part 1311, DEA will review the process used to determine whether the certification can be used as a substitute for a third-party audit. Based on a review of the information available on its Web site,[30] NASPO does not appear to address applications such as those used to create electronic prescriptions, but rather certifies organizations. Thus, DEA does not believe that NASPO is currently a suitable alternative to the third-party audits or certifications DEA is requiring in this rule.

Comments. Some commenters stated that there are multiple versions of applications in use and that third-party audits would not be feasible in these cases.

DEA Response. The existing certification programs test and certify multiple versions of applications. The application providers should, therefore, be familiar with the process of gaining approval for new versions. DEA notes that it is requiring a new audit more frequently than once every two years only when one of the functions required by part 1311 is affected by an update or upgrade to the application. If an application provider has multiple versions of the application, all of which use the same code and controls for the functions that DEA is requiring, a single audit may be able to address multiple versions if other changes could not impact these functions.

Comments. Some commenters thought that individual practitioners or pharmacies would have to obtain an audit of their applications.

DEA Response. As discussed above, a practice or pharmacy will be required to obtain an audit only if it developed the application itself. Although there may be some pharmacy chains that developed their own applications, it appears that even large hospital systems usually obtain applications from application providers. If the application provider has tailored its application to meet the specific needs of a healthcare system or a pharmacy chain, the application provider will have to determine whether the changes it made for a particular client affect the capability of the application to meet DEA's requirements. If the healthcare system or pharmacy-specific changes do not affect the functions specified in part 1311, a single audit may be able to address the multiple tailored versions of its application. DEA expects that, except for very large healthcare systems or practices, applications will not be tailored in ways that will affect compliance with part 1311.

Comments. One application provider stated that some of the controls that DEA wants addressed in the audit are not under the application provider's control when the application has been installed on a practice or pharmacy computer.

DEA Response. DEA recognizes that the proposed rule failed to address adequately the different roles played by application providers that install applications and those that serve as application service providers. To address the differences, DEA has revised the rule to clarify that a third-party audit does not need to address physical security of an application provider if its application is installed on practitioner office or pharmacy computers and servers. The audit for applications that will be installed on practice or pharmacy computers is limited to the application's ability to meet the part 1311 application requirements. The application provider, in this case, has no control over physical security of the application installed at the practice or pharmacy location and the security of its own operations is not of concern to DEA because the prescription records are not created or stored on computers that the application provider controls. A third-party audit for an application service provider, whose servers and Web sites host the files of practices or pharmacies, must, however, address physical security because the ability of the ASP to prevent insider and outsider attacks is critical to the security of prescription processing.

Comments. Pharmacy commenters stated that SureScripts/RxHub certification and HIPAA compliance should be sufficient to meet DEA regulatory requirements. One pharmacy chain asserted that it should be allowed to self-certify that its pharmacy application was compliant with DEA requirements for electronic prescriptions. Two retail pharmacy associations stated that the rule was not needed for pharmacies because State pharmacy boards may inspect their computer applications. They stated that their applications must comply with HIPAA and the SCRIPT standard. A State agency stated that these audits for pharmacies may not be needed and would impose additional costs on pharmacies.

DEA Response. SureScripts/RxHub certifies pharmacy and electronic prescription applications for interoperability and compliance with NCPDP SCRIPT, but not for their internal security or other functionalities; as commenters noted, SCRIPT supports, but does not mandate, the inclusion of all the DEA-required information. In addition, SureScripts/RxHub is not a neutral third party, but was established and is run by the pharmacy industry and may have a vested interest in promoting the existing model of transmission over others. Thus, DEA believes that SureScripts/RxHub certification, while beneficial from an industry perspective, is not suitable to address DEA's requirement for a neutral unbiased third-party audit of electronic prescription and pharmacy applications. DEA also notes that assertions (especially self-assertions, which are typically not verified by an outside party) of compliance with the HIPAA Security Rule provide limited assurance of security. The HIPAA Security Rule, which is focused on protecting personal health information from disclosure, is risk-based and designed to be flexible and scalable because the risks may vary with the number of patients. In contrast, DEA has based its requirements on its statutory obligations and must require all pharmacies to implement the defined security controls. As discussed above, application provider self-certification would not provide registrants with reasonable assurance of compliance.

DEA would be willing to evaluate a request from a pharmacy board to carry out a third-party audit or review of an audit, but as no State Board offered to take on this role in its comments to the NPRM, DEA doubts that this approach is feasible.

Comments. An application provider stated that the SysTrust and WebTrust audits are intended for e-commerce Web sites. The commenter asserted that a healthcare information application is considerably more complex than an e-commerce Web site, as an EMR may provide thousands of features/functions. The commenter asked what the auditor would examine and test during an audit of such a complex application. The commenter asked whether CPA firms are qualified to audit such complex applications in a consistent manner. With the overall complexity and the number of organizations that would be required to obtain the audits, it asked whether DEA had considered the impact of such a requirement if organizations are not able to get an audit performed due to overall demand.

DEA Response. The WebTrust audit is intended for Web sites, but the SysTrust

[30] *http://www.naspo.info.*

audit and the SAS 70 audits are not. DEA stated in the NPRM that the only aspects of the applications that are subject to the audit are processing integrity and, for ASPs, physical security as they relate to the creation and processing of controlled substance prescriptions. DEA is not requiring an application provider to have all aspects and functions of their applications audited. Although a provider may want an auditor to determine whether its application accurately moves data from one part of an EHR to another (*e.g.,* diagnosis codes from the patient record to an insurance form), DEA is not requiring that such functions be audited unless they directly affect the creation, signing, transmitting, or, for pharmacies, the processing of controlled substance prescriptions.

As discussed above, if an organization develops a program to certify electronic prescription or pharmacy applications, DEA will review the processes for certification of applications proposed by that organization to determine if the certification standards adequately evaluate compliance with part 1311. DEA will provide a list of those organizations whose certification processes adequately address compliance with DEA's requirements and allow such certifications to take the place of third-party audits. This should reduce the cost to application providers. As for the concern about the availability of third-party auditors, DEA notes that there are a limited number of applications, which are unlikely all to be ready for audits at the same time. DEA, however, has expanded the range of potential auditors by including those who have CISA credentials.

Comments. A number of commenters objected to the annual audit, stating that the applications do not change annually. They suggested a two- or three-year period would be more appropriate.

DEA Response. DEA agrees with commenters on the issue of annual audits and has revised the rule to require an initial audit prior to use of the application for electronic prescriptions for controlled substances, and to require subsequent audits once every two years or whenever functions related to creating and signing or processing of controlled substance prescriptions are altered, whichever occurs first. Application providers will be required to keep their most recent audit report and any other reports obtained in the previous two years. DEA notes that CCHIT now requires recertification every two year.

Comments. Practitioner organizations, healthcare organizations, and an intermediary stated that prescribers are not competent to review audits and that DEA should publish a list of qualifying applications. One association stated that the onus should be on the application provider to meet the requirements and fix any deficiencies so that practitioners do not need to stop using an application.

DEA Response. SysTrust and WebTrust audit reports are intended for the public. It should not be difficult for an application provider to insist that the report include a summary that clearly states whether the application meets DEA requirements. If certification bodies take on the role of certifying applications for compliance with part 1311, the existence of the certification will be enough to meet the requirement to use a compliant application. DEA expects that application providers will have an incentive to address any shortcomings quickly to ensure customer satisfaction.

Comments. Another commenter asked why the intermediaries are not required to be audited. A State agency asserted that intermediaries should be independently certified and audited annually. That commenter suggested that transmission should be limited to wired networks.

DEA Response. DEA's rule does not address the use of intermediaries in the transmission of electronic prescriptions for controlled substances. Rather, it addresses requirements for applications used to write electronic prescriptions for controlled substances and process them at pharmacies, and requirements for the registrants who use those applications. DEA requires registrants to use only applications that meet certain requirements because the registrants choose the applications. Registrants have no control over the string of three to five intermediaries involved in some electronic prescription transmissions. A practitioner might be able to determine from his application provider which intermediaries it uses to move the prescription from the practitioner to SureScripts/RxHub or a similar conversion service, but neither the practitioner nor the application provider would find it easy to determine which intermediaries serve each of the pharmacies a practitioner's patients may choose. Pharmacies have the problem in reverse; they may know which intermediaries send them prescriptions, but have no way to determine the intermediaries used to route prescriptions from perhaps hundreds of practitioners using different applications to SureScripts/RxHub or a similar service. Despite these considerations, DEA believes the involvement of intermediaries will not compromise the integrity of electronic prescribing of controlled substances, provided the requirements of the interim final rule are satisfied. Among these requirements is that the prescription record be digitally signed before and after transmission to avoid the need to address the security of intermediaries. DEA realizes that this approach will not prevent problems during the transmission, but it will at least identify that the problem occurred during transmission and protect practitioners and pharmacies from being held responsible for problems that may arise during transmission that are not attributable to them.

J. Risk Assessment

In the NPRM, DEA provided a detailed risk assessment, applying the criteria of OMB M–04–04, a guidance document for assessing risks for Federal agencies. (*See* 73 FR 36731–36739; June 27, 2008.) Under M–04–04, risks are assessed for four assurance levels (1—little or no confidence in asserted identity—to 4—very high certainty in the asserted identity) across six potential impacts. M–04–04 classifies risks as low, medium, and high as described in Table 1 and associates risk levels with assurance levels as shown in Table 2.

TABLE 1—M–04–04 POTENTIAL IMPACTS OF AUTHENTICATION ERRORS [31]

	Low impact	Moderate impact	High impact
Potential Impact of Inconvenience, Distress or Damage to Standing or Reputation.	At worst, limited short-term inconvenience, distress or embarrassment to any party.	At worst, serious short-term or limited long-term inconvenience or damage to the standing or reputation of any party.	Severe or serious long-term inconvenience, distress or damage to the standing or reputation to the party (ordinarily reserved for situations with particularly severe effects or which may affect many individuals).
Potential Impact of Financial Loss.	At worst, an insignificant or inconsequential unrecoverable financial loss to any party, or at worst, an insignificant or inconsequential agency liability.	At worst, a serious unrecoverable financial loss to any party, or a serious agency liability.	Severe or catastrophic unrecoverable financial loss to any party; or severe or catastrophic agency liability.
Potential impact of harm to agency programs or public interests.	At worst, a limited adverse effect on organizational operations, assets, or public interests. Examples of limited adverse effects are: (i) Mission capability degradation to the extent and duration that the organization is able to perform its primary functions with noticeably reduced effectiveness; or (ii) minor damage to organizational assets or public interests.	At worst, a serious adverse effect on organizational operations or assets, or public interests. Examples of serious adverse effects are: (i) Significant mission capability degradation to the extent and duration that the organization is able to perform its primary functions with significantly reduced effectiveness; or (ii) significant damage to organizational assets or public interests.	A severe or catastrophic adverse effect on organizational operations or assets, or public interests. Examples of severe or catastrophic effects are: (i) Severe mission capability degradation or loss of [sic] to the extent and duration that the organization is unable to perform one or more of its primary functions; or (ii) major damage to organizational assets or public interests.
Potential Impact of unauthorized release of sensitive information.	At worst, a limited release of personal, U.S. government sensitive, or commercially sensitive information to unauthorized parties resulting in a loss of confidentiality with a low impact, as defined in FIPS PUB 199.	At worst, a release of personal, U.S. government sensitive, or commercially sensitive information to unauthorized parties resulting in a loss of confidentiality with a moderate impact, as defined in FIPS PUB 199.	At worst, a release of personal, U.S. government sensitive, or commercially sensitive information to unauthorized parties resulting in a loss of confidentiality with a high impact, as defined in FIPS PUB 199.
Potential Impact to Personal Safety.	At worst, minor injury not requiring medical treatment.	At worst, moderate risk of minor injury or limited risk of injury requiring medical treatment.	A risk of serious injury or death.
Potential impact of civil or criminal violations.	At worst, a risk of civil or criminal violations of a nature that would not ordinarily be subject to enforcement efforts.	At worst, a risk of civil or criminal violations that may be subject to enforcement efforts.	A risk of civil or criminal violations that are of special importance to enforcement programs.

TABLE 2—MAXIMUM POTENTIAL IMPACTS FOR EACH ASSURANCE LEVEL

	Level 1	Level 2	Level 3	Level 4
Potential Impact of Inconvenience, Distress, or Damage to Standing or Reputation.	Low Impact	Moderate Impact	Moderate Impact	High Impact.
Potential Impact of Financial Loss	Low Impact	Moderate Impact	Moderate Impact	High Impact.
Potential impact of harm to agency programs or public interests.	n/a	Low Impact	Moderate Impact	High Impact.
Potential Impact of unauthorized release of sensitive information.	n/a	Low Impact	Moderate Impact	High Impact.
Potential Impact to Personal Safety	n/a	n/a	Low Impact	Moderate Impact.
Potential impact of civil or criminal violations	n/a	Low Impact	Moderate Impact	High Impact.

In the risk assessment conducted as part of the NPRM, DEA determined that the potential impact of financial loss and the potential impact of unauthorized release of sensitive information were not applicable to the rule; the risk related to the potential impact of inconvenience, damage, or distress to standing or reputation was rated as moderate. DEA rated the other three factors as high risk, which is associated with Level 4. As DEA discussed in the NPRM, inadequate requirements for authentication protocols would make it difficult to detect diversion and to enforce the statutory mandates of the Controlled Substances Act; DEA's ability to carry out its statutory mandate would be seriously undermined. As DEA discussed extensively in the NPRM, the consequences of diversion and abuse of controlled substances are clearly severe to the users. The criminal penalties associated with diversion involve imprisonment and/or fines. (See 73 FR 36733–36734, June 27, 2009, for a full description of the reasons for DEA's ratings.) Because the highest risk level rated for any element determines the overall assurance level, DEA proposed using Level 4 for the authentication protocols although it did not apply any assurance level to identity proofing.

Comments. Only four commenters directly addressed the risk assessment. An application provider and an information technology firm addressed the requirements for a hard token and

[31] Office of Management and Budget. "E-Authentication Guidance for Federal Agencies" M–04–04.

asserted that Level 4 would be very hard to implement and that Level 3 would be sufficient.

The information technology firm stated that Level 4 token technology is significantly more costly to distribute, manage, and operate than multi-token Level 3 technologies. The commenter asserted that cell phone-based multi-factor one-time-password devices require the distribution of code that is unique to each cell phone platform. Consequently, the commenter asserted, the cost and complexity for the end-users is significant. The logistical management of the software and cryptographic solutions for multi-factor cryptographic hardware devices make their cost untenable in a large scale, heterogeneous deployment. The application provider asserted that Level 4 requires that every system user use a Level 4 token to access the system, not just practitioners accessing select functions in a single application. Both commenters suggested that DEA require Level 3 tokens that are stored on a device "separate from the computer gaining access," citing OMB memorandum M–07–16 on safeguarding personal information.[32] These commenters asserted that this approach would eliminate the risk that DEA cited with NIST Level 3, which allows storage on the computer gaining access. They stated that "the use of such multi-token level 3 two-factor authentication solutions has been proven successful in mass scale deployments with heterogeneous user populations since no hardware or software is required by the end-user specific to the authentication transaction. This has been done with no provisioning complexity and a variety of integrated identity proofing capabilities including face-to-face and remote knowledge-based identity proofing." An intermediary stated that most PDAs or other handheld devices typically do not meet a FIPS 140–2 validation with physical security at Level 3 or higher. It also said that SP 800–63–1 does not require that approved cryptographic algorithms must be implemented in a cryptographic module validated under FIPS 140–2.

DEA Response. DEA agrees with some of the comments and has revised the interim final rule to allow authentication protocols that meet NIST Level 3; if the protocols involve a hard token, they must be either one-time-password devices or cryptographic modules that are not stored on the computer the practitioner is using to access the application. Contrary to the commenter's claim, NIST SP 800–63–1 requires both OTP devices and cryptographic tokens to be validated at FIPS 140–2 Security Level 1 or higher.[33]

The primary purpose of the higher level of physical security for Level 4 is to prevent tampering with the device. Given the technical expertise needed to tamper with a device without making it nonfunctional, DEA does not consider that such tampering is enough of a risk in healthcare settings to justify imposing the higher costs associated with such devices. DEA believes that the other steps it is implementing regarding identity proofing and logical access control are sufficient to mitigate the risk to allow for Level 3 rather than Level 4 tokens. By requiring that two factors are used to access the controlled substance functions in the application, DEA is limiting the threat from stolen or tampered-with tokens.

Comments. Another application provider objected to DEA's assessment and argued that Level 2 protections (single-factor) were adequate. The application provider stated that Level 2, with the use of a strong password in addition to a known Internet Protocol address or out-of-band token, would be sufficient. The application provider also suggested that DEA should adopt a tiered approach, with lesser requirements for Schedule III, IV, and V substances (just a strong password). For Schedule II, it suggested a combination of a strong password and other "something you know" (*e.g.,* out-of-band message, challenge response questions) plus a printout of every prescription, with the printout manually signed to create an audit trail. As an alternative the application provider suggested that if DEA requires two-factor authentication, DEA should allow a variety of second factors including whitelisted IP address, biometrics, soft tokens, and hard tokens, such as proximity badges, barcode readers, thumb drives, etc.

DEA Response. DEA disagrees with this commenter. DEA does not believe that one-factor authentication is adequate. As discussed at length above, passwords are not secure, particularly in healthcare settings where people work in close proximity to each other and many people may use the same computers. Even without the possibility of shoulder-surfing in such settings, strong passwords, because of their complexity and the need to change them frequently, are more likely to be written down. DEA also notes that maintenance of password systems imposes considerable costs.

DEA also disagrees with the commenter's suggestion for different requirements for Schedule II prescriptions. As DEA has discussed, electronic prescriptions are written prescriptions. Requirements for written prescriptions are uniform, regardless of the schedule of the controlled substance. Further, to establish differing requirements for Schedule II controlled substance prescriptions as compared with Schedule III, IV, and V prescriptions would add unnecessary complexity to the electronic prescription application. The commenter's suggestion appears to be based on the assumption that Schedule II substances, and their related prescriptions, are more likely to be diverted; however, DEA notes that both Schedule III and Schedule IV substances, and their related prescriptions, are regularly diverted for nonlegitimate use. DEA believes that a single approach more accurately reflects the statutory and regulatory requirements for written prescriptions, is more appropriate, and will be easier for application providers and practitioners to implement.

DEA has adopted some of the second factors that the commenter suggested, specifically the biometric and any hard token that meets NIST Level 3, which could include proximity cards and thumb drives that contain a cryptographic module. DEA does not believe that associating a prescription with a particular IP address will provide a pharmacy any assurance of the identity of the person who signed the prescription; any prescription generated on a practice's computers may have the same IP address. This suggestion also assumes that every pharmacy to which a practitioner may transmit would have the ability to determine whether the source IP address was whitelisted.

Comments. An intermediary asserted that DEA should implement electronic prescriptions for controlled substances with Level 2 and increase the requirements only if needed. The commenter asserted that the existing system includes authentication of the clinician and the connections, access controls, audit trails, and pharmacist as a gatekeeper. It stated that electronic prescribing could not increase the speed of diversion because the pharmacist acts as a gatekeeper. The commenter claimed that electronic prescribing would have a low impact on harm to the agency and public interest. The commenter asserted that the ability to breach the electronic

[32] *http://www.whitehouse.gov/omb/assets/omb/memoranda/fy2007/m07-16.pdf.*

[33] National Institute of Standards and Technology. Special Publication 800–63–1, Draft *Electronic Authentication Guideline,* December 8, 2008, pages 40–41.

prescribing infrastructure would take far greater expertise than today's paper system. The commenter further claimed that electronic prescribing would reduce the risk of injury and death by reducing undetectable diversion and abuse. The commenter asserted that personal safety should be considered low risk. Stronger authentication of the clinician minimally reduces the risk of alteration of the prescription; existing processes and controls audited by third parties reduce the overall risk more significantly. The commenter believed that existing electronic prescribing infrastructure and systems will dramatically reduce the chance of diversion and abuse seen in the existing paper process; thus, the commenter asserted, the risk of civil or criminal violations is actually reduced with electronic prescribing and should be considered low. The commenter stated that data mining would effectively address diversion concerns.

DEA Response. DEA strongly disagrees with this commenter's claims. The existing system, where some applications allow individuals to enroll online with no identity proofing, provides no assurance that the person issuing a prescription is a practitioner. It takes no technical expertise to steal an identity, particularly for office staff who have access to DEA registration certificates and State authorizations. Applications that do not have logical access controls or do not implement them may allow any person with access to a practitioner's computers to write and issue prescriptions. Passwords, as discussed previously, are the most common form of authentication credential and provide no proof that the person entering the password is the person associated with the password. The security of the prescription as it moves through intermediaries is of limited value if there is no evidence of who issued the prescription. Strong authentication is needed, not simply to prevent alteration, but to prevent nonregistrants from issuing controlled substance prescriptions. The risk of diversion without strong authentication is high. The practitioners could be subject to civil and criminal prosecution if their applications are misused and prescriptions are written in their names, or if their identity is stolen.

As to the claim that pharmacists will prevent wide-spread diversion, it is difficult to see how this could be the case. If someone issues multiple prescriptions to a patient and transmits them to multiple pharmacies, the pharmacists will have no ability to identify the problem, just as a single pharmacist will not be able to identify fraudulent prescriptions issued to multiple patients. Unlike paper prescriptions, electronic prescriptions lack many of the indications of a forged prescription that pharmacists use to identify a forged paper prescription. Electronic prescribing applications make it difficult for the person diverting to misspell a drug name or to select dosage forms that do not exist; they provide no indication of alterations.

The commenter assumes that such problems will be discovered through data mining and that data mining will reduce diversion. DEA, however, has no authority to collect data on all prescriptions issued and, therefore, no ability to conduct data mining. Even if DEA had the authority to collect prescription data, data mining would only work if all prescription data were available (electronic prescriptions, paper, fax, and oral) and in a common electronic format. If the per-prescription transaction fee charged by the commenter for transmission is any indication of the cost of that one step in data mining, the cost of data mining for controlled substance prescriptions to DEA could be high.

Data mining, were it legally possible and economically feasible, is based on being able to identify patterns of unusual activities. Data mining might detect individuals diverting controlled substances for themselves or registrants issuing large numbers of prescriptions potentially other than for legitimate medical purposes. It would not identify the organized diverters who would easily determine what patterns would trigger investigation and avoid those patterns. One problem with poorly controlled or uncontrolled electronic prescription issuance is that it would be easy for criminals to steal practitioner identities, issue a limited number of prescriptions under each identity to a limited number of patients, and move on to the next set of stolen identities. Nothing in the pattern would trigger investigation, regardless of whether data mining was being conducted.

Finally, data mining, even in real time if that were to be possible, would not prevent many of the injuries and deaths diversion causes because the drugs would have been obtained and used or sold before law enforcement could act. To claim that the risk to personal safety is low is to ignore the reality of the consequences of drug diversion. DEA considers it critical that electronic prescribing applications for controlled substance prescriptions be designed to limit the possibility of diversion to as great an extent as possible rather than assume that the problems will not occur. Fixing the problem after electronic prescribing applications are widely deployed, as the commenter suggested, could be done, would be far more difficult and more disruptive than implementing reasonable controls in the early stages of the applications' use.

Because of DEA's statutory responsibilities and the magnitude of the harm to the public health and safety that would result if an insufficiently secure system were to cause an increase in diversion of controlled substances, any regulations authorizing the use of electronic prescriptions for controlled substances must contain adequate security measures from the outset. DEA cannot, consistent with its obligations, set the bar lower than it believes necessary with an eye toward increasing the security requirements at some later date should the vulnerabilities be exploited. Regulatory changes take significant time—time during which there could be continuing harm to the public health and safety.

Comment. One application provider stated that the use of the government guidelines for risk assessment was inappropriate because those guidelines were developed to analyze people remotely accessing open networks.

DEA Response. DEA recognizes that the guidelines were developed for government systems, but believes that the basic principles can be applied to the security of both Federal and private applications. Although practitioners may write most of their prescriptions while at their offices, they will probably want the ability to access their office applications when they are away from the office so they can issue prescriptions remotely when needed; such access will frequently be through the Internet and may use wireless connections. In addition, practitioners using application service providers access the electronic prescription application over the Internet, which they may do from any computer or location. Security concerns must address both of these situations.

K. Other Issues

1. Definitions

In the NPRM, DEA proposed to move all of the existing definitions in part 1311 to a new section in part 1300 (§ 1300.03) and to add new definitions to that section. The proposed definitions included "audit," "audit trail," "authentication," "authentication protocol," "electronic prescription," "hard token," "identity proofing," "intermediary," "NIST SP 800–63," "paper prescription," "PDA," "SAS 70 audit," "service provider," "SysTrust," "token," "valid prescription," and "WebTrust."

Definition of "Service provider." In the NPRM, DEA proposed to define a service provider as follows:

Service provider means a trusted entity that does one or more of the following:

(1) Issues or registers practitioner tokens and issues electronic credentials to practitioners.

(2) Provides the technology system (software or service) used to create and send electronic prescriptions.

(3) Provides the technology system (software or service) used to receive and process electronic prescriptions at a pharmacy.

Comments. Practitioner and pharmacy organizations requested that DEA define service providers and intermediaries. A practitioner organization stated that DEA had used "service provider" for any third party (vendor or intermediary). It believed that these should have separate names. A standards organization asked who the service provider is in the case where the software is loaded to the practitioners' computers. A pharmacy organization also asked for clarification of the term "service provider" and whether their functions can be delegated.

An intermediary recommended modifying the definition of service provider to recognize that some prescribers and the entities for which they work have created their own electronic prescribing applications. The intermediary noted that some prescribers, as well as some pharmacies, have their own proprietary applications and do not connect to intermediaries through third-party service providers, but rather connect directly. Accordingly, some entities in fact act as both a prescriber or pharmacy, on the one hand, and an application provider, on the other hand. The intermediary also noted that the addition of the word "trusted" to the definition of service provider adds a subjective element that is not defined anywhere in the NPRM. While the word "trusted" is a term of art used in the industry, since it is not defined in the NPRM, the intermediary stated that DEA should delete the word "trusted" from the definition of service provider to avoid any ambiguity in the future. The intermediary argued that if an entity complies with the requirements as imposed by the rule, then that entity is and should be considered a trusted entity, and there is no need to introduce an undefined and subjective word such as "trusted" into the definition.

DEA Response. DEA agrees that further delineation among the various entities involved in electronic prescribing of controlled substances is needed. In addition, DEA has changed the terms to use the more accurate word "application," rather than service or system. In computer terminology, an application is software that performs specific tasks (*e.g.,* word processing, EHRs); a system is the underlying operating program. DEA has, therefore, revised the rule to add the following definitions.

Electronic prescription application provider means an entity that develops or markets electronic prescription software either as a stand-alone application or as a module in an electronic health record application.

Pharmacy application provider means an entity that develops or markets software that manages the receipt and processing of electronic prescriptions.

Application service provider means an entity that sells electronic prescription or pharmacy applications as a hosted service, where the entity controls access to the application and maintains the software and records on its servers.

Installed electronic prescription application means software that is used to create electronic prescriptions and that is installed on a practitioner's computers and servers, where access and records are controlled by the practitioner.

Installed pharmacy application means software that is used to process prescription information and that is installed on the pharmacy's computers or servers and is controlled by the pharmacy.

The definition of "intermediary" is unchanged from the NPRM: "*Intermediary* means any technology system that receives and transmits an electronic prescription between the practitioner and pharmacy."

DEA believes that these revisions will clarify the rule and allow DEA to make the distinction between application service providers, who host and manage the electronic prescription applications on an ongoing basis, and those providers that develop, market, or install software, but do not manage the application once it is installed. In the case of a closed system, a single entity may manage both the electronic prescription application and the pharmacy application and, therefore, would be considered to be the provider of both. Based on the inclusion of these new definitions, DEA has removed the term "service provider" from the interim final rule.

Definition of "electronic signature." In the NPRM, DEA proposed to define the term electronic signature as follows: "Electronic signature means a method of signing an electronic message that identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message." As DEA explained in the NPRM, this definition of electronic signature is taken directly from 21 CFR 1311.02, and was merely being merged into the definitions section for electronic ordering and prescribing activities.

Comments. Several commenters stated that DEA should adopt the E-Sign definition of electronic signature: "Electronic Signature means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record."

DEA Response. DEA disagrees. The definition of "electronic signature" in the proposed rule is the existing definition in § 1311.02 that was adopted in 2005 when DEA promulgated its "Electronic Orders for Controlled Substances" Final Rule (70 FR 16901, April 1, 2005). DEA is simply moving the definitions codified in that final rule to a new section. DEA believes that the E-Sign definition is too general to provide the necessary clarity in the context of this interim final rule.

Comments. A healthcare group asked DEA to further define "manually signed." It asked whether the act of a practitioner signing with an electronic signature would suffice or is a handwritten signature on the computer-generated prescription that is printed or faxed required.

DEA Response. DEA does not believe that "manually signed" requires further definition. The phrase "manually signed" has been a part of the DEA regulations since the inception of the CSA (and is currently found in § 1306.05(a)) without the need for elaboration. It has a plain language meaning that is clear: The practitioner must use a pen, indelible pencil, or other writing instrument to sign by hand the paper prescription.

Comments. An application provider organization stated that the word "signing" is imprecise; instead it should say "approve" and/or "transmit."

DEA Response. DEA has revised the proposed rule, as discussed, to require that two-factor authentication act as signing and that the application must label the function as signing as well as presenting a statement on the screen that informs the practitioner that executing the two-factor authentication protocol is signing the prescription. Signing is the practitioner's final authorization for the transmission and dispensing of a controlled substance prescription, issued for a legitimate medical purpose in the usual course of

professional practice, and indicating the practitioner's intent to be legally responsible for such authorization.

Comments. A State Board of Pharmacy provided definitions it uses for electronic prescriptions to define "point of care vendors," "network vendors," "prescribers," and "contracted."

DEA Response. DEA considered these definitions in developing its definitions for the interim final rule. The definitions offered by the Board of Pharmacy commenter include requirements, which are not generally part of Federal definitions. The commenter's definitions appear to rely on contracts among the various vendors for security, but it is not clear how these contracts would be enforced or how a practitioner or pharmacy would be able to determine that they were in place. DEA also notes that the network vendor definition fails to consider that many intermediaries connect only to other intermediaries, not to practitioners and pharmacies. A definition of prescriber is not needed as DEA's rules limit who can prescribe controlled substances. Thus, while DEA appreciates the Board of Pharmacy's suggestions, it did not adopt any of the definitions specifically included in the comment.

Definition of "closed system." DEA did not propose to define the term "closed system." This phrase would refer to situations in which both the electronic prescription application and the pharmacy application were controlled by the same entity and where practitioners and pharmacies outside of the closed system could not access or be accessed by users of the closed system.

Comments. An insurance industry organization suggested that DEA add a definition of "closed system" to address healthcare systems that employ both the practitioner and pharmacists and handle the prescriptions within a single system.

DEA Response. DEA does not believe that a definition of closed system is needed at this time because DEA is not imposing any additional or different requirements on closed systems. Closed systems are subject to the same rules as open systems. As discussed above, DEA is allowing non-Federal systems to use the rules proposed for Federal systems. Some closed systems may find it advantageous to adopt this approach, but they are not required to do so.

Definition of "hard token." In the NPRM, DEA proposed to define the term hard token as follows: "Hard token means a cryptographic key stored on a special hardware device (*e.g.,* a PDA, cell phone, smart card) rather than on a general purpose computer."

Comments. An information technology organization recommended that DEA add a USB fob to the list of hardware devices described in the definition of hard token. It also recommended the use of the term Key Storage Mechanism instead of hard token as this is the more standard industry term in current use.

DEA Response. DEA has added USB fob to the list of devices described in the definition of "hard token." DEA notes that this list merely provides examples and is not all-encompassing. If another hardware device meets DEA's requirements for security it can be used to meet the requirements of this interim final rule.

Definitions related to digital signatures. DEA did not propose any definitions in the NPRM related to digital signatures other than those it was transferring from 21 CFR 1311.02.

Comments. An information technology organization recommended adding definitions for registration agent and trusted agent. A security firm suggested the inclusion of several other definitions related to digital signatures.

DEA Response. DEA does not believe that definitions of registration agent and other certification authority terms are needed. DEA has, however, added a definition of "trusted agent," because institutional practitioners may fill this role if they elect to obtain authentication credentials from a certification authority or credential service provider for practitioners using their electronic prescription application to write controlled substances prescriptions. The definition is based on NIST's definition and describes the trusted agent as an entity authorized to act as a representative of a certification authority or credential Service provider in confirming practitioner identification as part of the identity proofing process.[34]

Definition of NIST SP 800–63. In the NPRM, DEA proposed to define the term NIST SP 800–63 as follows: "NIST SP 800–63, as incorporated by reference in § 1311.08 of this chapter, means a Federal standard for electronic authentication." While this term appeared in the definitions, DEA also notes that the Special Publication itself was also proposed to be incorporated by reference in proposed § 1311.08.

Comments. A healthcare organization stated that the definition of NIST SP 800–63 should be modified to cover future revisions.

DEA Response. DEA has revised the incorporation of NIST SP 800–63 to cover the current version. Federal agencies are not permitted to incorporate by reference future versions of documents.

Definitions of SysTrust and WebTrust. In the NPRM, DEA separately defined the terms SysTrust and WebTrust.

Comments. A healthcare organization believed that SysTrust and WebTrust have converged under the reference of Trust Services for business to business commerce. The commenter believed that a new definition for Trust Services should be introduced and language within the rule modified accordingly for such references.

DEA Response. Although SysTrust and WebTrust are considered part of Trust Services, they are still separate services and identified as such by the American Institute of Certified Public Accountants. Therefore, DEA has not revised these terms in this interim final rule.

Other Definition Issues:

Comment. One commenter stated that DEA should adopt the NIST SP 800–63 definition of "possession and control of a token" and recommended that DEA define "sole possession."

DEA Response. DEA does not believe that these definitions are necessary. Both phrases consist of plainly understood terms that have well-established legal meanings.

2. Other Issues

Comments. A number of commenters asked DEA to provide a list of application providers that met DEA's requirements. A practitioner organization, a pharmacy organization, and a physician suggested that DEA make available to prescribers and application providers a database of pharmacies that accept electronic prescriptions. The physician suggested that DEA require all pharmacies to register their ability to accept electronic prescriptions for controlled substances with DEA and for DEA to provide an online automatic directory that enables all electronic health record application providers and electronic prescription application providers to query for all pharmacies and determine immediately if an electronic prescription for a controlled substance can be sent to a particular pharmacy. The commenter suggested that, if it was determined that a particular pharmacy did not accept electronic prescriptions, the electronic health record application or electronic prescription application could then automatically switch to print and notify the prescribing physician of the change and requirement for wet signature and

[34] National Institute of Standards and Technology. IR–7298 *Glossary of Key Information Security Terms,* April 25, 2006.

providing the prescription to the patient. This commenter asserted that physicians have had considerable difficulty with the current noncontrolled substance electronic prescribing systems because they could not rely on pharmacy participation or have a reliable means of locating pharmacies. A practitioner organization suggested that DEA could require pharmacies to indicate whether they accept electronic prescriptions as part of DEA's registration process.

DEA Response. DEA does not believe that it is in a position to develop and maintain complete and accurate lists of either application providers that provide applications meeting DEA's requirements for electronic prescriptions for controlled substances, or of pharmacies that accept electronic prescriptions. Whether an application provider chooses to develop applications that comply with DEA's regulatory requirements and, thus, be in a position to supply applications that may lawfully be used by practitioners to create, sign, and transmit electronic prescriptions for controlled substances and by pharmacies to receive and process electronic prescriptions for controlled substances, is a business decision on the part of that provider. As all providers will be required to undergo third-party audits of their applications, DEA believes that these audit reports, which will be available to interested practitioners, will provide notice of application providers' compliance with DEA regulations. If certification organizations develop programs to certify compliance with DEA's requirements and DEA approves the programs, the certification will also provide practitioners with the information.

Similarly, DEA does not believe it appropriate for DEA itself to maintain a list of pharmacies that accept electronic prescriptions for controlled substances. Again, whether a pharmacy chooses to accept such prescriptions is a business decision left to that pharmacy. DEA is not in a position to proactively and continually monitor pharmacies' involvement in this arena, nor is DEA in a position to continually receive updates from its approximately 65,000 pharmacy registrants regarding their involvement. The electronic prescribing of controlled substances by prescribing practitioners, and the dispensing of those electronic prescriptions by DEA-registered pharmacies, is strictly voluntary. DEA notes that electronic prescription application providers maintain databases of pharmacies that accept electronic prescriptions for routing or other purposes. DEA believes that application providers and/or intermediaries are better suited to the task of maintaining these listings. This is particularly necessary as, due to potential interoperability issues, a pharmacy that can process prescriptions from one application provider may not be able to process prescriptions from other application providers.

Comments. A number of commenters urged DEA to adopt a particular version of the National Council for Prescription Drug Programs SCRIPT standard and cite particular SCRIPT functions. Several State pharmacist associations asserted that DEA should require the full support of all transaction types of the approved Centers for Medicare and Medicaid Services standards including fill status notification (RXFILL), cancel prescription notification (CANRX) transactions, and prescription change transactions (RXCHG), throughout the prescribing process for controlled substances. The commenters asserted that using these transactions supports medication adherence monitoring and decreases opportunities for diversion. These transactions are already present in the NCPDP SCRIPT standard. A pharmacy Application provider stated that DEA should clarify which SCRIPT transactions must be covered and recommended NEWRX, REFRES, and CHGRES. Pharmacy organizations noted that the SCRIPT standard does not provide explicit standards for some data elements in prescriptions (drug names, dosing, route, and frequency); without standards for these elements, interoperability between pharmacies and practitioners cannot be assured. A pharmacy organization urged DEA to encourage the development of discrete standards for these elements. Practitioner organizations also noted that the SCRIPT standard for sig (directions for use) has not been approved or accepted.

A pharmacy organization stated that it is receiving many reports of errors occurring in electronic prescriptions. The commenter indicated that the prescriptions are quite legible, but, occasionally, quite wrong. Pharmacists are reporting that many prescriptions are being received by the pharmacy with the drug names and directions for use truncated. In other cases, the directions are incorrect in the space allocated for directions, while the intended instructions are placed in the "comments" section. In other situations, the wrong drug, wrong strength, or totally incorrect directions are transmitted. Occasionally, the quantity of drug is incorrect. There have been a few instances where a computer application, according to anecdotal reports, actually "shuffled" prescriptions in the application, such that the drug intended for one patient appeared on screen for another patient. The organization asserted that errors have been caused by practitioner software and pharmacy software, as well as practitioner keying errors.

DEA Response. DEA shares the concern about prescription errors created by the SCRIPT standard, which is not yet fully functional. DEA, however, does not believe that mandating one version of the standard or particular functions would be useful. The standard continues to evolve; if DEA incorporated by reference one version, it would need to go through rulemaking to update the reference, which could delay implementation of improvements. DEA believes that the best approach is to set minimum requirements to ensure the integrity, authentication, and non-repudiation for controlled substance prescriptions (and in a manner consistent with maintaining effective controls against diversion) and leave the industry to develop all other aspects of electronic prescriptions. This will provide the maximum flexibility while ensuring that DEA's statutory obligations are addressed.

Comments. A few commenters suggested that DEA apply different standards for Schedule II prescriptions. One application provider suggested that Schedule II prescriptions should remain permissible only as paper prescriptions and that a single-factor authentication protocol be allowed for Schedule III, IV and V prescriptions.

DEA Response. It is true that prescriptions for Schedule II controlled substances are subject to greater statutory and regulatory controls than prescriptions for controlled substances in Schedules III, IV, and V. These differences in controls are commensurate with the differences among these drugs in relative potential for abuse and likelihood of causing dependence when abused. Along similar lines, it is accurate to state that, among the pharmaceutical controlled substances, drugs in Schedule II are subject to the most stringent controls because abuse of these drugs tends to be more harmful to the public health and welfare than abuse of pharmaceutical drugs in lower schedules. Nonetheless, DEA does not believe it is necessary or appropriate to disallow altogether the electronic prescribing of Schedule II controlled substances. Given the carefully crafted requirements contained in this interim final rule, DEA believes that electronic prescribing of all pharmaceutical controlled substances in

all schedules can take place without adversely affecting diversion control.

It should also be noted that the required elements of a prescription for a controlled substance (those set forth in 21 CFR 1306.05(a)) are the same for all prescriptions for controlled substances, and this same approach is followed in the interim final rule with respect to electronic prescriptions. Further, DEA believes that disallowing the electronic prescribing of Schedule II controlled substances could significantly hinder adoption of electronic prescribing of controlled substances in other schedules, as it would potentially create separate application requirements for separate schedules, causing confusion among practitioners, pharmacies, and application providers as to which requirements should be followed for which substances.

Comments. An application provider believed that proposed § 1311.100 is redundant in view of current § 1306.03 and should be deleted.

DEA Response. Current § 1306.03 ("Persons entitled to issue prescriptions.") provides general requirements for the issuance of all prescriptions, written and oral. While the requirements of proposed § 1311.100 ("Eligibility to issue electronic prescriptions.") restated principles from § 1306.03, DEA believes it appropriate to restate those important concepts specifically in regard to electronic prescriptions. Therefore, DEA is retaining the concepts proposed in § 1311.100.

Comments. A healthcare system asked DEA to clarify the specific consequences of non-compliance with each requirement.

DEA Response. The potential consequences of failing to comply with the requirements in this interim final rule regarding the electronic prescribing of controlled substances are the same as the potential consequences of failing to comply with longstanding requirements regarding the general prescribing and dispensing of controlled substances. Just as one cannot list all the potential scenarios in which the existing prescription requirements might be violated, one cannot list all the possible ways in which the various requirements of this interim final rule might be violated. However, as a general matter, if a person fails to comply with the requirements of this interim final rule in a manner that constitutes a criminal or civil violation of the CSA, that person is subject to potential criminal prosecution or civil action as contemplated by the Act. In addition, a DEA registrant who fails to comply with the requirements of the regulations is subject to potential administrative action that may result in suspension or revocation of his DEA registration.

Comments. A pharmacy organization and an intermediary stated that DEA should revise proposed § 1306.11(a) ("Requirement of prescription [for controlled substances listed in Schedule II].") to read "pursuant to a written or electronic prescription."

DEA Response. DEA has defined paper prescription in § 1300.03. A written prescription includes both paper and electronic prescriptions issued in conformity with the DEA regulations. Thus, the suggested revision is not necessary.

Comments. A number of pharmacist organizations submitted the same comment, listing the following as objectives DEA should pursue in developing the final rule:

- Promoting scalability and nationwide adoption of electronic prescribing by enabling all prescribers, regardless of the volume of controlled substances prescribed, to create and transmit prescriptions for controlled substances via the same electronic media as prescriptions for noncontrolled substances;
- Reducing and eliminating additional costs and administrative burden on pharmacists and prescribers;
- Ensuring compliance and consistency with the uniform standards relating to the requirements for electronic prescription drug programs;
- Improving patient safety and quality of care; and
- Allowing for the expeditious adoption of technological advances and innovation.

DEA Response. DEA has attempted to reduce the burden to practitioners, pharmacies, and others with changes in the interim final rule based on the comments received, providing flexibility to adopt other technologies as they become feasible, and facilitating adoption of electronic prescriptions for controlled substances. Although admirable goals, uniform standards and improved quality of care are not within DEA's statutory authority, other government agencies are responsible for these issues. DEA recognizes the benefits to pharmacies of uniform standards, but a variety of methods of signing and transmitting electronic prescriptions may satisfy the requirements of the interim final rule and should be allowed for those that wish to use them.

Comments. A number of practitioner organizations urged DEA to ensure that the requirements for electronic prescriptions for controlled substances were cost-effective, particularly for small practices.

DEA Response. DEA believes that the interim final rule will impose even lower costs on registrants than the proposed rule. DEA also notes that the incremental cost of its requirements is relatively small compared to the costs of adopting and installing new applications. A full discussion of the costs and benefits associated with this rule is provided in the required analyses section of this document.

Comments. One advocacy organization asserted that DEA is placing much of the responsibility for application security on practitioners and pharmacies, and asked if DEA has sufficient statutory authority to do so. The commenter asked whether such authority to require this new responsibility lies within the Controlled Substances Act authority to register practitioners.

DEA Response. As set forth at the outset of this preamble, DEA has broad statutory authority under the Controlled Substances Act to issue rules and regulations relating to, among other things, the control of the dispensing of controlled substances, and to issue and enforce rules and regulations that the agency deems necessary to effectuate the CSA.[35] Also, the structure of the CSA is unlike most statutory schemes in that it prohibits all transactions involving controlled substances except those specifically allowed by the Act and its implementing regulations.[36] The interim final rule is consistent with these aspects of the CSA. It is also worth reiterating here that DEA is not requiring any practitioner to issue electronic prescriptions for controlled substances or any pharmacy to accept them; it is simply setting the requirements that must be met before a practitioner may lawfully issue, and a pharmacy may lawfully process, electronic prescriptions for controlled substances.

As has been discussed previously, nothing in this rule prevents a practitioner or a practitioner's agent from using an existing electronic prescription application that does not comply with the interim final rule to prepare a controlled substance prescription, so that EHR and other electronic prescribing functionality may be used, and print the prescription for manual signature by the practitioner. Such prescriptions are paper

[35] 21 U.S.C. 821 & 871(b).

[36] 21 U.S.C. 841(a)(1). *See United States* v. *Moore,* 423 U.S. 122, 131 (1975) ("only the lawful acts of registrants are exempted" from the prohibition on distribution and dispensing of controlled substances set forth in 21 U.S.C. 841(a)(1)).

prescriptions and subject to the existing requirements for paper prescriptions.

Comments. Some commenters urged DEA to help tighten the security standards imposed under the Health Insurance Portability and Accountability Act. Others cited HIPAA as sufficient to protect the security of electronic prescriptions.

DEA Response. The Department of Health and Human Services is responsible for the HIPAA standards; questions or comments about these standards should be addressed to HHS. The HIPAA security standards are general, leaving many details on implementation to individual healthcare providers; many of the specifications to implement the security standards are addressable and not mandatory. HIPAA generally focuses on protecting the privacy of the individual patient's information rather than on the possibility of alteration of records or the creation of fraudulent records. As HIPAA was not designed to prevent the diversion of controlled substances, compliance with HIPAA standards alone will not result in the implementation of the types of measures contained in this interim final rule that are specifically tailored to safeguard against diversion.

Comments. A practitioner organization noted that the rule did not specify requirements for what the commenter termed "pharmacy-generated electronic refill requests." The commenter stated that existing electronic prescription applications allow physicians to quickly review and approve electronic refill requests from pharmacies. The commenter asserted that the efficiency of electronic refills is one of the major incentives for physicians to electronically prescribe. The commenter suggested that the final rule should explicitly state whether electronic refill requests will require physicians to take additional steps when authorizing refills of controlled substance prescriptions.

DEA Response. The interim final rule allows for a practitioner to authorize the refilling of an electronic prescription for a controlled substance in the same circumstances that the regulations currently allow a practitioner to authorize the refilling of a paper or oral prescription for a controlled substance. In this context, the following aspects of existing law and regulations should be noted. Part 1306 allows practitioners to authorize refills for controlled substances in Schedules III, IV, and V when the original prescription is written. Schedule II prescriptions may not be refilled, as set forth in the CSA, and DEA has no authority to depart from that statutory prohibition in the context of paper or electronic prescriptions. If a patient is seeking additional medication not authorized by the original prescription, the practitioner must issue a new prescription regardless of the Schedule. If a pharmacy electronically requests that a practitioner authorize the dispensing of medication not originally authorized on a prescription, or authorize a new prescription based on a previously dispensed prescription, DEA would view any prescriptions issued pursuant to those requests as new prescriptions. If they are written, regardless of whether they are electronic or on paper, they must be signed by the practitioner. Thus, a manual signature would be required for a paper prescription pursuant to § 1306.05, or a practitioner could follow the signature requirements for electronic prescriptions discussed in this rulemaking. Alternatively, for a Schedule III, IV, or V prescription, the pharmacy may receive an oral prescription for that controlled substance, but the pharmacy must immediately reduce that oral, unsigned, prescription to writing pursuant to current regulatory requirements.

Comments. A number of commenters asked that DEA postpone the effective date of the final rule, *i.e.,* grant what some commenters characterized as an "extended compliance date." Among these commenters, the range of suggested effective dates was from 18 months to four years after issuance of the final rule.

DEA Response. DEA believes it is unnecessary to postpone the effective date of the interim final rule because use of electronic prescriptions for controlled substances is voluntary. The interim final rule does not mandate that practitioners switch to electronic prescribing of controlled substances. As soon as electronic prescription applications can come into compliance with the requirements of these regulations they may be used for controlled substance prescriptions. Conversely, practitioners may not use existing electronic prescription applications to transmit electronic prescriptions for controlled substances until those applications are in compliance with the interim final rule. Pharmacy applications may also be used to process electronic prescriptions for controlled substances once they are in compliance with the interim final rule, but not before. DEA notes that existing electronic prescription applications may be used to create a prescription for controlled substances, but until the application is compliant with the rule, that prescription would have to be printed and signed manually, then given to the patient or, for Schedule III, IV, and V prescriptions, faxed to the pharmacy.

Similarly, DEA does not believe it prudent to delay the effective date of this rule for any length of time. DEA wishes to encourage adoption of electronic prescriptions for controlled substances as rapidly as industry is willing and able to comply with the requirements of this rule. DEA recognizes that some health care entities, particularly Federal healthcare facilities, may be more prepared to begin electronically prescribing controlled substances in compliance with this rule than others. To delay the effective date of this rule may unnecessarily hinder those organizations from electronically prescribing controlled substances as quickly as they are able.

Comments. A State pharmacy organization asserted that if it is required to use an intermediary in the transmission of a controlled substance prescription from a practitioner to a pharmacy, the only way to verify a prescription would be to call the practitioner.

DEA Response. DEA does not require the use of any intermediaries in the transmission of electronic prescriptions between prescribing practitioners and pharmacies. There is nothing in the rule that bars the direct transmission of an electronic prescription from a practitioner to a pharmacy. Until the SCRIPT standard is mature, however, a practitioner whose patients use multiple pharmacies may have to use intermediaries to ensure that the pharmacy will read the data file correctly. DEA believes that the requirements of the interim final rule will provide adequate protections.

Comments. A number of commenters believed that DEA would, could, or should conduct data mining of electronic controlled substance prescriptions. One commenter saw this as a potential threat to civil liberties. Others saw it as a benefit. A pharmacy organization and a chain pharmacy stated that adding requirements for electronic prescriptions will not improve DEA's ability to reduce abuse, but that data mining could. One commenter stated that the benefits to be gained from data mining would allow DEA to impose fewer requirements on electronic prescriptions.

DEA Response. DEA does not conduct a prescription monitoring program (as some States do) or otherwise engage in the generalized collection or analysis of controlled substance prescription data;

nor is it the intent of this rule to provide a mechanism for such an activity. The real-time data mining that some commenters feared and others saw as an advantage of electronic prescribing is not contemplated as part of this rulemaking. This rule permits practitioners to write electronic prescriptions for controlled substances and pharmacies to process those electronically written prescriptions. Those applications work independently of DEA and do not directly report prescription information to DEA. This rule merely establishes requirements those applications must meet to be used for electronic prescriptions for controlled substances.

DEA notes that 38 States have implemented prescription monitoring programs that are based on the submission of data from pharmacies after the prescriptions have been filled. These programs may be used to identify patients who are obtaining prescriptions from multiple practitioners at one time or practitioners who are issuing an unusual number of controlled substance prescriptions.

Comments. A State Board of Pharmacy asserted that there should be a requirement for application integration with all electronic medical record applications and State prescription data banks so that controlled substance prescriptions are readily identifiable.

DEA Response. DEA understands the Board's concern, but believes what the Board seeks is not feasible or appropriate as a DEA regulatory requirement at this time for two reasons. First, electronic prescription applications and electronic health record applications may be installed in many States. Unless all State data banks will be configured in exactly the same way, it would not be possible for an application provider to ensure its application would be integrated with any particular State system. DEA notes that the electronic prescription and electronic health record applications will have to be able to identify controlled substance prescriptions and generate logs of those prescriptions. Second, State systems have generally obtained data from pharmacies rather than practitioners. Pharmacy applications have to be able to identify controlled substance prescriptions.

Comments. A number of commenters representing practitioner organizations and one application provider stated that DEA should not impose any requirements until those requirements have been tested and shown ready for use.

DEA Response. DEA recognizes the value of pilot testing, but does not believe that waiting for pilot testing is necessary or appropriate. Many of the provisions DEA proposed in its NPRM have been revised based on comments received; DEA has provided options for some key items to give registrants and application providers alternatives. DEA also notes that with so many applications available, what may be feasible for one system may be burdensome for others, so that pilot testing would not necessarily prove whether a particular approach was feasible or difficult for any specific application provider. This is particularly true as electronic prescription applications can be either stand-alone applications or can be integrated into more robust applications, such as electronic health record applications.

Comments. A pharmacy organization asked if the statement in proposed § 1311.200(d) is imposing a strict liability standard.

DEA Response. The statement the commenter references appeared in both proposed § 1311.100(c) ("Eligibility to issue electronic prescriptions.") and proposed § 1311.200(d) ("Eligibility to digitally sign controlled substances prescriptions.") It reads: "The practitioner issuing an electronic controlled substance prescription is responsible if a prescription does not conform in all essential respects to the law and regulations." The statement in proposed § 1311.100(c) and § 1311.200(d) is simply a repetition of the existing requirement in current § 1306.05. This statement has been a part of the regulations implementing the CSA since the regulations were first issued in 1971 following the enactment of the CSA. In the ensuing 38 years, there has never been an occasion in which a court has declared the provision to be legally problematic or in need of elaboration. Accordingly, it is appropriate to retain the concept in the context of electronic prescriptions for controlled substances, which DEA is doing by incorporating the provision in § 1311.100 and § 1311.200.

Comments. Several commenters questioned DEA's concern about diversion. A State Board of Pharmacy asserted that it had found less risk of fraud with electronic prescriptions. Another State Board of Pharmacy disagreed that record integrity was needed to prosecute individuals forging prescriptions, asserting that it did not need to prove when and where a prescription was forged or altered. One physician stated that the problem with diversion was with the patient, not the doctor.

DEA Response. DEA notes that there is no substantial regulatory experience on which State Boards of Pharmacy or other regulating bodies may draw when it comes to electronic prescriptions for controlled substances as such method of prescribing has not, prior to the issuance of this interim final rule, been authorized by the DEA regulations. While there has been electronic prescribing of noncontrolled substances, it is not surprising that there may be little evidence of fraud with prescriptions for such drugs as they are far less likely to be abused and diverted than controlled substances. One State Board of Pharmacy seems to have misunderstood the purpose of the rule or the issues of establishing who altered a prescription when there is no forensic evidence. It is true that with a paper prescription, it may, depending on the circumstances, be unnecessary to establish when and where a prescription was altered because the alteration itself can provide evidence of who did it. With electronic prescriptions, however, there may be no effective means of proving who made the alteration absent evidence of when the change occurred. Likewise, without such evidence, it is difficult, if not impossible, to achieve non-repudiation, and thus the persons actually responsible for the prescription may be able to disclaim responsibility. As for the practitioner commenter who attributed the problem to the patient, DEA agrees that patients can be sources of diversion of controlled substances, but a considerable amount of diversion also occurs from within practitioners' offices and pharmacies as well.

Comments. One application provider stated that the evidence that DEA presented on insider threats in the NPRM would not have been available if these threats had not been identified. The commenter asserted that the ability of the Secret Service/Carnegie Mellon study [37] to identify the character of the employees as well as their "technical" status indicates that existing industry standards are sufficient to detect and investigate the nature of violations.

DEA Response. That studies have been able to identify the kinds of people who commit insider crimes does not support an argument that insider crimes are, therefore, not a problem or are easily identified or prosecuted. Further, most of the insider attacks mentioned in the study to which this commenter

[37] Insider Threat Study: Illicit Cyber Activity in the Banking and Financial Sector, August 2004; Insider Threat Study: Computer System Sabotage in Critical Infrastructure Sectors, May 2005.

referred were identified because the insiders or former insiders intended the attack to be obvious and destructive; these were usually revenge attacks by disgruntled employees or former employees. With financial insider attacks, the victim has reason to identify the attack because the attack results in financial losses. If insider attacks occur with electronic prescription applications, the application providers will not be the target or suffer financial losses; their applications will simply be used to commit a crime. In any event, regardless of what studies might purport to show with respect to insider attacks of computer-based systems, DEA has an obligation in this rulemaking to establish requirements that are particularly crafted to maintain effective controls against diversion of controlled substances in the context of electronic prescribing. DEA is aware of no study that refutes DEA's determination about the need for the controls contained in this interim final rule.

Comments. One commenter, a physician, suggested that DEA and the Centers for Medicare and Medicaid Services go back to the electronic prescribing and electronic health record industries and tell them to incorporate DEA's proposed system upgrades, that these be operational in any CCHIT-approved system before moving ahead with these standards, and that DEA tell Congress that no penalties should be applied to any non-adopting physician before the system has been upgraded to the satisfaction of DEA.

DEA Response. Consistent with the Administrative Procedure Act, DEA will articulate through this interim final rule those regulatory requirements regarding electronic prescriptions for controlled substances. DEA does not believe it would be legally sound or consistent with the public health and safety to declare that physicians or any other persons may disregard, without legal consequence, the standards established by this interim final rule.

Comment. A State said that checks for the validity and completeness of a prescription should occur at the prescriber's office. A pharmacy employee stated that prescribers should not be able to transmit prescriptions unless the prescription meets all regulations of the State where the prescription will be filled. This individual further believed that prescriptions should be allowed to be filled anywhere in the country. Finally, this individual recommended that there be provisions to permit the transfer of the prescription to another pharmacy even if it is out of State.

DEA Response. Section 1306.05 states that the practitioner is responsible for ensuring that a prescription conforms in all essential respects with the law and regulation; it also places a corresponding liability on pharmacies to ensure that only prescriptions that conform with the regulations are dispensed. The interim final rule requires that the electronic prescription application be capable of capturing all of the information and that the practitioner review the prescription before signing it. This requirement, however, does not relieve a pharmacy of its responsibility to ensure that the prescription it receives conforms to the law and regulations.

As this interim final rule is a *DEA* rule, it is, of course, focused on Federal, not State, requirements. In view of this comment, however, it should be noted that the CSA has long provided that a practitioner who fails to comply with applicable State laws relating to controlled substances is subject to loss of DEA registration.[38] Similarly, it has always been the case that compliance with the CSA or DEA regulations does not relieve anyone of the additional obligation to comply with any State requirements that pertain to the same activity.[39] Thus, it is both the practitioner's and the pharmacy's responsibility to ensure that the prescription complies with all applicable laws and regulations. DEA does not limit where a prescription may be filled, nor does it limit where a prescription may be transferred, provided such transfers take place in a manner authorized by the DEA regulations.

3. Beyond the Scope

A number of commenters raised issues that are beyond the scope of this rulemaking (*e.g.,* requirements on the number of registrations that a practitioner must hold, penalties and incentives for electronic prescribing, the inability to set an indefinite quantity in prescriptions for LTCF patients). Consistent with sound APA practice, and to avoid unnecessary discussion, DEA will not address in this interim final rule such comments that are not directly related to the electronic prescribing of controlled substances.

L. Summary of Changes From the Proposed Rule

In view of the comments that DEA received, the interim final rule contains a number of changes to the proposed rule. For the most part, the changes are logical outgrowths of the proposed rule and comments. In some instances, however, DEA has determined that the changes from the proposed rule warrant additional public comment. To assist the reader in understanding the changes, this section summarizes the major revisions. Commenters made a variety of recommendations on each issue. Where DEA determined that it could accept recommendations without lessening the security and integrity of controlled substance prescriptions, it has done so to provide more flexibility and lessen the burden on practitioners and pharmacies.

Identity proofing. DEA has adopted in the interim final rule an approach that is different from the approach it proposed. As some commenters recommended, the interim final rule requires individual practitioners to obtain NIST SP 800–63–1 Assurance Level 3 identity proofing from entities that are Federally approved to conduct such identity proofing; NIST SP 800–63–1 Assurance Level 3 allows either in-person or remote identity proofing, subject to the NIST requirements. The federally approved entities will provide the two-factor authentication credentials for individual practitioners. As commenters suggested, institutional practitioners have the option to conduct identity proofing in-house through their credentialing offices and may issue the two-factor authentication credentials themselves.

Access control. In contrast to the proposed rule, the interim final rule places the responsibility for checking the DEA and State authorities and setting logical access on the individual practice or institution rather than on the application provider. Commenters indicated that many application providers were not involved in these actions. Under the interim final rule, two individuals are required to enter or change logical access controls. The applications must limit access for indicating that a controlled substance prescription is ready for signing and signing to individuals authorized under DEA regulations to do so.

Two-factor authentication. The interim final rule retains the proposed requirement of two-factor authentication, but as commenters requested, allows the option of using a biometric to replace the hard token or the knowledge factor. DEA has also revised the rule to allow the hard token, when used, to be compliant with FIPS 140–2 Security Level 1 or higher, provided that the token is separate from the computer being accessed. DEA has revised the rule to allow practitioners with multiple DEA numbers to use a

[38] 21 U.S.C. 823(f)(4).

[39] *See* 21 U.S.C. 903.

single two-factor authentication credential per practitioner; the application must require these practitioners to select the appropriate DEA number for the prescription being issued. As commenters requested, the interim final rule also includes an application requirement that will allow a supervisor's DEA number to appear on the prescription provided it is clear which DEA number is associated with the prescribing practitioner.

Creating the prescription. As proposed, the interim final rule requires that practitioners indicate that each controlled substance prescription is ready to be signed. As commenters recommended, however, the patient's address need not appear on the review screen, but it must still be included on the transmitted prescription, consistent with longstanding regulations applicable to all prescriptions for controlled substances. The proposed attestation statement has been shortened and must appear on the screen at the time of the review, but, as some commenters recommended, does not require a separate keystroke. Also under the interim final rule, authentication to the application must occur at signing, eliminating the need for the proposed lock-out provision.

Signing and transmitting the prescription. As some commenters recommended, the interim final rule requires two-factor authentication to be synonymous with signing. In fact, the interim final rule expressly states that the completion of the two-factor authentication protocol by the practitioner legally constitutes that practitioner's signature of the prescription. When the practitioner completes the two-factor authentication protocol, the application must apply its (or the practitioner's) private key to digitally sign at least the information required under part 1306. That digitally signed record must be electronically archived. As commenters suggested, this revision allows other staff members to add information not required by DEA regulations after signature, such as pharmacy URLs, and at LTCFs, allows staff to review and annotate records before transmission, so that current workflows can be maintained. The interim final rule retains the proposed requirement that the electronic prescription application include an indication that the prescription was signed in the information transmitted to the pharmacy.

PKI. At the suggestion of many commenters, the interim final rule allows any practitioner to use the digital signature option proposed for Federal healthcare systems.

Transmission issues. The interim final rule adopts the suggestion of some commenters that printing of a transmitted electronic prescription be permissible provided the printed prescription is clearly marked as a copy not for dispensing. The interim final rule specifies the conditions for printing a prescription when transmission fails, as commenters asked. DEA has also clarified in the interim final rule that the prohibition on alteration of content during transmission applies to the actions of intermediaries; changes made by pharmacies are subject to the same rules that apply to all prescriptions for controlled substances. As proposed, intermediaries are not allowed under the interim final rule to transform an electronic prescription into a facsimile; facsimiles of prescriptions are paper prescriptions that must be manually signed.

Monthly logs. As some commenters recommended, DEA has retained in the interim final rule the requirement that the application automatically provide the practitioner with a monthly log of the practitioner's electronic prescribing of controlled substances. However, the interim final rule eliminates the proposed requirement that the practitioner indicate his review of the log. DEA has also maintained in the interim final rule the proposed requirement that the application provide practitioners a log on request. The interim final rule goes somewhat further than the proposed rule in this respect by requiring that the application allow the practitioner to specify the time period for log review, and to allow the practitioner to request and obtain a display of up to a minimum of two years of prior electronic prescribing of controlled substances and to request a display for particular patients or drugs.

Internal audit trails. DEA has provided in the interim final rule more detail on the requirements for the internal audit trails required for both prescription and pharmacy applications. The interim final rule does not provide a comprehensive list of auditable events as some commenters requested, but clarifies that auditable events should be limited to potential security problems. For pharmacy applications, the interim final rule eliminates the proposed requirement that the audit trail log each time a prescription is opened, as commenters suggested.

Other pharmacy issues. DEA has retained in the interim final rule the proposed requirement that either the last intermediary or the pharmacy digitally sign the prescription as received unless a practitioner's digital signature is attached and can be verified by the pharmacy. However, as commenters suggested, the interim final rule revises the requirement for checking the DEA registration of the practitioner to make it consistent with other prescriptions: the pharmacy must check the DEA registration when it has reason to suspect the validity of the registration or the prescription. Although DEA recommends as a best practice offsite storage of backup copies, it is not requiring it in the interim final rule as was proposed.

Third-party audits. As commenters recommended, the interim final rule allows certification of electronic prescription applications and pharmacy applications by a DEA-approved certification organization to replace a third-party audit. The interim final rule also expands beyond the proposed rule the list of potential auditors to include certified information system auditors. As commenters suggested, the interim final rule extends the time frame for periodic audits from one year to two years, or whenever a functionality related to controlled substance prescriptions is altered, whichever occurred first.

Recordkeeping. Based on the comments received, the interim final rule reduces the recordkeeping period to two years from the proposed five years.

DEA wishes to emphasize that the electronic prescribing of controlled substances is in addition to, not a replacement of, existing requirements for written and oral prescriptions for controlled substances. This rule provides a new option to prescribing practitioners and pharmacies. It does not change existing regulatory requirements for written and oral prescriptions for controlled substances. Prescribing practitioners will still be able to write, and manually sign, prescriptions for Schedule II, III, IV, and V controlled substances, and pharmacies will still be able to dispense controlled substances based on those written prescriptions and archive those records of dispensing. Further, nothing in this rule prevents a practitioner or a practitioner's agent from using an existing electronic prescription application that does not comply with the interim final rule to prepare a controlled substance prescription electronically, so that EHR and other electronic prescribing functionality may be used, and print the prescription for manual signature by the practitioner. Such prescriptions are paper prescriptions and subject to the existing requirements for paper prescriptions.

V. Section-by-Section Discussion of the Interim Final Rule

In Part 1300, DEA is adding a new § 1300.03 ("Definitions relating to electronic orders for controlled substances and electronic prescriptions for controlled substances.") The definitions currently in § 1311.02 are moved to § 1300.03. Definitions of the following are established without revision from the NPRM: "audit trail," "authentication," "electronic prescription," "identity proofing," "intermediary," "paper prescription," "PDA," "SAS 70," "SysTrust," "token," "valid prescription," and "WebTrust." Based on comments received, DEA is establishing the definition of "hard token," with changes as discussed above. Based on comments received, DEA is adding definitions of the terms "application service provider," "electronic prescription application provider," "installed electronic prescription application," "installed pharmacy application," "pharmacy application provider," and "signing function." DEA is updating the proposed definition of "NIST SP 800–63" to reflect the most current version of this document.

Other changes to definitions. Beyond the revisions discussed above, DEA has made several changes to the definitions section established in this rulemaking. Although not specifically discussed by commenters, DEA has made other changes to certain definitions to provide greater clarity, specificity, or precision. Changes are discussed below.

To address the use of a biometric as one possible factor in a two-factor authentication credential, DEA is adding definitions specific to that subject. Specifically, DEA is adding definitions of "biometric subsystem," "false match rate," "false non-match rate," "NIST SP 800–76–1," and "operating point." While DEA is adding a definition of "password" to mean "a secret, typically a character string (letters, numbers, and other symbols), that a person memorizes and uses to authenticate his identity," DEA is not establishing any regulations regarding password strength, length, format, or character usage.

In the definition of authentication protocol, DEA revised the language slightly to read: "Authentication protocol means a well specified message exchange process that verifies possession of a token to remotely authenticate a person to an application." The proposed language had read "to remotely authenticate a prescriber."

As discussed elsewhere in this rule, DEA is revising certain recordkeeping requirements. To ensure that terms used regarding recordkeeping are understood, DEA has repeated the definition of "readily retrievable" from 21 CFR 1300.01(b)(38). This definition is longstanding and is well understood by the regulated industry. DEA does not believe that this definition will cause the regulated industry any difficulty. Since the inception of the CSA, the DEA regulations have defined the term as follows: "*Readily retrievable* means that certain records are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records."

In its NPRM, DEA proposed to define the term "audit" as follows: "*audit* means an independent review and examination of records and activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures." To provide greater specificity to this term, DEA has revised the term to be "third-party audit" rather than simply "audit." The definition remains unchanged from the NPRM in all other respects.

DEA has added definitions of credential and credential service provider based on the NIST definitions in NIST SP 800–63–1.

DEA has added definitions for the updated NIST FIPS standards. Finally, DEA is defining the term "trusted agent" to provide greater specificity regarding identity proofing conducted by institutional practitioners.

In Part 1304, § 1304.04 is revised to limit records that cannot be maintained at a central location to paper order forms for Schedule I and II controlled substances and paper prescriptions. In paragraph (b)(1), DEA is removing the reference to prescriptions; all prescription requirements are moved to paragraph (h). Paragraph (h), which details pharmacy recordkeeping, is revised to limit the current requirements to paper prescriptions and to state that electronic prescriptions must be retrievable by prescriber's name, patient name, drug dispensed, and date filled. The electronic records must be in a format that will allow DEA or other law enforcement agencies to read the records and manipulate them; preferably the data should be downloadable to a spreadsheet or database format that allows DEA to sort the data. The data extracted should only include the items DEA requires on a prescription. Records are required to be capable of being printed upon request.

DEA is adding a new § 1304.06 ("Records and reports for electronic prescriptions.") This section does not create new recordkeeping requirements, but rather simply consolidates and references in one section requirements that exist in other parts of the rule. This new section is intended to make it easier for registrants and application providers to understand the records and reports they are required to maintain. Practitioners who issue electronic prescriptions for controlled substances must use electronic prescription applications that retain the record of the digitally signed prescription information and the internal audit trail and any auditable event identified by the internal audit trail. Institutional practitioners must retain a record of identity proofing and issuance of the two-factor authentication credential, where applicable, as required by § 1311.110. Pharmacies that process electronic prescriptions for controlled substances must use a pharmacy application that retains all prescription and dispensing information required by DEA regulations, the digitally signed record of the prescription as received by the pharmacy, and the internal audit trail and any auditable event identified by the internal audit trail. Registrants and application service providers must retain a copy of any security incident report filed with the Administration. Application providers must retain third-party audit or certification reports and any adverse audit or certification reports filed with the Administration regarding problems identified by the third-party audit or certification. All records must be retained for two years unless otherwise specified. DEA is not establishing any recordkeeping requirements for credential service providers or certification authorities because they are already subject to such requirements under the terms of certificate policies or frameworks they must meet to gain Federal approval.

In Part 1306 ("Prescriptions") § 1306.05 is amended to state that electronic prescriptions must be created and signed using an application that meets the requirements of part 1311 and to limit some requirements to paper prescriptions (*e.g.,* the requirement that paper prescriptions have the practitioner's name stamped or hand-printed on the prescriptions). The section also adds "computer printer" to the list of methods for creating a paper prescription and clarifies that a computer-generated prescription that is printed out or faxed must be manually

signed. DEA is aware that in some cases, an intermediary transferring an electronic prescription to a pharmacy may convert a prescription to a facsimile if the intermediary cannot complete the transmission electronically. As discussed previously in this rule, for controlled substance prescriptions, transformation to facsimile by an intermediary is not an acceptable solution. The section, as proposed, is also revised to divide paragraph (a) into shorter units.

Section 1306.08 is added to state that practitioners may sign and transmit controlled substance prescriptions electronically if the applications used are in compliance with part 1311 and all other requirements of part 1306 are met. Pharmacies are allowed to handle electronic prescriptions if the pharmacy application complies with part 1311 and the pharmacy meets all other applicable requirements of parts 1306 and 1311.

As proposed, §§ 1306.11, 1306.13, and 1306.15 are revised to clarify how the requirements for Schedule II prescriptions apply to electronic prescriptions.

As proposed, § 1306.21 is revised to clarify how the requirements for Schedule III, IV, and V prescriptions apply to electronic prescriptions.

As proposed, § 1306.22 is revised to clarify how the requirements for Schedule III and IV refills apply to electronic prescriptions and to clarify that requirements for electronic refill records for paper, fax, or oral prescriptions do not apply to electronic refill records for electronic prescriptions. Pharmacy applications used to process and retain electronic controlled substance prescriptions are required to comply with the requirements in part 1311. In addition, DEA is breaking up the text of the existing section into shorter paragraphs to make it easier to read.

As proposed, § 1306.25 is revised to include separate requirements for transfers of electronic prescriptions. These revisions are needed because an electronic prescription could be transferred without a telephone call between pharmacists. Consequently, the transferring pharmacist must provide, with the electronic transfer, the information that the recipient transcribes when accepting an oral transfer. DEA notes that the NPRM contained language proposing to permit an electronic prescription to be transferred more than once, in conflict with the requirements for paper and oral prescriptions. DEA has removed this proposed requirement; all transfer requirements for electronic prescriptions are consistent with those for paper and oral prescriptions.

Finally, DEA notes that it had proposed a new § 1306.28 to state the basic recordkeeping requirements for pharmacies for all controlled substance prescriptions. Those requirements are present in § 1304.22. Although DEA initially believed that including these requirements in part 1306 would be beneficial, after further consideration DEA believes that they would be redundant and could, in fact, create confusion. Therefore, DEA is not finalizing proposed 21 CFR 1306.28.

DEA is revising the title of part 1311 as proposed.

Section 1311.08 is revised to include the incorporations by reference of FIPS 180–3, Secure Hash Standard; FIPS 186–3, Digital Signature Standard; and NIST SP 800–63–1 Draft Electronic Authentication Guideline.

Subpart C is being added by this interim final rule. DEA has revised the content of proposed subpart C, as discussed above, and has reorganized the subpart. The following describes each of the sections in the interim final subpart C.

Section 1311.100 provides the general requirements for issuing electronic controlled substance prescriptions. It clarifies that the rules apply to all controlled substance prescriptions; the same electronic prescription requirements apply to Schedule II prescriptions as apply to other controlled substance prescriptions. DEA notes that the statutory prohibition on refilling Schedule II prescriptions remains in effect regardless of whether the prescription is issued electronically or on paper (21 U.S.C. 829(a), 21 CFR 1306.12(a)). Only a practitioner registered or exempt from registration and authorized to issue the prescription may do so; the prescription must be created on an application that meets all of the requirements of part 1311 subpart C. A prescription is not valid if the application does not meet the requirements of the subpart or if any of the required application functions were disabled when it was created. A pharmacy may process electronic controlled substance prescriptions only if its application meets the requirements of the subpart.

Section 1311.102 specifies the practitioner's responsibilities. A practitioner must retain sole control of the hard token, where applicable, and must not share the password or other knowledge factor or biometric information. The practitioner must notify the individuals designated to set logical access controls within one business day if the hard token has been lost, stolen, or compromised, or the authentication protocol has otherwise been compromised.

If the practitioner is notified by an intermediary or pharmacy that an electronic prescription was not successfully delivered, he must ensure that any paper or oral prescription (where permitted) issued as a replacement of the original electronic prescription indicates that the prescription was originally transmitted electronically to a particular pharmacy and that the transmission failed.

As discussed previously, if the third-party auditor or certification organization finds that an electronic prescription application does not accurately and consistently record, store, and transmit the information related to the name, address, and registration number of the practitioner, patient name and address, and prescription information (drug name, strength, quantity, directions for use), the indication of signing, and the number of refills, the practitioner must not use the application to sign and transmit electronic prescriptions for the controlled substances.

Further, if the third-party auditor or certification organization finds that an electronic prescription application does not accurately and consistently record, store, and transmit other information required for prescriptions, the practitioner must not sign and transmit electronic prescriptions for controlled substances that are subject to the additional information requirements.

In most cases, this will not be an issue as the SCRIPT standard supports the standard information required for a prescription. A limited number of prescriptions, however, require special information. Prescriptions for GHB require a note on medical need; prescriptions for drugs used for detoxification and maintenance treatment require an additional DEA identification number. Schedule II prescriptions may be issued with written instructions indicating the earliest date that the prescription may be filled. DEA is not certain that the existing SCRIPT standard accommodates the additional information or that existing pharmacy applications accurately and consistently capture and display such information. Because there are relatively few prescriptions with these requirements, DEA decided to place the onus on the third-party auditors or certification organizations to determine whether applications can create, transmit, import, display, and store all of the information needed for these prescriptions. If an electronic

prescription application does not allow the entry of this additional information, the practitioner must not issue the prescriptions electronically. DEA decided that this approach was preferable to making it an application requirement that all applications would have to meet before they could be used to issue or process any controlled substance prescriptions electronically. DEA believes that there may be a difference between adding a single-character field to the SCRIPT standard, indicating that the prescription was signed, which would be transmitted with almost all prescriptions, and adding a set of additional fields, some of which could be defined in multiple ways. For example, future fill dates could be placed in fields defined as future fill dates and presented as dates or they could be presented as text. NCPDP may need time to decide how to add fields to capture this information; application providers cannot begin to reprogram until decisions on the standard are reached. DEA does not believe it is necessary or appropriate to delay adoption of electronic controlled substance prescriptions until these issues are resolved.

Section 1311.102 also states that a practitioner must not use the application for controlled substance prescriptions if any of the functions have been disabled or is not working properly. Finally, if the application provider notifies him that the third-party audit indicated that the application does not meet the requirements of part 1311, or that the application provider has identified a problem that makes the application non-compliant, the practitioner must immediately cease to issue controlled substance prescriptions using the application and must ensure that access for signing controlled substance prescriptions is terminated. The practitioner must not use the application to issue controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.

Sections 1311.105 and 1311.110 specify the requirements for obtaining an authentication credential for individual practitioners and practitioners using an institutional practitioner's application, as discussed above.

Section 1311.115 specifies the requirements for two-factor authentication. It allows the authentication protocol to use any two of the three authentication factors (something you know, something you are, and something you have) and sets the requirements that hard tokens must meet.

Section 1311.116 specifies the requirements that biometric subsystems must meet.

Section 1311.120 provides the electronic prescription application requirements.

Section 1311.120(b)(1) requires an electronic prescription application to link each registrant, by name, with a DEA registration number. For practitioners exempt from the requirement of registration under § 1301.22(c), the application must link each practitioner to the institutional practitioner's DEA registration number and the specific internal code number required under § 1301.22(c)(5).

Section 1311.120(b)(2) requires an electronic prescription application to allow setting of logical access controls for indicating that prescriptions are ready to be signed and signing controlled substance prescriptions. It also requires the application to allow the setting and changing of logical access controls.

Section 1311.120(b)(3) states that logical access controls must be set by user name or role. If the application uses role-based access controls, it must not allow an individual to be assigned the role of registrant unless the individual is linked to a DEA registration number.

Section 1311.120(b)(4) requires that setting and changing of logical access controls must take the actions of two individuals, as discussed above.

Section 1311.120(b)(5) states that the application must accept two-factor authentication credentials and require their use for approving logical access controls and signing prescriptions.

Section 1311.120(b)(6) states that an electronic controlled substance prescription must contain all of the information required under part 1306. As commenters pointed out, although the SCRIPT standard has fields for most of this information, the use of these fields is not always mandated. Some of the required information may have to be put in free text fields (*e.g.,* internal institutional code data or service identification numbers for practitioners exempt from registration, the medical need for GHB prescriptions, a separate identification number for certain prescriptions).

Section 1311.120(b)(7) states that the application must require the practitioner or his agent to select the DEA number to be used for the prescription where the practitioner issues prescriptions under more than one DEA number. This provision is intended to prevent the application from automatically filling in the DEA number field when a practitioner uses more than one number.

Section 1311.120(b)(8) states that the electronic prescription application must have a time application that is within five minutes of the official National Institute of Standards and Technology time source.

Section 1311.120(b)(9) specifies the information that must appear on the review screen. As explained above, if a practitioner has written several prescriptions for a single patient, the practitioner's and patient's information may appear only once on the review screen.

Section 1311.120(b)(10) states that the application must require the practitioner to indicate that each controlled substance prescription is ready for signing. If any of the information required under part 1306 is altered after the practitioner has indicated that it is ready for signing, the application must remove the indication that it is ready for signing and require another indication before allowing it to be signed. The application must not allow the signing or transmission of a prescription that was not indicated as ready to be signed.

Section 1311.120(b)(11) provides the requirement that the practitioner use the two-factor authentication protocol to sign the prescription.

Section 1311.120(b)(12) states that the application must not allow a practitioner to sign a prescription if his two-factor authentication credential is not associated with the prescribing practitioner's DEA number listed on the prescription (or an institutional practitioner's DEA number and the prescriber's extension data). The application will have to associate each two-factor authentication credential with the registrant's DEA number(s) (or institutional practitioner's DEA number plus the individual practitioner's extension data) and ensure that only the authentication credentials associated with the number on the prescription can indicate the prescription as ready for signing and sign it. This provision is needed to prevent one registrant in a practice from reviewing and signing prescriptions written by other registrants. DEA recognizes that with paper prescriptions, DEA numbers for every member of a practice may be printed on a prescription pad; only the signature indicates which practitioner issued the prescription. For electronic prescriptions, however, only one prescribing practitioner's name will appear and one DEA number. Although the authentication credential will be associated with only one practitioner, it

may be associated with more than one DEA number. If a practitioner needs to sign a prescription originally created and indicated as ready for signing by another practitioner in a practice, he must change the practitioner name and DEA number to his own, then indicate that the prescription is ready to sign and execute the two-factor authentication protocol to sign it.

Section 1311.120(b)(13) states that where a practitioner seeks to prescribe more than one controlled substance at one time for a particular patient, the electronic prescription application may allow the practitioner to sign multiple prescriptions for a single patient at one time using a single invocation of the two-factor authentication protocol provided that the practitioner has individually indicated that each controlled substance prescription is ready to be signed while all the prescription information and the statement described in § 1311.140 are displayed.

Section 1311.120(b)(14) states that the application must time and date stamp the prescription on signing.

Section 1311.120(b)(15) states that when the practitioner executes the two-factor authentication protocol, the application must digitally sign and electronically archive at least the information required by DEA. If the practitioner is signing the prescription with his own private key, the application must electronically archive the digitally signed prescription, but need not digitally sign the prescription a second time.

Section 1311.120(b)(16) specifies the requirements for a digital signature. The cryptographic module must be validated at FIPS 140–2 Security Level 1. The digital signature application and hash function must comply with FIPS 186–3 and FIPS 180–3. The electronic prescription application's private key must be stored encrypted on a FIPS 140–2 Security Level 1 validated cryptographic module using a FIPS-approved encryption algorithm. For software implementations, when the signing module is deactivated, the application must clear the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key.

Section 1311.120(b)(17) states that the prescription transmitted to the pharmacy must include an indication that the prescription was signed unless the prescription is being transmitted with the practitioner's digital signature.

Section 1311.120(b)(18) states that a prescription must not be transmitted unless the signing function was used.

Section 1311.120(b)(19) states that the information required under part 1306 must not be altered after the prescription is digitally signed. If any of the required information is altered, the prescription must be canceled.

Section 1311.120(b)(20) through (22) specify the requirements for printing transmitted prescriptions.

Section 1311.120(b)(23) states that the application must maintain an audit trail related to the following: The creation, alteration, indication of readiness for signing, signing, transmission, or deletion of a controlled substance prescription; the setting or changing of logical access controls related to controlled substance prescriptions; and any notification of failed transmission. Section 1311.120(b)(24) specifies the information that must be maintained in the audit trail: Date and time of the action, type of action, identity of the person taking the action, and outcome.

Section 1311.120(b)(25) states that the application must be capable of conducting an internal audit and generating a report on auditable events.

Section 1311.120(b)(26) states that the application must protect audit trail records from unauthorized deletion, and must prevent modifications to the records.

Section 1311.120(b)(27) specifies the requirements for the monthly log.

Section 1311.120(b)(28) specifies that all records that the application is required to generate and archive must be retained electronically for at least two years.

Sections 1311.125 and 1311.130 specify the requirements for setting and changing logical access controls at an individual practitioner's practice and at an institutional practitioner, respectively.

Section 1311.135 sets the basic application requirements for creating an electronic controlled substance prescription. It states that either a practitioner or his agent may enter prescription information. If a DEA registrant holds more than one registration that he uses to issue prescriptions, the application must require him to select the registration number for each prescription. The application cannot set a default or pre-fill the field if the practitioner has more than one registration. If a practitioner has only one registration, as most practitioners do, the application could automatically fill that field. If required by State law, a supervisor's name and DEA number may be listed on a prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

Section 1311.140 provides the application requirements for signing an electronic prescription for a controlled substance. It requires that the screen displaying the prescription information for review include the statement that completing the two-factor authentication protocol signs the prescription and that only the practitioner whose name and DEA number are on the prescription may sign it. After the practitioner has indicated that one or more controlled substance prescriptions for a single patient are ready for signing, the application must prompt the practitioner to execute the two-factor authentication protocol. The completion of the two-factor authentication protocol must apply the application's (or practitioner's) digital signature to the DEA-required information and electronically archive the digitally signed record. The application must clearly label as the signing function the function that applies the digital signature. Any controlled substance prescription not signed in this manner must not be transmitted.

Section 1311.145 specifies the requirements for the use of a practitioner's digital certificate and the associated private key. The digital certificate must have been obtained in accordance with the requirements of § 1311.105. The digitally signed record must be electronically archived. The section specifies that if the prescription is transmitted without the digital signature attached, the application must check the Certificate Revocation List to ensure that the certificate is valid and must not transmit the prescription if the certificate has expired. The section also clarifies that if a practitioner uses his own private key, the application need not apply its private key to sign the record.

Section 1311.150 specifies the requirements for auditable events for electronic prescription applications. Auditable events must include at least the following: attempted or successful unauthorized access to the application; attempted or successful unauthorized deletion or modification of any records required by part 1311; interference with application operations related to prescriptions; any setting of or changes to logical access controls related to controlled substance prescriptions; attempted or successful interference with audit trail functions; and, for application service providers, attempted or successful creation, modification, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee

of the application service provider. The application must run the internal audit once every calendar day and generate a report that identifies any auditable event. This report must be reviewed by an individual authorized to set access controls. If the auditable event compromised or could have compromised the integrity of the records, this must be reported to DEA and the application provider within one business day of discovery.

Section 1311.170 requires that the application transmit the prescription as soon as possible after signature by the practitioner. The section requires that the electronic prescription application not allow the printing of an electronic prescription that has been transmitted unless the pharmacy or intermediary notifies the practitioner that the electronic prescription could not be delivered to the pharmacy designated as the recipient or was otherwise rejected. If a practitioner is notified that an electronic prescription was not successfully delivered to the designated pharmacy, the application may print the prescription for the practitioner's manual signature. The prescription must include information noting that the prescription was originally transmitted electronically to [name of specific pharmacy] on [date/time], and that transmission failed.

The section indicates that the application may print copies of the transmitted prescription if they are clearly labeled as copies not valid for dispensing. Data on the prescription may be electronically transferred to medical records and a list of prescriptions written may be printed for patients if the list indicates that it is for informational purposes only. The section clarifies that the electronic prescription application must not allow the transmission of an electronic prescription if a prescription was printed for signature prior to attempted transmission.

Finally, the section specifies that the contents of the prescription required under part 1306 must not be altered during transmission between the practitioner and pharmacy. Any change to this required content during transmission, including truncation or removal of data, will render the prescription invalid. The contents may be converted from one software version to another; conversion includes altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data into its application. At no time may an intermediary convert an electronic controlled substance prescription data file to another form (*e.g.,* facsimile) for transmission.

Section 1311.200 specifies the pharmacy's responsibility to process controlled substance electronic prescriptions only if the application meets the requirements of part 1311. The section also requires the pharmacy to determine which employees may access functions for annotating, altering, and deleting prescription information (to the extent such alteration is permitted by the CSA and its implementing regulations) and for implementing those logical access controls. As discussed previously, if the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display the information related to the name, address, and registration number of the practitioner, patient name and address, and prescription information (drug name, strength, quantity, directions for use), the indication of signing, and the number of refills, the pharmacy must not accept electronic prescriptions for the controlled substance. If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display other information required for prescriptions, the pharmacy must not accept electronic prescriptions for controlled substances that are subject to the additional information requirements.

The section specifies that if a prescription is received electronically, all annotations and recordkeeping related to that prescription must be retained electronically. The section reiterates the responsibility of the pharmacy to dispense controlled substances only in response to legitimate prescriptions.

Section 1311.205 provides the requirements for pharmacy applications.

Section 1311.205(b)(1) states that the application must allow the pharmacy to set access controls to limit access to functions that annotate, alter, or delete prescription information, and to the setting or changing of logical access controls.

Section 1311.205(b)(2) states that logical access controls must be set by name or role.

Section 1311.205(b)(3) specifies that the application must digitally sign and archive an electronic prescription upon receipt or be capable of receiving and archiving a digitally signed record.

Section 1311.205(b)(4) specifies the requirements for the digital signature functionality for pharmacy applications that digitally sign prescription records upon receipt.

Section 1311.205(b)(5) states that the pharmacy application must validate a practitioner's digital signature if the pharmacy accepts prescriptions digitally signed by the practitioner and transmitted with the digital signature.

Section 1311.205(b)(6) states that if a practitioner's digital signature is not sent with the prescription, either the application must check for the indication that the prescription was signed or the application must display the indication for the pharmacist to check.

Section 1311.205(b)(7) states that the application must read and retain the entire DEA number including the specific internal code number assigned to an individual practitioner prescribing controlled substances using the registration of the institutional practitioner.

Section 1311.205(b)(8) states that the application must read and store, and be capable of displaying, all of the prescription information required under part 1306.

Section 1311.205(b)(9) states that the pharmacy application must read and store in full the information required under § 1306.05(a). Either the pharmacist or the application must verify all the information is present.

Section 1311.205(b)(10) states that the application must allow the pharmacy to add information on the number/volume of the drug dispensed, the date dispensed, and the name of the dispenser.

Section 1311.205(b)(11) specifies that the application must be capable of retrieving prescription information by practitioner name, patient name, drug name, and date dispensed.

Section 1311.205(b)(12) states that the application must allow downloading of prescription data into a form that is readable and sortable.

Section 1311.205(b)(13) states that the application must maintain an audit trail related to the following: The receipt, annotation, alteration, or deletion of a controlled substance prescription; and the setting or changing of logical access controls related to controlled substance prescriptions.

Section 1311.205(b)(14) specifies the information that must be maintained in the audit trail: Date and time of the action, type of action, identity of the person taking the action, and outcome.

Section 1311.205(b)(15) states that the application must generate a daily report of auditable events (if they have occurred).

Section 1311.205(b)(16) states that the application must protect the audit trail

from unauthorized deletion and shall prevent modification of the audit trail.

Section 1311.205(b)(17) states that the application must back up files daily.

Section 1311.205(b)(18) states that the application must retain records for two years from the date of their receipt or creation.

Section 1311.210 sets the requirements for digitally signing the prescription as received and archiving the record. It also sets the requirements for validating a prescription that has the practitioner's digital signature attached.

Section 1311.215 specifies the requirements for auditable events for pharmacy applications. Auditable events must include at least the following: Attempted or successful unauthorized access to the application; attempted or successful unauthorized deletion or modification of any records required by part 1311; interference with application operations related to prescriptions; any setting of or changes to logical access controls related to controlled substance prescriptions; attempted or successful interference with audit trail functions; and, for application service providers, attempted or successful annotation, alteration, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider. The application must run the internal audit once every calendar day and generate a report that identifies any auditable event. This report must be reviewed by the pharmacy. If the auditable event compromised or could have compromised the integrity of the records, this must be reported to DEA and the application service provider, if applicable, within one business day of discovery.

Section 1311.300 specifies the requirements for third-party audits discussed above and includes the option of substituting a certification from an organization and certification program approved by DEA. Audits or certifications must occur before the application may be used to create, sign, transmit, or process electronic controlled substance prescriptions, and whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first. Audits must be conducted by a person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit, or a Certified Information System Auditor who performs compliance audits as a regular ongoing business activity. DEA is seeking comment regarding the use of Certified Information System Auditors.

Application providers must make audit reports available to any practitioner or pharmacy that uses or is considering using the application to handle controlled substance prescriptions. The rule also requires application providers to notify both their users and DEA of adverse audit reports or certification decisions. Users must be notified within five business days; DEA must be notified within one business day.

Section 1311.302 requires application providers to notify practitioners or pharmacies, as applicable, of any problem that they identify that makes the application noncompliant with part 1311. When providing patches and updates to the application to address these problems, the application provider must inform the users that the application may not be used to issue or process electronic controlled substance prescriptions until the patches or updates have been installed. DEA is requiring that practitioners and pharmacies be notified as quickly as possible, but no later than five business days after the problem is identified.

Section 1311.305 specifies recordkeeping requirements for records required by part 1311.

VI. Incorporation by Reference

The following standards are incorporated by reference:

- FIPS Pub 180–3, Secure Hash Standard (SHS), October 2008.
- FIPS Pub 186–3, Digital Signature Standard (DSS), June 2009.
- Draft NIST Special Publication 800–63–1, Electronic Authentication Guideline, December 8, 2008; Burr, W. *et al.*
- NIST Special Publication 800–76–1, Biometric Data Specification for Personal Identity Verification, January 2007.

These standards are available from the National Institute of Standards and Technology, Computer Security Division, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930 and are available at *http://csrc.nist.gov/*.

VII. Required Analyses

A. Risk Assessment for Electronic Prescriptions for Controlled Substances

The Office of Management and Budget's E-Authentication Guidance for Federal Agencies (M–04–04) requires agencies to ensure that authentication processes provide the appropriate level of assurance.[40] The guidance describes four levels of identity assurance for electronic transactions and provides standards to be used to determine the level of risk associated with a transaction and, therefore, the level of assurance needed. Assurance is the degree of confidence in the vetting process used to establish the identity of an individual to whom a credential was issued, the degree of confidence that the individual who uses the credential is the individual to whom the credential was issued, and the degree of confidence that a message when sent is secure. OMB established four levels of assurance:

Assurance Level 1: Little or no confidence in the asserted identity's validity.

Assurance Level 2: Some confidence in the asserted identity's validity.

Assurance Level 3: High confidence in the asserted identity's validity.

Assurance Level 4: Very high confidence in the asserted identity's validity.

M–04–04 states that to determine the appropriate level of assurance in the user's asserted identity, agencies must assess the potential risks and identify measures to minimize their impact. The document states that the risk from an authentication error is a function of two factors: (a) Potential harm or impact and (b) the likelihood of such harm or impact. NIST SP 800–63–1 supplements M–04–04 and defines the steps necessary to reach each assurance level for identity proofing that precedes the issuance of the credential; the use of credential once issued; and the transmission of any document "signed" with the credential. In plain language, an e-authentication risk assessment considers two issues:

- How important is it to know that the person who is issued a credential is, in fact, the person whose identity is associated with the credential.
- How important is it to be certain that the person who uses the credential, once it is issued, is the person to whom it was issued.

This risk assessment addresses the level of assurance needed to allow the use of electronic prescriptions for controlled substances. This section summarizes the assessment that DEA conducted for the interim final rule. The full risk assessment is available in the docket.

As discussed in Section IV J of this preamble, M–04–04 requires that an Agency assess risks as low, moderate, or

[40] Office of Management and Budget. "E-Authentication Guidance for Federal Agencies" M–04–04. December 16, 2003.

high for six factors (*see* Table 1), then determines the Assurance Level needed based on the ratings. Table 3 presents the ratings DEA developed in its risk assessment for the proposed rule and the rationale for each (for the full discussion, see 73 FR 36731–36739).

TABLE 3—INITIAL RATING OF POTENTIAL IMPACTS FOR AUTHENTICATION ERRORS FOR ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES

Potential impact	Initial rating	Rationale
Inconvenience, Distress, or Damage to Standing or Reputation.	Moderate—At worst, serious short-term or limited long-term inconvenience, distress, or damage to the standing or reputation of any party.	Identity theft, issuance of illegitimate prescriptions in a practitioner's name, or alteration of prescriptions could expose practitioners to legal difficulties and force them to prove that they had not used an electronic prescription application or issued specific prescriptions.
Financial Loss	N/A.	
Harm to Agency Programs or Public Interests	High—A severe or catastrophic adverse effect on organizational operations or assets, or public interests. Examples of severe or catastrophic effects are: (i) severe mission capability degradation or loss of (sic) to the extent and duration that the organization is unable to perform one or more of its primary functions; or (ii) major damage to organizational assets or public interests.	Were there identity theft or the misuse of a credential issued to a registrant, the potential exists for widespread and rapid diversion of controlled substances. Such diversion would undermine the effectiveness of prescription laws and regulations of the United States. This diversion would, by its very nature, harm the public health and safety, as any illicit drug use does. Such diversion would undermine the effectiveness of the entire United States closed system of distribution created by the CSA and would, for the same reason, be incompatible with United States obligations under international drug control treaties.
Unauthorized release of Sensitive Information	N/A.	
Personal Safety	High—A risk of serious injury or death	Failure to limit the potential for diversion could result in an increase in drug abuse and in the associated deaths and illnesses as well as other social harms.
Civil or Criminal Violations	High—A risk of civil or criminal violations that are of special importance to enforcement programs.	A practitioner whose identity was stolen to gain a credential or whose credential was used by someone else to issue a prescription for a controlled substance could be subject to legal action in which the practitioner would have to prove that he was not responsible for the prescriptions. Such legal action against the practitioner could include criminal prosecution, civil fine proceedings, and administrative proceedings to revoke the practitioner's DEA registration.

Under M–04–04, the overall rating is driven by the highest rating assigned. Therefore, the potential impact of not being able to limit authentication credentials to DEA registrants is rated as high, which means that without mitigating factors, DEA should impose requirements that meet Assurance Level 4 under NIST SP 800–63–1.

Mitigating Factors:

DEA included a number of elements in the interim final rule that mitigate the risks of unauthorized access to the electronic prescription application and reduce the potential for diversion. While some of these relate to authentication to the application, others relate to use of the application itself.

Separation of duties. DEA's premise for its requirements regarding the access to any electronic prescription application to prescribe controlled substances rests on the principle of separation of duties. The interim final rule requires that practitioners wishing to prescribe controlled substances undergo identity proofing by an independent third-party credential service provider (CSP) or certification authority (CA) that is recognized by a Federal agency as conducting identity proofing at the basic assurance level (Assurance Level 3 for CAs) or greater. The CSP or CA will then issue the credential. This approach removes the electronic prescription application provider from the process of issuing the credential, which limits the ability of individuals at the application provider to steal identities and ensures, to as great an extent as possible, that a person will not be issued a credential using someone else's identity.

Access control. The possession of a credential by the practitioner, while necessary to legally sign controlled substance prescriptions, is not sufficient to do so. After the practitioner has obtained the credential, a person in the practitioner's office (assuming that the practitioner is in private practice in an office setting) must enter information into the electronic prescription application identifying the practitioner as a person authorized to prescribe controlled substances. A second person in that office, who must be a DEA registrant, must approve the information entered and grant the practitioner access to the electronic prescription application for the purpose of signing controlled substance prescriptions using the practitioner's credential. (Note that a similar system involving separation of duties is being implemented for

institutional practitioners, *i.e.,* hospitals and clinics. That system has similar conceptual requirements, but involves different people in the physical processes.)

This separation of duties ensures that even if someone is able to impersonate a practitioner and obtain a credential from an independent third-party CSP or CA, that impersonator will not be able to gain access to the electronic prescription application to sign controlled substance prescriptions unless the impersonator also has the assistance of two persons (one of whom is a DEA registrant) within a practitioner's office. In this way, it will be significantly more difficult for impersonators to gain access to sign controlled substance prescriptions, reducing the possibility of authentication errors and lessening the potential for diversion.

Use of two-factor authentication. DEA is requiring the use of two-factor authentication. Assurance Level 4 requires a hard token that is separate from the computer to which the person is gaining access, but also imposes more stringent requirements on the cryptographic module and the token. DEA has determined that combining the requirements for Assurance Level 3 tokens (*i.e.,* FIPS 140–2 Security Level 1 tokens used in combination with another factor to reach Assurance Level 3) with the requirement that the token be separate from the computer will provide sufficient security to mitigate the risk of misuse. Keeping the token separate from the computer being accessed makes it much easier for the practitioner to control access to his credential. A person would have to obtain both the token and the second factor to gain access. (Note that DEA is also permitting the use of biometrics as one of the factors that may be used for authentication; the biometric could replace either the hard token or the knowledge factor.)

Application requirements. In addition to the requirements discussed above, DEA is also imposing the following requirements on the electronic prescription application that will mitigate the risks:

- The application must have the ability to set logical access controls as discussed above and limit access to indicating that prescriptions are ready for signing and signing prescriptions to DEA registrants or those exempted from registration.
- The application must require the use of the two-factor credential to sign the prescription and digitally sign and archive the record when the two-factor authentication protocol is executed. This step ensures that there is a record of the prescription as signed and allows other people in the practice or facility to add information not required by DEA, (*e.g.,* pharmacy URLs) or review the prescription before transmission.
- The application must not allow a practitioner to sign a prescription if his credential is not linked to the DEA number listed on the prescription.
- The application must undergo a third-party audit to determine whether it complies with the requirements of the interim final rule.

In addition, as part of their approval by the Federal Government, CSPs and CAs issuing credentials undergo third-party audits to ensure compliance with Federal Government standards.

Conclusion:

Consistent with M–04–04, DEA believes that it is appropriate for the agency to accept lower level credentials in view of the mitigating factors discussed above. M–04–04 states, in pertinent part (in Section 2.5):

> Agencies may also decrease reliance on identity credentials through increased risk-mitigation controls. For example, an agency business process rated for Level 3 identity assertion assurance may lower its profile to accept Level 2 credentials by increasing system controls or 'second level authentication' activities.

Following this approach, DEA has concluded that, even though the agency rates overall identity assurance for electronic prescribing of controlled substances at Assurance Level 4, the agency believes that Level 3 credentials are acceptable in view of the system controls that are mandated by this interim final rule. Specifically, DEA believes that the requirements that the interim final rule imposes for identity proofing, logical access controls, the separation of the hard token from the computer being accessed, and the application requirements lower the potential for a nonregistrant to steal an identity or gain access to a registrant's credential and issue illegal prescriptions sufficiently to render acceptable remote identity proofing, consistent with NIST SP 800–63–1 Assurance Level 3 requirements, and the use of FIPS 140–2 Security Level 1 hard tokens that in combination with a second factor provided that the token is not stored on the computer to which the person is gaining access. With these requirements in place, the potential for diversion through misuse of a credential will be limited, which supports the closed system of control DEA is mandated to maintain, protect practitioners from misuse of their identity, and protects the public from the harm of drug abuse. (Note that DEA is not imposing any requirements on the security of the transmission.)

As has been discussed previously, it is important to note that the electronic prescribing of controlled substances is voluntary—practitioners may still dispense controlled substances through the use of written prescriptions, regardless of whether they choose to write controlled substances prescriptions electronically. Also, the compromise of an authentication protocol through loss, credential invalidation, or other cause, does not invalidate the practitioner's authority to write controlled substances prescriptions. Practitioners may continue to write controlled substances prescriptions on paper or generate a prescription electronically to be printed and signed manually even if their authentication credential has been compromised, so long as the practitioner continues to possess a DEA registration.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), DEA must determine whether a regulatory action is "significant" and, therefore, subject to Office of Management and Budget review and the requirements of the Executive Order. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

(1) 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 government or communities.

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A copy of the *Economic Impact Analysis of the Electronic Prescriptions for Controlled Substances Rule* can be obtained by contacting the Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, Telephone (202) 307–7297. The initial analysis is also available on DEA's Diversion Control Program Web site at *http://www.deadiversion.usdoj.gov.*

Comments:

DEA conducted an initial economic analysis of the proposed rule and sought comments. DEA received several comments regarding the estimates provided in the NPRM.

Comments. A practitioner organization stated that DEA underestimated the costs for registration, hard token hardware and software, software upgrades, annual system audits, and, especially, for separate prescribing workflows for controlled drugs. The commenter asserted that the analysis did not include the added costs for each prescriber every time a controlled substance prescription is written. The commenter believed that the comparison should not be with the current system where controlled substance prescriptions require a separate workflow, but rather with a commenter-preferred system where all prescribing takes place in a single workflow. The commenter asserted that the costs of prosecutions are dwarfed by the potential benefits offered by a single, manageable electronic prescribing system. The commenter stated that DEA acknowledged in the analysis it did not have valid data on all costs to society from diversion of controlled substances. Without valid estimates of the cost of the problem, the commenter asserted, it is impossible to justify the expense of the proposed solution.

DEA Response. DEA disagrees with this comment, but notes that the revisions to the interim final rule reduce the costs and the additional keystrokes. The only change to the usual workflow will be the use of the two-factor authentication credential to sign the prescription. Wherever possible, in the economic analysis of the interim final rule, DEA has used estimates based on current prices.

DEA's concern is not simply or primarily with the costs of prosecutions, but with the diversion of controlled substances and the societal harm caused by abuse of these drugs. The cost of emergency room treatment alone for people using prescription controlled substances for nonmedical reasons is far higher than the cost of this rule. Without appropriate security measures, electronic prescriptions could facilitate increased drug abuse, with a concomitant increase in deaths, medical treatment, and other societal costs associated with drug dependency.

Although DEA supports electronic prescribing and shares the hope that it will reduce adverse drug events and improve the efficiency of the healthcare system, there is little, if any, evidence that electronic prescribing is achieving this goal. The limited studies that have examined the impacts of electronic prescribing have found that the primary benefit is improved formulary compliance. DEA has not found any studies that quantify the number of adverse drug events associated with illegible prescriptions. The data often cited regarding medication errors are based primarily on inpatient hospital and long-term care facility adverse drug events and include "errors" that are unrelated to legibility (*e.g.,* administering a drug to the wrong patient, dispensing the wrong drug); some of the errors cited may not result in adverse drug events (*e.g.,* failing to include all of the label information or the insert). In addition, as discussed below in the *Benefits* section, studies of pharmacy experiences with electronic prescriptions have found that there may be an increase in errors with these prescriptions. DEA notes that although illegible handwritten prescriptions are unquestionably a problem, in most cases the pharmacists resolve the problem by calling the practitioner to clarify the prescription rather than risk dispensing the wrong drug.

Comments. A pharmacy organization asserted that unless there is a compelling law enforcement need, DEA must eliminate provisions that increase the burden and costs on prescribers and pharmacies. The commenter claimed that these burdens and costs will fall disproportionately on independent, rural and small primary care and physician practices, pharmacies and health care facilities and programs. State pharmacy associations stated that DEA should perform an economic analysis that details the financial impact on safety-net clinics using appropriate metrics (net revenue) and actual fees, and that DEA should consider options that reduce these identified costs. One organization indicated that the analysis did not adequately address the cost of storage, technology, staff resources, and oversight.

DEA Response. DEA disagrees that the costs fall disproportionately on small or rural practices. Most of the costs of the rule will be borne by practitioners, to obtain identity proofing, and the application providers. DEA has revised the process for identity proofing to reduce the burden on rural practitioners. The primary cost will be to complete an application for a credential or digital certificate and to pay for the credential. The frequency with which a practitioner must do this will be determined by the credential service provider or certification authority.

Although the application providers will have to recover their costs from their customers, the incremental costs for any single customer will be low, particularly when compared to the cost of an electronic health record application. DEA has revised the rule to reduce the costs to application providers by both lengthening the time between audits/certifications and allowing them to substitute certification by an approved organization, where one exists, for a third-party audit. Because the American Recovery and Reinvestment Act requires that an application be certified before a practitioner will be eligible for an incentive payment, it is reasonable to assume that all electronic prescription application providers will be seeking certification and incurring those costs regardless of DEA's rules. On the pharmacy application side, the third-party audit will only need to address compliance with DEA's requirements, most of which existing pharmacy applications already meet.

DEA has removed the requirement for offsite storage. As for the costs for technology, staff resources, and oversight, these apply to acquisition of the application, not to DEA's requirements. DEA is not requiring any registrant to issue or accept electronic prescriptions for controlled substances. Any registrant that purchases an application will incur these costs whether they use the application for controlled substance prescriptions or not.

Comments. An organization representing dentists stated that the number of dentists used in the calculations in the economic analysis was high; the commenter noted that the Bureau of Labor Statistics lists 161,000 dentists as opposed to DEA's estimate of 170,969. The commenter also asserted that DEA did not include potential practitioner reprogramming cost(s) in this figure. The commenter believed that the addition of any reprogramming costs will make this figure much greater and create additional burden for practicing dentists who wish to transmit prescriptions for controlled substances electronically.

DEA Response. In the interim final Economic Impact Analysis, DEA used the organization's estimate for the number of dentists, adjusted to account for growth. DEA has estimated the cost for reprogramming, but notes that this will be done by the application provider, not at the practice level. Unless an individual practice decides to implement biometrics as part of their two-factor authentication credentials, there should not be additional hardware or software needed; the software needed to use a biometric can be relatively

inexpensive. DEA expects that there will be considerable variation in the extent of reprogramming an application provider needs to do based on the degree to which an application already meets the requirements being implemented in this rule. Application providers, however, routinely reprogram their software to add new features, upgrade functions, and fix problems. Reprogramming to meet the interim final rule is likely to occur as part of this routine process.

Comments. A pharmacy organization asserted that the cost of dispensing for the average independent community pharmacy is already high. The commenter believed that the regulation would necessitate the purchase of new technology, generating more reports at the end of the day, and then storing those corresponding reports for five years. The commenter claimed that these processes will only add to the monetary costs and time constraints that pharmacists have to abide by to responsibly consult with and serve their patients. The commenter asserted that such gains from electronic prescribing are relatively minimal when compared to such costs, considering that independent community pharmacies already connected for electronic prescribing only receive around 2 percent of their prescriptions through such technology.

DEA Response. DEA is not requiring any pharmacy to accept electronic prescriptions for controlled substances. Based on industry comments, the existing pharmacy applications already have most, if not all, of the functions that DEA is requiring. It is unlikely, therefore, that any pharmacy will have to replace its existing application. Where additional functionality is needed, it can be added as an upgrade or patch, as occurs routinely with most widely used software applications. The only reports that will be generated are on security incidents, which should be rare events. Pharmacies should not have daily reports to review. DEA has revised the record retention period to two years. DEA also notes that in allowing electronic prescriptions, it is relieving pharmacies of the burden of storing paper prescriptions.

Comments. A pharmacy organization asserted that costs of several cents per prescription will be significant to some pharmacies.

DEA Response. DEA estimates that the average cost of the rule will be less than one cent per controlled substance prescription, which as some commenters noted is far less than the $0.30 per prescription fee some commenters stated they are paying intermediaries.

Comments. A healthcare system stated that PDAs may not be able to function as tokens and thumb drives would require software changes and take too much time to connect. The commenter believed that other solutions would be more expensive. The commenter also noted that mid-level practitioners would be likely to use the same kind of tokens as practitioners, which differed from the assumptions DEA made in its initial analysis. That commenter and a second healthcare system also stated that the initial Economic Impact Analysis did not include staff time for audits.

DEA Response. DEA has not included PDAs in its cost analysis of the interim final rule although some practitioners may use them. The range of possible tokens is considerable and the costs associated with them wide. For example, one-time-password (OTP) devices are slightly more expensive than smart cards or tap-and-go cards, but do not require a separate reader. Where readers are needed, they may exist on keyboards, or can be separate devices. Because it has no basis for estimating how many computers would need readers, DEA has based its cost estimates on OTP devices, recognizing that practices may find other options more suitable.

DEA has not estimated staff time for application providers for audits in part because the interim final rule limits the audit to determining whether the application meets DEA's requirements. An auditor will usually make this determination by testing the application, which will not involve provider staff time. In addition, DEA assumes that once a certification organization is ready to make this determination as part of its certification process, application providers will not need audits. They will obtain the certification for reasons other than compliance with DEA rules.

Comments. An application provider stated that financial incentives may speed adoption more quickly than assumed in the initial Economic Impact Analysis. It further stated that the average salary of a primary care physician is $104,000, but provided no sourcing for this assertion.

DEA Response. DEA has increased (*i.e.,* shortened) the implementation rate to account for the financial incentives that may be available to practitioners. According to the Bureau of Labor Statistics the average salary rate for a physician in family practice is $167,970 (May of 2008). Some hospital-based physicians have lower salary rates, but their costs are likely to be borne by the institutional practitioner.

Comments. An application provider estimated that cost per unit for two-factor authentication at $329 to $349, comprising a hand-held reader at $300, a desktop reader at $20, and a smart card ($29). The commenter estimated support costs between $300 to $400 a year per prescriber to deal with malfunctions. The commenter asserted that it would take 3 to 7 days to replace the smart card. The commenter further indicated that its current support metrics indicate 7 trouble tickets per year per prescriber, 10 percent of which require an office visit. The commenter claimed that the average prescriber writes six controlled substance prescriptions a week and would not pay as much as DEA indicated the costs would be to write controlled substances prescriptions electronically. It noted that these costs would disproportionately burden stand-alone electronic prescription applications because they represent a higher proportion of the annual fee. The commenter indicated that the first year cost of $629–749 would be a 35 percent increase in the $2000 first year fee. Subsequent year costs ($300–400) would be a 58% increase in the $600 charge. The costs represent a much smaller percentage of EHR costs. The commenter asserted that these costs would deter practitioners from adopting electronic prescribing.

DEA Response. DEA notes that most of the costs the commenter estimated relate to a hand-held reader, but the commenter failed to explain why this was needed. It also failed to explain why the smart card would cost so much, when many are available for a tenth the amount listed, and why it would take days to replace the card. If the practitioner acquires the card locally, then registers or activates the credential, replacement would take little time. The commenter appears to be incurring the support costs for problems already. It is unclear to DEA, based on the commenter's comments, why the commenter believes this would change or increase. Under the interim final rule, the application provider is not involved in providing the authentication credential. If its application has problems after it has been programmed, that is not a cost that accrues to the interim final rule. DEA recognizes that any incremental costs will represent a higher proportion of the annual fee for stand-alone electronic prescription applications. DEA notes, however, that the Federal incentive payments available under the American Recovery and Reinvestment Act are for EHR

applications, not electronic prescription applications. It is likely, therefore, that the trend toward EHRs rather than stand-alone electronic prescription applications will accelerate.

The Interim Final Rule Analysis:

DEA has determined that this interim final rule is an economically significant regulatory action; therefore, DEA has conducted an analysis of the options. The following sections summarize the economic analysis conducted in support of this rule. DEA is seeking further comments on the assumptions used in this revised economic analysis and is especially interested in any data or information that commenters can provide that would reduce the many uncertainties in the estimates as discussed below and improve the options considered in the analysis of a final rule.

Options Considered:

DEA considered three options for the electronic prescribing of controlled substances:

Option 1: The interim final rule as described in this preamble.

Option 2: The interim final rule with the requirement that one of the factors used to authenticate to the application must be a biometric.

Option 3: No additional requirements for electronic prescription or pharmacy applications, but a callback for each controlled substance electronic prescription.

Universe of Affected Entities:

The entities directly affected by this rule are the following:

- DEA individual practitioner registrants who issue controlled substance prescriptions or individual practitioners who are exempt from registration and who are authorized to issue controlled substance prescriptions under an institutional practitioner's registration.
- Hospitals and clinics where practitioners may issue controlled substance prescriptions.
- Pharmacies.

In addition, application providers are indirectly affected because their applications must meet DEA's requirements before a registrant may use them to create or process controlled substance prescriptions. The practitioners who prescribe controlled substances are primarily physicians, dentists, and mid-level practitioners. Hospitals and clinics will be affected if practitioners working for or affiliated with the hospital or clinic use the institutional practitioner's application to issue prescriptions for persons leaving the institution (inpatient medical orders are not subject to these rules). Several thousand institutional practitioner registrants (*e.g.,* prisons, jails, veterinarians, medical practices, and Federal facilities) are not included either because they are unlikely to have staff issuing prescriptions, are already counted in the practitioner total, or, in the case of Federal facilities, already comply with more stringent standards. Table 4 presents the estimates of entities directly affected and estimated growth rates, which are based on recent trends. As the number of hospitals and retail pharmacies have been declining, DEA did not project growth (or decline) for these sectors.

TABLE 4—UNIVERSE OF DIRECTLY AFFECTED ENTITIES

	In offices/ in hospitals	Growth rate
Physicians	328,772	
	169,337	2.1 percent.[1]
Mid-levels	82,579	
	48,841	2.2 percent.
Dentists	171,328	
	([2])	1.3 percent.
Total Practitioner	582,729/	
	218,178	1.9 percent.
Hospitals and Clinics	12,412	DEA assumes no future growth.
Pharmacies	65,421	DEA assumes no future growth.

[1] This rate does not include physicians in hospitals.
[2] Not applicable.

The number of application providers is based on the number of providers currently certified by SureScripts/RxHub or CCHIT. For practitioners, that number is about 170, which DEA assumes will increase to 200 by the third year and then begin declining. Pharmacy application providers are estimated to be about 40; the actual number is lower but DEA increased the number to account for pharmacy chains that may have developed their own applications.

The number of controlled substance prescriptions written is relevant to the estimate of cost-savings. DEA estimates the number of prescriptions based on the assumption that the percentage of controlled substance prescriptions in the top 200 brand name and top 200 generic drug prescriptions is the same as it is for the remainder of the prescriptions.[41] According to data from SDI/Verispan, in 2008, controlled substances represented about 12 percent of prescriptions for the top 400 drugs.[42] IMS Health data reported a total of 3.8431 billion prescriptions in 2008.[43] Based on these data, DEA estimates that, with a three percent growth rate for prescriptions, there will be about 475 million controlled substance prescriptions in Year 1 of the analysis. IMS Health data indicate that about 86 percent of prescriptions are filled at retail outlets, which is relevant to estimating public wait time as long-term care prescriptions and mail order prescriptions will not be affected. Previous DEA analysis has indicated that 75 percent of controlled substance prescriptions are original prescriptions or 356 million prescriptions in Year 1. DEA has previously estimated that about 19 percent of prescriptions are currently faxed or phoned into pharmacies. Applying both the 86 percent and 19 percent to the number of original prescriptions results in an estimate of 247 million prescriptions that may have reduced public wait time as electronic prescriptions for controlled substances is implemented.

Unit Costs

For the interim final Economic Impact Analysis, DEA based all labor costs on May 2008 BLS data, inflated to 2009

[41] The top 400 drugs represent about 87% of all prescriptions dispensed at retail.

[42] See *http://www.drugtopics.com* for the top 200 generic and top 200 brand name drugs.

[43] See *http://www.imshealth.com.* IMS Health data are used for total prescriptions because the data include prescriptions for long-term care and mail order.

dollars and loaded with fringe and overhead. Using BLS data provides a consistent source of data. For the NPRM, DEA used other estimates for physician and dentist costs, but these were based on salary surveys that may be weighted toward larger practices and were not clearly wage as opposed to compensation figures. The effect of the change is to lower the wage rates for these practitioners.

Practitioners will have to complete an application to apply for identity proofing and a credential. As these applications generally ask for standard information that practitioners will be able to fill in without needing to collect documents that they would not carry with them (*e.g.,* credit cards, driver's licenses), DEA estimates that it will take them 10 minutes to complete the form. Credential providers generally require subscribers to renew the credential periodically. This renewal can take the form of an e-mail request that is signed with the credential. To be conservative, DEA estimates that it will take 5 minutes to renew.

For hospitals and clinics, DEA estimates that practitioners and someone at the credentialing office will spend 2 minutes to verify the identity document presented. Practitioners are assumed to take 30 minutes total for this process because they will need to go to the credentialing office. This review will occur only when the hospital or clinic first implements controlled substance electronic prescribing and will involve only those practitioners that already work at or have privileges at the hospital or clinic. All practitioners that are hired or gain privileges later will have this step done as part of their regular initial credentialing.

Prior to granting access, someone at each office must verify that each practitioner has a valid DEA registration and State authorization to practice and, where applicable, dispense controlled substances. As this requires nothing more than checking the expiration dates of these documents, which are often visibly displayed, DEA estimates that this will take an average of one minute. In small practices, which are the majority of offices, it may take no time because the registrant will be one of the people granting access and the status of every registrant will be known. Checking registrations and State authorizations is done as part of credentialing at hospitals and clinics and is, therefore, not a cost of the rule. Similarly, once the rule is implemented at offices, it should not be a cost because credentials should be checked before a person is hired.

Prior to granting access, those who will be given this responsibility will need to be trained to do so. DEA estimates the time at one hour per person at practices. This estimate may be high, particularly for smaller offices. It may also be the case that in some larger practices, people already perform this task for other reasons and training may be unnecessary. Because it is likely that in larger pharmacies, access controls are already being set, DEA estimates that the training time will be five minutes.

DEA estimates that it will take, on average, five minutes to enter the data to grant access for the first time at a practice or a pharmacy. The approval of the data entry is estimated to take one minute. The actual approval may take only a few seconds, but the approver may take time away from some other work, but would presumably do it when using the computer for other tasks.

DEA has not estimated the cost of setting logical access controls at hospitals because hospital applications should already do this. The CCHIT criteria for in-patient applications include logical access controls; the HL7 standard used by most hospitals includes logical access controls. In addition, an application used by as many different departments as exist at hospitals necessarily will impose limits on who can carry out certain functions. Consequently, DEA's requirements should not entail any actions not already being performed.

Auditable events reported on security incident logs should be rare once the application has been implemented and staff understand their permission levels. Because of the size of hospitals and clinics and the volume of controlled substance prescriptions at pharmacies, DEA estimates that each of them will review security incident logs monthly; DEA estimates that the review will take hospitals ten minutes per month and pharmacies five minutes per month. Because of the smaller size of private practices and the much lower volume of controlled substance prescriptions issued, DEA estimates that a review will be needed only once a quarter. The review time remains at 5 minutes.

DEA estimates that reprogramming for electronic prescription applications will take, on average, 2,000 hours, an estimate based on industry information obtained during the development of DEA's Controlled Substances Ordering System rule.[44] The requirements for pharmacy applications are simpler and include functionalities that the industry has indicated it already has, so DEA assumes an average of 1,000 hours of reprogramming for pharmacy applications.

To estimate the cost of obtaining identity proofing from a credential service provider, DEA used the fee SAFE BioPharma charges for a three-year digital certificate and a hard token using remote identity proofing ($110). This figure may be high because it assumes a medium rather than the basic assurance level that DEA is requiring. Based on standard industry practice for digital certificates, DEA estimates that the credential will need to be renewed every three years, but that a complete reapplication will not be required until the ninth year. These assumptions are based on the standards incorporated in the Federal PKI Policy Authority Common Policy. The cost for the three-year renewal is estimated to be $35.00, which is what SAFE charges for a three-year digital certificate at the basic assurance level. Hospitals and clinics are assumed to use or adapt their existing access cards to store the credential and, therefore, incur no additional costs for the credential.

In the initial years, application providers may have to obtain a third-party audit to determine whether the application meets the requirements of the rule. DEA estimates the cost of this audit at $15,000. This estimated cost is about 50 percent of the application fee for CCHIT testing and certification of a full ambulatory electronic health record application ($29,000). DEA chose to use the CCHIT fees as a basis because the interim final rule narrows the scope of the third-party audit and allows a larger number of auditors to conduct the audit. The higher cost estimates in the NPRM were based on obtaining particular types of audits and having the audits cover functions that will not be subject to auditing for installed applications. In addition, the one commenter that already obtained the third-party audits specified in the NPRM stated that the costs were much lower than DEA had estimated. DEA estimates that within five years, all electronic prescription application providers will obtain certification from an approved certification organization; because the providers already seek these certifications for other reasons, the cost of continuing to obtain certifications will not accrue to the rule after that point.

[44] "Electronic Orders for Controlled Substances" 70 FR 16901, April 1, 2005; Economic Impact Analysis of the Electronic Orders Rule available at *http://www.DEAdiversion.usdoj.gov/fed_regs/rules/2005/index.html*

Table 5 presents the unit costs for both labor-based costs and fees.

TABLE 5—UNIT COSTS

Requirement	Item, or labor, required	Unit cost
Non-Labor Costs		
Identity proofing and credential	Remote identity proofing and downloadable code for registrant (includes hard token).	$110.00
Renewal of credential	Three-year renewal	35.00
	Nine-year renewal	110.00
Initial audit of application	Certification that application meets DEA requirements	15,000.00
Reaudit of application	Certification that application still meets DEA requirements	15,000.00
Labor Costs		
Application for identity proofing and credential	Registrant must fill out form; 10 minutes required	28.23
Renewal application for credential	Registrant must only fill out parts where information has changed; 5 minutes needed.	14.12
Registration check	Requires one minute for a non-registrant.	
	Physician office—nurse	1.12
	Dental office—dental assistant	0.57
Access control—training (practice office)	One hour per person; one is a registrant	
Physician plus nurse		259.35
Mid-level plus nurse		151.49
Dentist plus dental assistant		201.01
Access control—granting (practice office)	Requires one minute for registrant, five minutes for non-registrant (nurse).	
	Physician plus nurse	8.66
	Mid-level plus nurse	7.00
	Dentist plus dental assistant	5.64
Access control—training (pharmacy)	Requires five minutes for pharmacy technician	2.33
Access control—granting (pharmacy)	Requires five minutes for pharmacy technician	2.33
Review of security logs (practice office)	Requires five minutes per quarter; 20 minutes per year for nurse	22.39
Review of security logs (pharmacy)	Requires five minutes per quarter; 20 minutes per year for pharmacy tech	11.43
Review of security logs (hospital)	Requires ten minutes per month per year for system administrator	136.64
ID check, face to face (hospital only)	Requires two minutes for HR person AND	1.20
	30 minutes per hospital practitioner OR	55.22
	30 minutes per private physician	96.08
Reprogramming applications for practices	Requires 2,000 hours of application provider engineer's time	184,197
Reprogramming pharmacy applications	Requires 1,000 hours of application provider engineer's time	92,099

Total Costs

To proceed from unit costs to total costs, it is necessary to establish the frequency of occurrence of cost items and the distribution of those occurrences, and thus of costs, over time. DEA assumes that all application providers will reprogram their applications in the first year and that after the fifth year they will be able to substitute certification for the third-party audit. DEA assumes that pharmacies will be able to accept electronic prescriptions in the first year and set initial access controls in that year, but that they will incur ongoing costs for checking security incident logs. Hospitals and clinics are assumed to adopt applications within five years; identity proofing costs occur only in the first year of adoption. Practitioners are assumed to adopt electronic prescribing over seven years; after that point implementation for practitioners basically covers new practitioners and offices as well as ongoing costs. Practitioners incur ongoing costs for renewal of the credential, reviewing security incident logs, and adding new staff to the access list. DEA estimates costs for 15 years. Table 6 presents the implementation rate for practitioners.

TABLE 6—IMPLEMENTATION RATES FOR PRACTITIONERS

	Implementation rate (percentage)	Cumulative percentage
YEAR 1	6.0	6.0
YEAR 2	10.0	16.0
YEAR 3	20.0	36.0
YEAR 4	20.0	56.0
YEAR 5	20.0	76.0
YEAR 6	10.0	86.0
YEAR 7	5.0	91.0
YEAR 8	2.0	93.0
YEAR 9	1.0	94.0
YEAR 10	1.0	95.0
YEAR 11	1.0	96.0
YEAR 12	1.0	97.0
YEAR 13	1.0	98.0
YEAR 14	1.0	99.0
YEAR 15	1.0	100.0

Total costs are calculated by multiplying the unit cost for an item or activity by the number of entities that will incur the cost in each year. Tables 7 and 8 present the Option 1 annualized costs by item and regulated entity at both a 7 percent and 3 percent discount rate.

TABLE 7—OPTION 1 ANNUALIZED COSTS BY ITEM AND BY SECTOR—7.0 PERCENT

	Practitioners' offices	Hospitals	Pharmacies	Application providers	Totals
Credential	$14,669,488				$14,669,488
Credential application	3,844,882				3,844,882
Registration check	30,405				30,405
Granting access	303,086		$16,752		319,838
Training for granting	7,147,886		50,255		7,198,142
Review security logs	4,248,868	$1,524,079	1,959,040		7,731,986
ID verification		4,717,580			4,717,580
Reprogram applications				$3,842,530	3,842,530
Obtain certification				391,021	391,021
Audit of applications				583,957	583,957
Totals	30,244,615	6,241,658	2,026,046	4,817,509	43,329,829

TABLE 8—OPTION 1 ANNUALIZED COSTS BY ITEM AND BY SECTOR—3.0 PERCENT

	Practitioners' offices	Hospitals	Pharmacies	Application providers	Totals
Credential	$14,761,504				$14,761,504
Credential application	3,817,785				3,817,785
Registration check	27,259				27,259
Granting access	281,572		$12,781		294,353
Training for granting	6,315,405		38,342		6,353,747
Review security logs	4,399,243	$1,518,215	1,885,804		7,803,262
ID verification		3,834,522			3,834,522
Reprogram applications				$3,842,530	3,842,530
Obtain certification				393,356	393,356
Audit of applications				650,592	650,592
Totals	29,602,769	5,352,737	1,936,927	4,886,478	41,778,910

Option 2

Option 2 is the same as Option 1, except that the two-factor authentication credential requires a biometric identifier and a hard token. Passwords would not be permitted as an authentication factor. The cost items are:

- Biometric readers for practitioners' offices, hospitals, and clinics.
- Software packages for practitioners' offices and clinics.
- Reprogramming of applications for hospitals.

A biometric reader would be needed for every practitioner's computer. DEA estimates that hospitals would need one for every 15 beds, and each clinic would need an average of two readers. Based on American Hospital Association data, DEA estimates the number of community hospital beds to be 802,658. The number of clinics is estimated to be 7,485. There are 20 firms providing applications to hospitals, and their number is not expected to change.[45] All of these firms would reprogram their applications in YEAR 1. Costs of readers and software packages would be incurred as hospitals and clinics adopt electronic prescriptions for controlled substances. Hospital beds and clinics are phased in as shown in Table 9.

TABLE 9—PHASE-IN OF HOSPITAL BEDS AND CLINICS

	Beds	Clinics
YEAR 1	200,665	1,871
YEAR 2	200,665	1,871
YEAR 3	160,532	1,497
YEAR 4	160,532	1,497
YEAR 5	80,266	749

There are no costs for hospitals and clinics after YEAR 5. All reprogramming costs are in YEAR 1. Costs for practitioners' offices and registrants extend over 15 years following the projected start-up of electronic prescriptions for controlled substances in practitioners' offices and number of registrants in practitioners' offices starting electronic prescriptions for controlled substances.

A biometric reader that meets the requirements costs $114.00.[46] The software package for clinics and offices is $86.00. Reprogramming of applications for hospitals would require 200 hours for an application provider's engineer at $92.10 per hour. Cost is $18,420 per application provider. Table 10 presents the annualized costs of adding the biometric.

TABLE 10—COST OF OPTION 2

	7.0 percent	3.0 percent
YEAR 1	$8,037,011	$8,037,011
YEAR 2	10,862,145	11,283,976
YEAR 3	18,424,735	19,883,569
YEAR 4	17,750,891	19,900,309
YEAR 5	16,454,640	19,163,490
YEAR 6	8,085,656	9,782,458
YEAR 7	4,387,114	5,513,892
YEAR 8	2,278,677	2,975,149
YEAR 9	1,570,416	2,130,037
YEAR 10	1,502,772	2,117,445
YEAR 11	1,437,996	2,104,861
YEAR 12	1,375,970	2,092,286
YEAR 13	1,316,578	2,079,722
YEAR 14	1,259,712	2,067,171
YEAR 15	1,205,265	2,054,634
Total	95,949,579	111,186,009

	7.0 percent	3.0 percent
Annualized	$10,534,748	$9,313,672

[45] The estimate is based on the number of application providers that have obtained CCHIT certification for inpatient EHRs.

[46] Based on the cost of BioTouch 500, which is a separate reader. Where the reader is part of a keyboard, the bundled reader and software is available for $200. The software cost was derived from this price.

	7.0 percent	3.0 percent
Annualized plus Option 1	53,864,576	51,092,582

The cost of the biometrics requirement is additive to the interim final rule cost, since no other requirements are eliminated.

Option 3

Under this option the security requirements of the interim final rule are set aside and sole reliance for security is placed on a requirement that, on receipt of an electronic prescription for a controlled substance, a pharmacy must call the practitioner's office for verification of the prescription. For the sake of simplicity, DEA has not included in this option estimates of the time that will be required to reprogram existing applications to conform to the basic information included on every controlled substance prescription. DEA has no basis for determining how many existing applications do not include or do not transmit all of this information. Similarly, there may be some pharmacy applications that will require reprogramming to incorporate the requirements for annotations. The costs of reprogramming, however, will be relatively small compared with the primary cost of this option.

The cost of this option depends on the number of prescriptions to be verified. There were 461,172,000 controlled substance prescriptions in 2008.[47] Annual growth rate has been 3.0 percent. Therefore, DEA expects 475,007,160 prescriptions in YEAR 1 and growth thereafter at 3.0 percent annually. Of these prescriptions, 75.0 percent will be original prescriptions, requiring verification if electronic; the remainder are refills that are authorized on the original prescription and require no contact between the pharmacy and practitioner.

Industry estimates indicate that 30 percent of original prescriptions generate callbacks to deal with formulary issues, requests to change to generic forms of the prescribed drug, illegibility, and other problems. Based on data from a 2004 Medical Group Management Association survey, 34 percent of callbacks on original prescriptions were for formulary issues, 31 percent were about generic drugs, and 35 percent were on other issues.[48] The callback rate for controlled substance prescriptions is likely to be lower than 30 percent because more than 85 percent of controlled substance prescriptions are for generic drugs. Adjusting for a lower number of calls related to generic drugs, DEA estimates that currently 22 percent of controlled substance prescriptions require callbacks. The callback option applies only to new calls that would need to be placed, or 78 percent of the original prescriptions: 277,879,189 ($0.78 \times 0.75 \times 475{,}007{,}160$). For the 22 percent of prescriptions that already require callbacks, the confirmation would simply be part of a call that is being made anyway and, therefore, is not an additional cost. The number of electronic prescriptions each year requiring calls will be determined by the rate of adoption of electronic prescriptions for controlled substances. Because these are callbacks simply to confirm the legitimacy of the prescription, DEA assumes that each call would require three minutes of a pharmacy technician's time, three minutes of a medical assistant's time, and one minute of the practitioner's time. Table 11 presents the present value and annualized costs of Option 3.

TABLE 11—PRESENT VALUE AND ANNUALIZED COST OPTION 3

	7.0 percent	3.0 percent
YEAR 1	$100,904,733	$100,904,733
YEAR 2	259,020,250	269,079,289
YEAR 3	561,008,812	605,428,399
YEAR 4	840,056,809	941,777,510
YEAR 5	1,097,457,393	1,278,126,621
YEAR 6	1,195,435,021	1,446,301,176
YEAR 7	1,217,649,690	1,530,388,454
YEAR 8	1,197,891,176	1,564,023,365
YEAR 9	1,165,509,232	1,580,840,821
YEAR 10	1,133,874,313	1,597,658,276
YEAR 11	1,102,975,819	1,614,475,732
YEAR 12	1,072,802,902	1,631,293,187
YEAR 13	1,043,344,493	1,648,110,643
YEAR 14	1,014,589,338	1,664,928,098
YEAR 15	986,526,025	1,681,745,554
Total	13,989,046,006	19,155,081,859
Annualized	1,535,922,056	1,604,555,706

TABLE 12—TOTAL ANNUALIZED COSTS OF OPTIONS

	7.0 percent	3.0 percent
Option 1	$43,329,829	$41,778,910
Option 2—Required Use of Biometrics	53,864,576	51,092,582
Option 3—Callbacks	1,535,922,056	1,604,555,706

[47] In 2008, controlled substances represented 12.15% of the top 400 brand name and generic drugs sold at retail. The estimated number of controlled substance prescriptions is based on the assumption that 12% of all prescriptions (3.8431 billion according to IMS Health data) are for controlled substances.

[48] *http://www.mgma.com/WorkArea/DownloadAsset.aspx?id=19248,* accessed 08/06/09.

Benefits:

Electronic prescriptions are widely expected to reduce errors in medication dispensing because they will eliminate illegible written prescriptions and misunderstood oral prescriptions. They are also expected to reduce the number of callbacks from pharmacy to practitioner to address legibility, formulary, and contraindication issues. Electronic prescriptions may also reduce processing time at the pharmacy and wait time for patients. These benefits are likely to be mitigated to some extent. As a Rand study suggested, practitioners may fail to review the prescription and notice errors that occur when the wrong item is selected from one or more drop-down menus; pharmacists may be less likely to question a legible electronic prescription.[49] The formulary and contraindication checks are functions that practitioners sometimes disable because they do not work as they should or take too much time.[50] In addition, recent studies indicate that electronic prescriptions sometimes are missing information, particularly directions for use and dosing errors.[51] [52] Nonetheless, electronic prescriptions may provide benefits in avoided medication errors, reduced processing time, and reduced callbacks. These benefits of electronic prescriptions are not directly attributable to this rule because they accrue to electronic prescribing, not the incremental changes being required in this rule.

DEA has quantified three types of benefits: reduced number of callbacks to clarify prescriptions, the reduction in wait time for patients picking up prescriptions, and the cost-savings pharmacies will realize from eliminating storage of paper records. One of the greatest burdens in the paper system is the need for callbacks to clarify prescriptions. Clarifications and changes may be required for several reasons: the prescription is not legible; required information is not included on the prescription; the prescribed dosage unit does not exist; the particular medication is not approved by the patient's health insurance; and the drug prescribed is contraindicated because it reacts with other medications the patient is taking or because it negatively affects other conditions from which the patient suffers. Each callback involves the pharmacy staff and one or more staff at the practitioner's office, often including the practitioner. Electronic prescriptions will eliminate illegible prescriptions and could eliminate those with missing information or unavailable dosage units or forms. The recent studies cited above indicate that at least some prescription applications do not prevent practitioners from transmitting electronic prescriptions that are incomplete. At present, the field for directions for use in the NCPDP SCRIPT has not been standardized; when it is, the issues cited in the studies related to these directions may be resolved. Whether formulary and contraindication callbacks are eliminated will depend on the functions of the electronic prescription applications and the accuracy of the drug databases that they use.

The public is also affected by the current system. For the majority of controlled substance prescriptions, the patient (or someone acting for the patient) presents a paper prescription to the pharmacy and then waits for the pharmacy to fill it. The time between the point when the prescription is handed to the pharmacist and the point when it is ready for pick-up is a cost to the public.

The percentage of callbacks that will be eliminated by electronic prescribing is unclear. The Centers for Medicare and Medicaid Services, in its November 16, 2007, proposed rule on formulary and generic transactions, estimated a 25 percent reduction in time spent on callbacks.[53] DEA similarly assumes that callbacks will be reduced by 25 percent. For these callbacks, which require more effort than the simple confirmation required for Option 3, DEA used the time estimates from the MGMA survey (6.9 minutes of staff time per call and 4.2 minutes of practitioner time).[54] Assuming that electronic controlled substance prescriptions phase in over 15 years, as described above, the annualized time-saving for eliminating 25 percent of these callbacks would be $420 million (at 7% discount) or $439 million (at 3% discount).

Electronic prescriptions could also reduce the patient's wait time at the pharmacy. The number of original controlled substance prescriptions that could require public wait time is based on the estimated number of original prescriptions (approximately 356 million in 2009), reduced by 19 percent, to account for those prescriptions phoned to the pharmacy[55] plus another 14 percent to remove those that are currently filled by mail order pharmacies or long-term care facilities.[56] Assuming the average wait time is 15 minutes for the 81 percent of original prescriptions that are presented on paper to retail pharmacies (not mail order or long-term care prescriptions), if those waiting times are eliminated, at the current United States average hourly wage ($20.49), the annualized savings over 15 years would be $1 billion (at 7% discount) or $1.03 billion (at 3% discount).

The estimate for public wait time is an upper bound, as such it is not included in the primary estimate for the benefits of this interim final rule. It assumes that the practitioner will transmit the prescription and that the pharmacist will open the record and fill it before the patient arrives at the pharmacy. Recent research on electronic prescriptions found that 28 percent of electronic prescriptions transmitted were never picked up by patients; for painkillers, more than 50 percent were not picked up.[57] If pharmacies prepared electronic prescriptions before the patient arrives, the pharmacy will have spent time for which it will not be reimbursed if the patient does not pick up the prescription and will spend further time returning the drugs to stock and correcting records. It is possible, therefore, that pharmacies will not be willing to fill electronic prescriptions for controlled substances until they are certain that the patient wants to fill the prescription. The primary estimate for public wait time, therefore, is zero.

Table 13 presents the annualized gross benefits at a 7.0 percent and 3.0 percent discount rate.

[49] Bell, D.S. *et al.,* "Recommendations for Comparing Electronic Prescribing Systems: Results of An Expert Consensus Process," *Health Affairs,* May 25, 2004, W4–305–317.

[50] Grossman, J.M. *et al.,* "Physicians' Experiences Using Commercial E-Prescribing Systems," *Health Affairs,* 26, no. 3 (2007), w393–w404.

[51] Warholak, T.L. and M.T. Rupp. "Analysis of community chain pharmacists' interventions on electronic prescriptions." *Journal of American Pharm Association,* 2009, Jan–Feb; 49(1): 59–64.

[52] Astrand, B. *et al.,* "Assessment of ePrescription Quality: an observational study at three mail order pharmacies." *BMC Med Inform Decis Mak,* 2009 Jan 26; 9:8.

[53] 72 FR 64900, November 16, 2007.

[54] *http://www.mgma.com/WorkArea/DownloadAsset.aspx?id=19248,* accessed 08/06/09.

[55] A 1999 Drugtopics.com survey indicated that 36% of all prescriptions were phoned in; because refills are usually authorized on the original prescription and do not require second calls, and slightly less than half of prescriptions are refills, the analysis uses 19% for phoned in prescriptions.

[56] Based on IMS Health 2008 channel distribution by U.S. dispensed prescriptions. *http://imshealth.com*, accessed June 16, 2009.

[57] Solomon, M., and S.R. Majumdar. "Primary Non-Adherence of Medications: Lifting the Veil on Prescription-filling Behavior" *Journal of General Internal Medicine,* March 2, 2010.

TABLE 13—ANNUALIZED GROSS BENEFITS

	7%	3%
Callbacks Avoided	$419,745,516	$438,502,110

These benefits are gross rather than net benefits, but it is not possible to compare these cost-savings to the costs of the rule or to estimate net benefits. These savings will accrue to any electronic prescription application. The only way to assess net benefits is to compare them with the costs of the full application and its implementation, not the incremental costs of DEA's requirements.

Pharmacies are required to retain all original controlled substance prescriptions, including oral prescriptions that the pharmacist reduces to writing, on paper for two years. As electronic prescriptions replace paper records, pharmacies will be able to eliminate file cabinets, freeing up space for other uses. The annualized cost of a prescription file cabinet is $78.50 ($715 annualized over 15 years at 7%); the cost of the floor space is $55.34 per cabinet (2.77 square feet times $20/square feet rental price for retail space). The annualized cost-savings for pharmacies are $1.38 million at 7 percent and $1.4 million at 3 percent.

Other Benefits

DEA has not attempted to quantify or monetize the benefits of the rule that relate to diversion because of a lack of data on the extent of diversion of controlled substances through forged or altered prescriptions and alteration of pharmacy records. Electronic prescriptions for controlled substances will directly affect the following types of diversion:

- Stealing prescription pads or printing them, and writing non-legitimate prescriptions.
- Altering a legitimate prescription to obtain a higher dose or more dosage units (*e.g.,* changing a "10" to a "40").
- Phoning in non-legitimate prescriptions late in the day when it is difficult for a pharmacy to complete a confirmation call to the practitioner's office.
- Altering a prescription record at the pharmacy to hide diversion from pharmacy stock.

These are examples of prescription forgery that contribute significantly to the overall problem of drug diversion. DEA expects this rule to reduce significantly these types of forgeries because only practitioners with secure prescription-writing applications will be able to issue electronic prescriptions for controlled substances and because any alteration of the prescription at the pharmacy will be discernible from the audit log and a comparison of the digitally signed records. DEA expects that over time, as electronic prescribing becomes the norm, practitioners issuing paper prescriptions for controlled substances may find that their prescriptions are examined more closely.

The Substance Abuse and Mental Health Services Administration (SAMHSA) runs the Drug Abuse Warning Network (DAWN), a public health surveillance system that monitors drug-related visits to hospital emergency departments and drug-related deaths investigated by medical examiners and coroners. SAMHSA reported that in 2003, in six States (Maine, Maryland, New Hampshire, New Mexico, Utah, and Vermont) there were 352 deaths from misuse of oxycodone and hydrocodone, both prescription controlled substances. SAMHSA data for 2006 show that 195,000 emergency department visits involved nonmedical use of benzodiazepines (Schedule IV) and 248,000 involved nonmedical use of opioids (Schedule II and III). Of all visits involving nonmedical use of pharmaceuticals, about 224,000 resulted in admission to the hospital; about 65,000 of those individuals were admitted to critical care units; 1,574 of the visits ended with the death of the patient. More than half of the visits involved patients 35 and older. Using a value per life of $5.8 million, the costs of the 2003 deaths from misuse of prescription controlled substances in the six States is more than $2 billion.[58] The cost of the 2006 emergency room visits is above $350 million (at $1,000 per visit), not including the cost of further in-patient care for those admitted. These costs are some fraction of the total cost to the Nation. DEA has no basis for estimating what percentage of these costs could be addressed by the rule. If, however, the rule prevents even a small fraction of the deaths and emergency care the benefits will far exceed the costs.

These costs also do not represent all of the costs of drug abuse to society. Drug abuse is associated with crime and lost productivity. Crime imposes costs on the victims as well as on government. DEA does not track information on controlled substance prescription drug diversion because enforcement is generally handled by State and local authorities. The cost of enforcement is, however, considerable. In 2007, DEA spent between $2,700 for a small case and $147,000 for a large diversion case just for the primary investigators; adjudication costs and support staff are additional. It is reasonable to assume that State and local law enforcement agencies are spending similar sums per case. Some cases involve multiple jurisdictions, all of which bear costs for collecting data and deposing witnesses. The rule could reduce the number of cases and, therefore, reduce the costs to governments at all levels. A reduction in forgeries will also benefit practitioners who will be less likely to be at risk of being accused of diverting controlled substances and of then having to prove that they were not responsible.

Adverse drug events that result from medication errors are frequently cited as a benefit of electronic prescriptions. Illegible prescriptions and misunderstood oral prescriptions can result in the dispensing of the wrong drug, which may cause medical problems and, at the very least, fail to provide the treatment a practitioner has determined is necessary. Once a practitioner has access to a patient's complete medication list, electronic prescription applications hold the promise of identifying contraindication problems so that a patient is not prescribed drugs that taken together cause health problems or cancel the benefits. Allergy alerts will also warn practitioners of potential medication concerns.

DEA has not attempted to estimate the extent of these benefits for two reasons. First, there are few data that indicate the extent of the problem as it relates to prescriptions. The data most frequently cited on medication errors and adverse drug events (1.5 million preventable adverse drug events) are from two literature reviews conducted by the

[58] The DAWN mortality data from 2005 indicate that almost 4,900 people died with prescription opioids in their bloodstream; about 600 were not using any other drug or alcohol. These numbers, however, do not indicate how many of the people were using the drugs for nonmedical purposes.

Institute of Medicine.[59] These reviews and the estimate are based on studies that looked at medication errors that occur in hospitals, nursing homes, clinics, and ambulatory settings. Similarly, a 2008 review of studies found fewer errors with electronic medication orders, but at least 24 of the 27 studies reviewed covered only inpatient medication orders, which DEA does not regulate.[60] [61] Many of the studies cover errors that will not be addressed by electronic prescribing, such as inpatient administration errors (*i.e.,* either the chart was incorrect or the chart was correct, but the wrong drug or dosage was administered or the drug was given to the wrong patient), pharmacy dispensing errors (*i.e.,* the prescription was correct, but the wrong drug was given to the patient), failure to include the dosage or other information on the label, and failure to include informational inserts with the dispensed drug. All of these may cause adverse drug events, but will not be addressed by electronic prescribing. Other errors, such as the practitioner's selection of the wrong dose, wrong drug, or wrong frequency of use, may or may not be addressed by electronic prescribing. DEA has no basis to determine what number of adverse drug events could be prevented by the use of an electronic prescription application. Although illegible prescriptions have caused adverse drug events when the wrong drug or dosage was dispensed, most often pharmacies contact the practitioner to decipher prescriptions rather than guess at the drug or dosage intended. In addition, the assumption that the use of electronic prescription applications will alert practitioners to contraindications and allergies is based on the assumption that the patient's medical record will be complete. Although this may be the case when every patient has an EHR and all of the applications are interoperable so that a practitioner can access pharmacy records, until that time the medical record will be only as complete as the patient is willing or able to make it, which will limit the ability of the application to alert the practitioner to potential problems. Similarly, until EHRs have databases that link drug names to diagnostic codes and dosage units to age and weight, the applications will have no way to prevent a practitioner from issuing a prescription with an inappropriate drug name or dosage.

Second, the use of electronic prescription applications and transmission systems may introduce errors. Keystroke and data entry errors may replace some of the errors that occur with illegible handwriting. A comment on the proposed rule from a State pharmacy board indicated that, at least at this early stage of implementation, the translation of the electronic data file to the pharmacies has caused data to be placed in the wrong fields and, in some cases, in the wrong patient's file. Similarly, a 2006 survey of chain pharmacy experience with electronic prescribing noted both positive experiences (improved clarity and speed) and negative, prescribing errors, particularly those with wrong drugs or directions.[62]

DEA believes that electronic prescribing will reduce the number of prescription errors, but it has no basis for estimating the scope of the problem or the extent of reduction that will occur and the speed at which it will occur. Some of the problems will not be solved until EHRs are common and linked; others could be addressed more easily by programming applications to require all of the fields to be completed before transmission. Even the best system is unlikely to be able to eliminate human errors.

Uncertainties:

Any economic analysis involves some level of uncertainty about elements of the analysis. This is particularly true for this analysis, which must estimate costs for implementation of a new technology and project voluntary adoption rates. This section discusses the elements that have the greatest level of uncertainty associated with them.

The American Recovery and Reinvestment Act (Pub. L. 111–5) provides incentives for practitioners to adopt electronic health record applications; the incentives are scheduled to end after 2016. The analysis assumes that practitioners will adopt electronic prescribing by that time; after that point all of the implementation occurs with new entrants. Whether adoption is, in fact, that rapid will depend on a number of factors unrelated to this rulemaking. The barriers to adoption continue to be the high cost of the applications, which may be greater than the subsidies; the disruption that implementation creates in a practice; and uncertainty about the applications themselves.[63] The pattern with software applications is that a large number of firms enter a market, but the vast majority of them fail, leaving a very few dominant providers.[64] The health IT market is still in the early phases of this process. DEA has no basis for estimating when dominant players will emerge. The 7-year implementation period projected may be too conservative or too optimistic.

The time for reprogramming existing applications is estimated to be between 1,000 hours and 2,000 hours. DEA based the upper estimate on information provided by the industry for DEA's rulemaking regarding electronic orders for controlled substances. The actual cost to existing application providers is likely to vary widely. Some providers may meet all or virtually all of the requirements and need little reprogramming. Many of the requirements are standard practice for software (*e.g.,* logical access controls for hospitals) and should need minimal adjustments. Most electronic prescription applications appear to present the data DEA will require on prescriptions. Any software firm that uses the Internet for any transaction will have digital signature capability. Electronic health record applications must control access to gain Certification Commission for Healthcare Information Technology certification. Nonetheless, DEA expects that for some existing providers, the requirements may take more than the estimated time. The extent to which this requires additional time will also depend on whether the changes are incorporated into other updates to the application or are done on a different schedule.

Another uncertainty of application provider costs relates to the third-party audit and the time that will elapse before a certification organization is able to certify compliance with DEA's requirements. If the Certification Commission for Healthcare Information Technology includes DEA's requirements in its criteria, the costs for third-party audits may be eliminated sooner than estimated. The interim final rule provides more options for obtaining a third-party audit, which should reduce its cost. DEA has not assumed

[59] "To Err is Human: Building a Safer Health System," IOM 2000; "Preventing Medication Errors," IOM 2007. *http://www.nap.edu.*

[60] Ammenwerth, E. *et al.* "The Effect of Electronic Prescribing on Medication Errors and Adverse Drug Events: A Systematic Review." *Jour. Am. Medical Informatics Assn.,* June 25, 2008.

[61] Most of the studies label all medical orders as prescriptions, whether they are included on a patient's chart in a hospital or LTCF or are written and given to a patient to fill at a pharmacy.

[62] Rupp, M.T. and T.L. Warholack. "Evaluation of e-prescribing in chain community pharmacy: best-practice recommendations." *J. Am. Pharm. Assoc.* 2008 May–Jun; 48(3):364–370.

[63] California HealthCare Foundation, Snapshot: The State of Health Information Technology in California, 2008.

[64] Bergin, T.J., "The Proliferation and Consolidation of Word Processing Software: 1985–1995." *IEEE Annals of the History of Computing.* Volume 28, Issue 4, Oct.–Dec. 2006 Page(s):48–63.

that any organization will certify pharmacy applications because no organization currently does so except for determining whether the pharmacy application can read a SCRIPT format.

The single largest cost for practitioners is obtaining identity proofing and an authentication credential. DEA used the cost of a three-year digital certificate at a medium assurance level from the SAFE BioPharma Certification Authority for the cost estimate. SAFE meets the criteria set in the rule. Other firms that meet the criteria provide digital certificates and other credentials for more and for less. The actual cost will not be known until the rule is implemented and practitioners and providers decide on the type of credential they will use. Some commenters on the proposed rule stated that remote identity proofing, which is allowable, can be done very quickly, which could lower the cost. The firms providing the service, however, may impose other requirements beyond those of DEA, which could increase the cost.

There will also be costs associated with lost or compromised credentials. DEA has not attempted to estimate those costs because the frequency with which this will occur and the requirements that credential providers will impose is not known. Some practitioners will never incur these costs while others may incur them multiple times. Credential providers may require a practitioner to go through identity proofing or may impose lesser requirements. If one of the two factors is a password, credential providers may deal with password resets as they do now; password resets do not usually involve issuing a new token or a fee.

C. Regulatory Flexibility Act

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601–612) (RFA), Federal agencies must evaluate the impact of rules on small entities and consider less burdensome alternatives. In its Economic Impact Analysis, DEA has evaluated the cost of the rule on individual practitioners and small pharmacies. The initial costs to the smallest practitioner office will be about $400 ($110 for identity proofing including the authentication credential, and $290 in labor costs to complete the application, receive access control training, and set logical access controls). The main ongoing costs for the rule will be the renewal of the credential ($49 every three years) and checking security logs ($22 per year) plus any incremental cost of the software or application. The initial costs for the basic rule elements represent about 0.3 percent of the annual income of the lowest paid practitioner and 0.1 percent of average revenues. The ongoing costs are considerably lower. For practices with a physician and a mid-level practitioner, the costs would be lower because access control training would not need to involve the physician. (Mid-level practitioners, because they are generally employees, are not small entities under the Regulatory Flexibility Act.)

Determining the incremental cost of the application requirements per practitioner is difficult because it depends on the number of application providers, the number of customers, the number of application requirements that an application provider does not already meet, and how costs are recovered (in the year in which the money is spent or over time). For example, an electronic health record application that had to reprogram to the full extent will have incremental application costs of $199,000 ($15,000 for the third-party audit and $184,000 for reprogramming). If the provider recovered the costs from 1,000 practitioners (charges are usually on a per practitioner, not per practice basis), the incremental cost to those customers will be $199 or about $17 a month. The costs for the application provider in the out years will be much lower ($15,000 every two years) because no further programming is needed. Even if the application provider did not add practitioners and continued to obtain a third-party audit rather than rely on certification, the incremental cost to practitioners will be less than a dollar a month.

For pharmacies, the costs will be the incremental cost that their application provider charges to cover the costs of reprogramming and audits ($92,000 plus $15,000) plus the cost of reviewing the security log ($11.43 per year) and initial access control training and initial access control setting ($4.66). In the first year, if the application providers recover the programming costs and initial audit costs in a single year, the average incremental cost to a pharmacy for these two activities will be $65 ($4,284,900 first year cost divided by 65,421 pharmacies). The total first year cost will, therefore, be less than $100. After that, the incremental charge to recover the cost of the third-party audit will be $9 per pharmacy every two years, assuming the cost is evenly distributed across all pharmacies. The pharmacy will have continuing labor costs for reviewing security logs ($11.43). The first year charge represents less than 0.01 percent of an independent pharmacy's annual sales. The annual cost is less than $0.01 per controlled substance prescription. It also represents a far lower cost than the pharmacy will pay its application provider to cover the fee charged by SureScripts/RxHub or another intermediary for processing the prescriptions. According to comments DEA received to its notice of proposed rulemaking, the application provider charges a transaction fee of $0.30 per electronic prescription to cover intermediary charges for routing and, where necessary converting, prescriptions to ensure that the pharmacy system will be able to capture the data electronically. Based on National Association of Chain Drug Stores data on the average price of prescriptions ($71.69) and the average value of prescription sales, an independent pharmacy processes about 36,000 prescriptions a year and will have to pay about $10,800 to cover the transaction fee.[65]

The average annualized cost to hospitals and clinics is about $180, which does not represent a significant economic impact. Most of the hospital tasks are part of their routine business practices related to credentialing.

Application providers are not directly regulated by the rule and, therefore, are not covered by the requirements of the RFA. DEA notes, however, that the costs of the rule are not so high that any of these firms will not be able to recover them from their customers. Reprogramming is a routine practice in the software industry; applications are updated with some frequency to add features and fix problems. The additional requirements of the rule can be incorporated during the update cycle. Many of these firms are already spending more than DEA has estimated to obtain CCHIT certification; in time, DEA expects that this certification (or a similar certification) will replace the third-party audit, further reducing their costs.

Based on the above analysis, DEA has determined that although the rule will impact a substantial number of small entities, it will not impose a significant economic impact on any small entity directly subject to the rule.

D. Congressional Review Act

It has been determined that this rule is a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule is voluntary and could result in a net reduction in costs. This rule will not result in a major increase in costs or

[65] *http://www.nacds.org/wmspage.cfm?parm1=507,* accessed 6/17/09.

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.

E. Paperwork Reduction Act

As part of its NPRM, DEA included a discussion of the hour burdens associated with the proposed rule. DEA did not receive any comments specific to the information collection aspects of the NPRM.

The Department of Justice, Drug Enforcement Administration, has submitted the following information collection request to the Office of Management and Budget for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995.

All suggestions or questions regarding additional information, to include obtaining a copy of the information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152.

Overview of information collection 1117–0049:

(1) *Type of Information Collection:* New collection.

(2) *Title of the Form/Collection:* Recordkeeping for electronic prescriptions for controlled substances.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

Form number: None.

Office of Diversion Control, Drug Enforcement Administration, 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: non-profit healthcare facilities.

Abstract: DEA is requiring that each registered practitioner apply to a credential service provider approved by the Federal government to obtain identity proofing and a credential. Hospitals and other institutional practitioners may conduct this process in-house as part of their credentialing. For practitioners currently working at or affiliated with a registered hospital or clinic, the hospital/clinic will have to check a government-issued photographic identification. In the future, this will be done when the hospital/clinic issues credentials to new hires or newly affiliated physicians. At practitioner offices, two people will need to enter logical access control data into the electronic prescription application to grant permissions for individual practitioner registrants to approve and sign controlled substance prescriptions. For larger offices (more than two registrants), DEA registrations will be checked prior to granting access. Similarly pharmacies will have to enter permissions for access to prescription records. Finally, practitioners, hospitals/clinics, and pharmacies will have to check security logs periodically to determine if security incidents have occurred.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

DEA estimates in the first three years of implementation 217,740 practitioners, 8,688 hospitals and clinics, and 65,421 pharmacies will adopt electronic prescribing for a total of 291,849 respondents. The average practitioner is expected to spend 0.17 hours, the average hospital or clinic, 2.23 hours, and the average pharmacy 0.36 hours annually or an average across all respondents of 0.27 hours per year. Table 14 presents the burden hours by activity, registrant type, and year.

TABLE 14—BURDEN HOURS BY ACTIVITY, REGISTRANT TYPE, AND YEAR

Year 1	Practitioner	Hospitals	Pharmacies	Total hours
Application	5,827			5,827
Registration check	264			264
Access control	1,826		5,452	7,277
Security log	6,086	6,206	21,807	34,099
ID check		27,712		27,712
Total	14,003	33,918	27,259	75,180
Year 2	**Practitioner**	**Hospitals**	**Pharmacies**	**Total hours**
Application	10,004			10,004
Registration check	454			454
Access control	3,101			3,101
Security log	16,423	12,412	21,807	50,642
ID check		28,887		28,887
Total	29,983	41,299	21,807	93,089
Year 3	**Practitioner**	**Hospitals**	**Pharmacies**	**Total hours**
Application	20,459			20,459
Registration check	931			931
Access control	6,292		0	6,292
Security log	37,395	9,120	21,807	68,322
ID check		24,319		24,319
Total	65,076	41,696	21,807	128,579

(6) *An estimate of the total public burden (in hours) associated with the collection:*

The three year burden hours are estimated to be 296,848 or 98,949 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.

F. 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.

G. 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.

H. Unfunded Mandates Reform Act of 1995

This rule will not result in the net 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. Because this rule will not affect other governments, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995. The economic impact on private entities is analyzed in the Economic Impact Analysis of the Electronic Prescription Rule.

List of Subjects

21 CFR Part 1300

Chemicals, Drug traffic control.

21 CFR Part 1304

Drug traffic control, Reporting and recordkeeping requirements

21 CFR Part 1306

Drug traffic control, Prescription drugs.

21 CFR Part 1311

Administrative practice and procedure, Certification authorities, Controlled substances, Digital certificates, Drug traffic control, Electronic signatures, Incorporation by reference, Prescription drugs, Reporting and recordkeeping requirements.

■ For the reasons set out above, 21 CFR parts 1300, 1304, 1306, and 1311 are amended as follows:

PART 1300—DEFINITIONS

■ 1. The authority citation for part 1300 continues to read as follows:

Authority: 21 U.S.C. 802, 821, 829, 871(b), 951, 958(f).

■ 2. Section 1300.03 is added to read as follows:

§ 1300.03 Definitions relating to electronic orders for controlled substances and electronic prescriptions for controlled substances.

For the purposes of this chapter, the following terms shall have the meanings specified:

Application service provider means an entity that sells electronic prescription or pharmacy applications as a hosted service, where the entity controls access to the application and maintains the software and records on its servers.

Audit trail means a record showing who has accessed an information technology application and what operations the user performed during a given period.

Authentication means verifying the identity of the user as a prerequisite to allowing access to the information application.

Authentication protocol means a well specified message exchange process that verifies possession of a token to remotely authenticate a person to an application.

Biometric authentication means authentication based on measurement of the individual's physical features or repeatable actions where those features or actions are both distinctive to the individual and measurable.

Biometric subsystem means the hardware and software used to capture, store, and compare biometric data. The biometric subsystem may be part of a larger application. The biometric subsystem is an automated system capable of:

(1) Capturing a biometric sample from an end user.

(2) Extracting and processing the biometric data from that sample.

(3) Storing the extracted information in a database.

(4) Comparing the biometric data with data contained in one or more reference databases.

(5) Determining how well the stored data matches the newly captured data and indicating whether an identification or verification of identity has been achieved.

Cache means to download and store information on a local server or hard drive.

Certificate policy means a named set of rules that sets forth the applicability of the specific digital certificate to a particular community or class of application with common security requirements.

Certificate revocation list (CRL) means a list of revoked, but unexpired certificates issued by a certification authority.

Certification authority (CA) means an organization that is responsible for verifying the identity of applicants, authorizing and issuing a digital certificate, maintaining a directory of public keys, and maintaining a Certificate Revocation List.

Certified information systems auditor (CISA) means an individual who has been certified by the Information Systems Audit and Control Association as qualified to audit information systems and who performs compliance audits as a regular ongoing business activity.

Credential means an object or data structure that authoritatively binds an identity (and optionally, additional attributes) to a token possessed and controlled by a person.

Credential service provider (CSP) means a trusted entity that issues or registers tokens and issues electronic credentials to individuals. The CSP may be an independent third party or may issue credentials for its own use.

CSOS means controlled substance ordering system.

Digital certificate means a data record that, at a minimum—

(1) Identifies the certification authority issuing it;

(2) Names or otherwise identifies the certificate holder;

(3) Contains a public key that corresponds to a private key under the sole control of the certificate holder;

(4) Identifies the operational period; and

(5) Contains a serial number and is digitally signed by the certification authority issuing it.

Digital signature means a record created when a file is algorithmically transformed into a fixed length digest that is then encrypted using an asymmetric cryptographic private key associated with a digital certificate. The combination of the encryption and algorithm transformation ensure that the signer's identity and the integrity of the file can be confirmed.

Digitally sign means to affix a digital signature to a data file.

Electronic prescription means a prescription that is generated on an electronic application and transmitted as an electronic data file.

Electronic prescription application provider means an entity that develops or markets electronic prescription software either as a stand-alone application or as a module in an electronic health record application.

Electronic signature means a method of signing an electronic message that

identifies a particular person as the source of the message and indicates the person's approval of the information contained in the message.

False match rate means the rate at which an impostor's biometric is falsely accepted as being that of an authorized user. It is one of the statistics used to measure biometric performance when operating in the verification or authentication task. The false match rate is similar to the false accept (or acceptance) rate.

False non-match rate means the rate at which a genuine user's biometric is falsely rejected when the user's biometric data fail to match the enrolled data for the user. It is one of the statistics used to measure biometric performance when operating in the verification or authentication task. The false match rate is similar to the false reject (or rejection) rate, except that it does not include the rate at which a biometric system fails to acquire a biometric sample from a genuine user.

FIPS means Federal Information Processing Standards. These Federal standards, as incorporated by reference in § 1311.08 of this chapter, prescribe specific performance requirements, practices, formats, communications protocols, etc., for hardware, software, data, etc.

FIPS 140–2, as incorporated by reference in § 1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled "Security Requirements for Cryptographic Modules," a Federal standard for security requirements for cryptographic modules.

FIPS 180–2, as incorporated by reference in § 1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled "Secure Hash Standard," a Federal secure hash standard.

FIPS 180–3, as incorporated by reference in § 1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled "Secure Hash Standard (SHS)," a Federal secure hash standard.

FIPS 186–2, as incorporated by reference in § 1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled "Digital Signature Standard," a Federal standard for applications used to generate and rely upon digital signatures.

FIPS 186–3, as incorporated by reference in § 1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled "Digital Signature Standard (DSS)," a Federal standard for applications used to generate and rely upon digital signatures.

Hard token means a cryptographic key stored on a special hardware device (*e.g.,* a PDA, cell phone, smart card, USB drive, one-time password device) rather than on a general purpose computer.

Identity proofing means the process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person.

Installed electronic prescription application means software that is used to create electronic prescriptions and that is installed on a practitioner's computers and servers, where access and records are controlled by the practitioner.

Installed pharmacy application means software that is used to process prescription information and that is installed on a pharmacy's computers or servers and is controlled by the pharmacy.

Intermediary means any technology system that receives and transmits an electronic prescription between the practitioner and pharmacy.

Key pair means two mathematically related keys having the properties that:

(1) One key can be used to encrypt a message that can only be decrypted using the other key; and

(2) Even knowing one key, it is computationally infeasible to discover the other key.

NIST means the National Institute of Standards and Technology.

NIST SP 800–63–1, as incorporated by reference in § 1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled "Electronic Authentication Guideline," a Federal standard for electronic authentication.

NIST SP 800–76–1, as incorporated by reference in § 1311.08 of this chapter, means the National Institute of Standards and Technology publication entitled "Biometric Data Specification for Personal Identity Verification," a Federal standard for biometric data specifications for personal identity verification.

Operating point means a point chosen on a receiver operating characteristic (ROC) curve for a specific algorithm at which the biometric system is set to function. It is defined by its corresponding coordinates—a false match rate and a false non-match rate. An ROC curve shows graphically the trade-off between the principal two types of errors (false match rate and false non-match rate) of a biometric system by plotting the performance of a specific algorithm on a specific set of data.

Paper prescription means a prescription created on paper or computer generated to be printed or transmitted via facsimile that meets the requirements of part 1306 of this chapter including a manual signature.

Password means a secret, typically a character string (letters, numbers, and other symbols), that a person memorizes and uses to authenticate his identity.

PDA means a Personal Digital Assistant, a handheld computer used to manage contacts, appointments, and tasks.

Pharmacy application provider means an entity that develops or markets software that manages the receipt and processing of electronic prescriptions.

Private key means the key of a key pair that is used to create a digital signature.

Public key means the key of a key pair that is used to verify a digital signature. The public key is made available to anyone who will receive digitally signed messages from the holder of the key pair.

Public Key Infrastructure (PKI) means a structure under which a certification authority verifies the identity of applicants; issues, renews, and revokes digital certificates; maintains a registry of public keys; and maintains an up-to-date certificate revocation list.

Readily retrievable means that certain records are kept by automatic data processing applications or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records are kept on which certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

SAS 70 Audit means a third-party audit of a technology provider that meets the American Institute of Certified Public Accountants (AICPA) Statement of Auditing Standards (SAS) 70 criteria.

Signing function means any keystroke or other action used to indicate that the practitioner has authorized for transmission and dispensing a controlled substance prescription. The signing function may occur simultaneously with or after the completion of the two-factor authentication protocol that meets the requirements of part 1311 of this chapter. The signing function may have different names (e.g., approve, sign, transmit), but it serves as the practitioner's final authorization that he intends to issue the prescription for a

legitimate medical reason in the normal course of his professional practice.

SysTrust means a professional service performed by a qualified certified public accountant to evaluate one or more aspects of electronic systems.

Third-party audit means an independent review and examination of records and activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures.

Token means something a person possesses and controls (typically a key or password) used to authenticate the person's identity.

Trusted agent means an entity authorized to act as a representative of a certification authority or credential service provider in confirming practitioner identification during the enrollment process.

Valid prescription means a prescription that is issued for a legitimate medical purpose by an individual practitioner licensed by law to administer and prescribe the drugs concerned and acting in the usual course of the practitioner's professional practice.

WebTrust means a professional service performed by a qualified certified public accountant to evaluate one or more aspects of Web sites.

PART 1304—RECORDS AND REPORTS OF REGISTRANTS

■ 3. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 831, 871(b), 958(e), 965, unless otherwise noted.

■ 4. Section 1304.03 is amended by revising paragraph (c) and adding paragraph (h) to read as follows:

§ 1304.03 Persons required to keep records and file reports.

* * * * *

(c) Except as provided in § 1304.06, a registered individual practitioner is not required to keep records of controlled substances in Schedules II, III, IV, and V that are prescribed in the lawful course of professional practice, unless such substances are prescribed in the course of maintenance or detoxification treatment of an individual.

* * * * *

(h) A person is required to keep the records and file the reports specified in § 1304.06 and part 1311 of this chapter if they are either of the following:

(1) An electronic prescription application provider.

(2) An electronic pharmacy application provider.

■ 5. Section 1304.04 is amended by revising paragraph (b) introductory text, paragraph (b)(1), and paragraph (h) to read as follows:

§ 1304.04 Maintenance of records and inventories.

* * * * *

(b) All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:

(1) The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.

* * * * *

(h) Each registered pharmacy shall maintain the inventories and records of controlled substances as follows:

(1) Inventories and records of all controlled substances listed in Schedule I and II shall be maintained separately from all other records of the pharmacy.

(2) Paper prescriptions for Schedule II controlled substances shall be maintained at the registered location in a separate prescription file.

(3) Inventories and records of Schedules III, IV, and V controlled substances shall be maintained either separately from all other records of the pharmacy or in such form that the information required is readily retrievable from ordinary business records of the pharmacy.

(4) Paper prescriptions for Schedules III, IV, and V controlled substances shall be maintained at the registered location either in a separate prescription file for Schedules III, IV, and V controlled substances only or in such form that they are readily retrievable from the other prescription records of the pharmacy. Prescriptions will be deemed readily retrievable if, at the time they are initially filed, the face of the prescription is stamped in red ink in the lower right corner with the letter "C" no less than 1 inch high and filed either in the prescription file for controlled substances listed in Schedules I and II or in the usual consecutively numbered prescription file for noncontrolled substances. However, if a pharmacy employs a computer application for prescriptions that permits identification by prescription number and retrieval of original documents by prescriber name, patient's name, drug dispensed, and date filled, then the requirement to mark the hard copy prescription with a red "C" is waived.

(5) Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of part 1311 of this chapter. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the Administration or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

■ 6. Section 1304.06 is added to read as follows:

§ 1304.06 Records and reports for electronic prescriptions.

(a) As required by § 1311.120 of this chapter, a practitioner who issues electronic prescriptions for controlled substances must use an electronic prescription application that retains the following information:

(1) The digitally signed record of the information specified in part 1306 of this chapter.

(2) The internal audit trail and any auditable event identified by the internal audit as required by § 1311.150 of this chapter.

(b) An institutional practitioner must retain a record of identity proofing and issuance of the two-factor authentication credential, where applicable, as required by § 1311.110 of this chapter.

(c) As required by § 1311.205 of this chapter, a pharmacy that processes electronic prescriptions for controlled substances must use an application that retains the following:

(1) All of the information required under § 1304.22(c) and part 1306 of this chapter.

(2) The digitally signed record of the prescription as received as required by § 1311.210 of this chapter.

(3) The internal audit trail and any auditable event identified by the internal audit as required by § 1311.215 of this chapter.

(d) A registrant and application service provider must retain a copy of any security incident report filed with the Administration pursuant to §§ 1311.150 and 1311.215 of this chapter.

(e) An electronic prescription or pharmacy application provider must retain third party audit or certification reports as required by § 1311.300 of this chapter.

(f) An application provider must retain a copy of any notification to the

Administration regarding an adverse audit or certification report filed with the Administration on problems identified by the third-party audit or certification as required by § 1311.300 of this chapter.

(g) Unless otherwise specified, records and reports must be retained for two years.

PART 1306—PRESCRIPTIONS

■ 7. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 831, 871(b), unless otherwise noted.

■ 8. Section 1306.05 is revised to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

(b) A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the Administrator under § 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of § 1301.28(e) of this chapter.

(c) Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription.

(d) A practitioner may sign a paper prescription in the same manner as he would sign a check or legal document (*e.g.,* J.H. Smith or John H. Smith). Where an oral order is not permitted, paper prescriptions shall be written with ink or indelible pencil, typewriter, or printed on a computer printer and shall be manually signed by the practitioner. A computer-generated prescription that is printed out or faxed by the practitioner must be manually signed.

(e) Electronic prescriptions shall be created and signed using an application that meets the requirements of part 1311 of this chapter.

(f) A prescription may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

(g) An individual practitioner exempted from registration under § 1301.22(c) of this chapter shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in § 1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each paper prescription shall have the name of the practitioner stamped, typed, or handprinted on it, as well as the signature of the practitioner.

(h) An official exempted from registration under § 1301.23(a) of this chapter must include on all prescriptions issued by him his branch of service or agency (*e.g.,* "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each paper prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.

■ 9. Section 1306.08 is added to read as follows:

§ 1306.08 Electronic prescriptions.

(a) An individual practitioner may sign and transmit electronic prescriptions for controlled substances provided the practitioner meets all of the following requirements:

(1) The practitioner must comply with all other requirements for issuing controlled substance prescriptions in this part;

(2) The practitioner must use an application that meets the requirements of part 1311 of this chapter; and

(3) The practitioner must comply with the requirements for practitioners in part 1311 of this chapter.

(b) A pharmacy may fill an electronically transmitted prescription for a controlled substance provided the pharmacy complies with all other requirements for filling controlled substance prescriptions in this part and with the requirements of part 1311 of this chapter.

(c) To annotate an electronic prescription, a pharmacist must include all of the information that this part requires in the prescription record.

(d) If the content of any of the information required under § 1306.05 for a controlled substance prescription is altered during the transmission, the prescription is deemed to be invalid and the pharmacy may not dispense the controlled substance.

■ 10. In § 1306.11, paragraphs (a), (c), (d)(1), and (d)(4) are revised to read as follows:

§ 1306.11 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule II that is a prescription drug as determined under section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to a written prescription signed by the practitioner, except as provided in paragraph (d) of this section. A paper prescription for a Schedule II controlled substance may be transmitted by the practitioner or the practitioner's agent to a pharmacy via facsimile equipment, provided that the original manually signed prescription is presented to the pharmacist for review prior to the actual dispensing of the controlled substance, except as noted in paragraph (e), (f), or (g) of this section. The original prescription shall be maintained in accordance with § 1304.04(h) of this chapter.

* * * * *

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule II only pursuant to a written prescription signed by the prescribing individual practitioner or to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user.

(d) * * *

(1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner);

* * * * *

(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period.

Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

* * * * *

■ 11. In § 1306.13, paragraph (a) is revised to read as follows:

§ 1306.13 Partial filling of prescriptions.

(a) The partial filling of a prescription for a controlled substance listed in Schedule II is permissible if the pharmacist is unable to supply the full quantity called for in a written or emergency oral prescription and he makes a notation of the quantity supplied on the face of the written prescription, written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion of the prescription may be filled within 72 hours of the first partial filling; however, if the remaining portion is not or cannot be filled within the 72-hour period, the pharmacist shall notify the prescribing individual practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

* * * * *

■ 12. In § 1306.15, paragraph (a)(1) is revised to read as follows:

§ 1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.

* * * * *

(a) * * *

(1) Write the words "CENTRAL FILL" on the face of the original paper prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal. For electronic prescriptions the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record.

* * * * *

■ 13. In § 1306.21, paragraphs (a) and (c) are revised to read as follows:

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V that is a prescription drug as determined under section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(b)) only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the practitioner.

* * * * *

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III, IV, or V only pursuant to a paper prescription signed by an individual practitioner, a facsimile of a paper prescription or order for medication transmitted by the practitioner or the practitioner's agent to the institutional practitioner-pharmacist, an electronic prescription that meets the requirements of this part and part 1311 of this chapter, or an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1306.05 except for the signature of the individual practitioner), or pursuant to an order for medication made by an individual practitioner that is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

■ 14. Section 1306.22 is revised to read as follows:

§ 1306.22 Refilling of prescriptions.

(a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued. No prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times.

(b) Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document or electronic prescription record. If entered on another document, such as a medication record, or electronic prescription record, the document or record must be uniformly maintained and readily retrievable.

(c) The following information must be retrievable by the prescription number:

(1) The name and dosage form of the controlled substance.

(2) The date filled or refilled.

(3) The quantity dispensed.

(4) The initials of the dispensing pharmacist for each refill.

(5) The total number of refills for that prescription.

(d) If the pharmacist merely initials and dates the back of the prescription or annotates the electronic prescription record, it shall be deemed that the full face amount of the prescription has been dispensed.

(e) The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:

(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.

(2) The pharmacist obtaining the oral authorization records on the reverse of the original paper prescription or annotates the electronic prescription record with the date, quantity of refill, number of additional refills authorized, and initials the paper prescription or annotates the electronic prescription record showing who received the authorization from the prescribing practitioner who issued the original prescription.

(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

(4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five-refill, six-month limitation.

(f) As an alternative to the procedures provided by paragraphs (a) through (e) of this section, a computer application may be used for the storage and retrieval of refill information for original paper prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(1) Any such proposed computerized application must provide online retrieval (via computer monitor or hard-copy printout) of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number; date of issuance of

the original prescription order by the practitioner; full name and address of the patient; name, address, and DEA registration number of the practitioner; and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(2) Any such proposed computerized application must also provide online retrieval (via computer monitor or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

(3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original paper, fax, or oral prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes use of such an application. If such an application provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated are correct and then sign this document in the same manner as he would sign a check or legal document (*e.g.,* J.H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized application within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such an application for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized application shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized application employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Diversion Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its application by documentation (*e.g.,* postmark).

(5) In the event that a pharmacy which employs such a computerized application experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must ensure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again.

(g) When filing refill information for original paper, fax, or oral prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two applications described in paragraphs (a) through (e) or (f) of this section.

(h) When filing refill information for electronic prescriptions, a pharmacy must use an application that meets the requirements of part 1311 of this chapter.

■ 15. Section 1306.25 is revised to read as follows:

§ 1306.25 Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes.

(a) The transfer of original prescription information for a controlled substance listed in Schedule III, IV, or V for the purpose of refill dispensing is permissible between pharmacies on a one-time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

(b) Transfers are subject to the following requirements:

(1) The transfer must be communicated directly between two licensed pharmacists.

(2) The transferring pharmacist must do the following:

(i) Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.

(ii) Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.

(iii) Record the date of the transfer and the name of the pharmacist transferring the information.

(3) For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist pursuant to § 1306.21(a), the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to be on a prescription pursuant to § 1306.05 and include:

(i) Date of issuance of original prescription.

(ii) Original number of refills authorized on original prescription.

(iii) Date of original dispensing.

(iv) Number of valid refills remaining and date(s) and locations of previous refill(s).

(v) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.

(vi) Name of pharmacist who transferred the prescription.

(vii) Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

(4) For electronic prescriptions being transferred electronically, the

transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

(i) The date of the original dispensing.

(ii) The number of refills remaining and the date(s) and locations of previous refills.

(iii) The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.

(iv) The name of the pharmacist transferring the prescription.

(v) The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

(5) The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription under paragraph (b)(4) of this section.

(c) The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

(d) Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.

(e) The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

PART 1311—REQUIREMENTS FOR ELECTRONIC ORDERS AND PRESCRIPTIONS

■ 16. The authority citation for part 1311 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 829, 871(b), 958(e), 965, unless otherwise noted.

■ 17. The heading for part 1311 is revised to read as set forth above.

■ 18. Section 1311.01 is revised to read as follows:

§ 1311.01 Scope.

This part sets forth the rules governing the creation, transmission, and storage of electronic orders and prescriptions.

■ 19. Section 1311.02 is revised to read as follows:

§ 1311.02 Definitions.

Any term contained in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

■ 20. Section 1311.08 is revised to read as follows:

§ 1311.08 Incorporation by reference.

(a) These incorporations by reference were approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be inspected at the Drug Enforcement Administration, 600 Army Navy Drive, Arlington, VA 22202 or at the National Archives and Records Administration (NARA). For information on the availability of this material at the Drug Enforcement Administration, call (202) 307–1000. For information on the availability of this material at NARA, call (202) 741–6030 or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

(b) These standards are available from the National Institute of Standards and Technology, Computer Security Division, Information Technology Laboratory, National Institute of Standards and Technology, 100 Bureau Drive, Gaithersburg, MD 20899–8930, (301) 975–6478 or TTY (301) 975–8295, *inquiries@nist.gov*, and are available at *http://csrc.nist.gov/*. The following standards are incorporated by reference:

(1) Federal Information Processing Standard Publication (FIPS PUB) 140–2, Change Notices (12–03–2002), Security Requirements for Cryptographic Modules, May 25, 2001 (FIPS 140–2) including Annexes A through D; incorporation by reference approved for §§ 1311.30(b), 1311.55(b), 1311.115(b), 1311.120(b), 1311.205(b).

(i) *Annex A:* Approved Security Functions for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, September 23, 2004.

(ii) *Annex B:* Approved Protection Profiles for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, November 4, 2004.

(iii) *Annex C:* Approved Random Number Generators for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, January 31, 2005.

(iv) *Annex D:* Approved Key Establishment Techniques for FIPS PUB 140–2, Security Requirements for Cryptographic Modules, February 23, 2004.

(2) Federal Information Processing Standard Publication (FIPS PUB) 180–2, Secure Hash Standard, August 1, 2002, as amended by change notice 1, February 25, 2004 (FIPS 180–2); incorporation by reference approved for §§ 1311.30(b) and 1311.55(b).

(3) Federal Information Processing Standard Publication (FIPS PUB) 180–3, Secure Hash Standard (SHS), October 2008 (FIPS 180–3); incorporation by reference approved for §§ 1311.120(b) and 1311.205(b).

(4) Federal Information Processing Standard Publication (FIPS PUB) 186–2, Digital Signature Standard, January 27, 2000, as amended by Change Notice 1, October 5, 2001 (FIPS 186–2); incorporation by reference approved for §§ 1311.30(b) and 1311.55(b).

(5) Federal Information Processing Standard Publication (FIPS PUB) 186–3, Digital Signature Standard (DSS), June 2009 (FIPS 186–3); incorporation by reference approved for §§ 1311.120(b), 1311.205(b), and 1311.210(c).

(6) Draft NIST Special Publication 800–63–1, Electronic Authentication Guideline, December 8, 2008 (NIST SP 800–63–1); Burr, W. et al.; incorporation by reference approved for § 1311.105(a).

(7) NIST Special Publication 800–76–1, Biometric Data Specification for Personal Identity Verification, January 2007 (NIST SP 800–76–1); Wilson, C. et al.; incorporation by reference approved for § 1311.116(d).

■ 21. Subpart C, consisting of §§ 1311.100 through 1311.305, is added to read as follows:

Subpart C—Electronic Prescriptions

Sec.

1311.100 General.
1311.102 Practitioner responsibilities.
1311.105 Requirements for obtaining an authentication credential—Individual practitioners.
1311.110 Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner.
1311.115 Additional requirements for two-factor authentication.
1311.116 Additional requirements for biometrics.
1311.120 Electronic prescription application requirements.
1311.125 Requirements for establishing logical access control—Individual practitioner.
1311.130 Requirements for establishing logical access control—Institutional practitioner.
1311.135 Requirements for creating a controlled substance prescription.
1311.140 Requirements for signing a controlled substance prescription.
1311.145 Digitally signing the prescription with the individual practitioner's private key.
1311.150 Additional requirements for internal application audits.
1311.170 Transmission requirements.
1311.200 Pharmacy responsibilities.
1311.205 Pharmacy application requirements.
1311.210 Archiving the initial record.
1311.215 Internal audit trail.

1311.300 Application provider requirements—Third-party audits or certifications.
1311.302 Additional application provider requirements.
1311.305 Recordkeeping.

Subpart C—Electronic Prescriptions

§ 1311.100 General.

(a) This subpart addresses the requirements that must be met to issue and process Schedule II, III, IV, and V controlled substance prescriptions electronically.

(b) A practitioner may issue a prescription for a Schedule II, III, IV, or V controlled substance electronically if all of the following conditions are met:

(1) The practitioner is registered as an individual practitioner or exempt from the requirement of registration under part 1301 of this chapter and is authorized under the registration or exemption to dispense the controlled substance;

(2) The practitioner uses an electronic prescription application that meets all of the applicable requirements of this subpart; and

(3) The prescription is otherwise in conformity with the requirements of the Act and this chapter.

(c) An electronic prescription for a Schedule II, III, IV, or V controlled substance created using an electronic prescription application that does not meet the requirements of this subpart is not a valid prescription, as that term is defined in § 1300.03 of this chapter.

(d) A controlled substance prescription created using an electronic prescription application that meets the requirements of this subpart is not a valid prescription if any of the functions required under this subpart were disabled when the prescription was indicated as ready for signature and signed.

(e) A registered pharmacy may process electronic prescriptions for controlled substances only if all of the following conditions are met:

(1) The pharmacy uses a pharmacy application that meets all of the applicable requirements of this subpart; and

(2) The prescription is otherwise in conformity with the requirements of the Act and this chapter.

(f) Nothing in this part alters the responsibilities of the practitioner and pharmacy, specified in part 1306 of this chapter, to ensure the validity of a controlled substance prescription.

§ 1311.102 Practitioner responsibilities.

(a) The practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. Failure by the practitioner to secure the hard token, knowledge factor, or biometric information may provide a basis for revocation or suspension of registration pursuant to section 304(a)(4) of the Act (21 U.S.C. 824(a)(4)).

(b) The practitioner must notify the individuals designated under § 1311.125 or § 1311.130 within one business day of discovery that the hard token has been lost, stolen, or compromised or the authentication protocol has been otherwise compromised. A practitioner who fails to comply with this provision may be held responsible for any controlled substance prescriptions written using his two-factor authentication credential.

(c) If the practitioner is notified by an intermediary or pharmacy that an electronic prescription was not successfully delivered, as provided in § 1311.170, he must ensure that any paper or oral prescription (where permitted) issued as a replacement of the original electronic prescription indicates that the prescription was originally transmitted electronically to a particular pharmacy and that the transmission failed.

(d) Before initially using an electronic prescription application to sign and transmit controlled substance prescriptions, the practitioner must determine that the third-party auditor or certification organization has found that the electronic prescription application records, stores, and transmits the following accurately and consistently:

(1) The information required for a prescription under § 1306.05(a) of this chapter.

(2) The indication of signing as required by § 1311.120(b)(17) or the digital signature created by the practitioner's private key.

(3) The number of refills as required by § 1306.22 of this chapter.

(e) If the third-party auditor or certification organization has found that an electronic prescription application does not accurately and consistently record, store, and transmit other information required for prescriptions under this chapter, the practitioner must not create, sign, and transmit electronic prescriptions for controlled substances that are subject to the additional information requirements.

(f) The practitioner must not use the electronic prescription application to sign and transmit electronic controlled substance prescriptions if any of the functions of the application required by this subpart have been disabled or appear to be functioning improperly.

(g) If an electronic prescription application provider notifies an individual practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies him that the application provider has identified an issue that makes the application non-compliant, the practitioner must do the following:

(1) Immediately cease to issue electronic controlled substance prescriptions using the application.

(2) Ensure, for an installed electronic prescription application at an individual practitioner's practice, that the individuals designated under § 1311.125 terminate access for signing controlled substance prescriptions.

(h) If an electronic prescription application provider notifies an institutional practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies it that the application provider has identified an issue that makes the application non-compliant, the institutional practitioner must ensure that the individuals designated under § 1311.130 terminate access for signing controlled substance prescriptions.

(i) An individual practitioner or institutional practitioner that receives a notification that the electronic prescription application is not in compliance with the requirements of this part must not use the application to issue electronic controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.

(j) The practitioner must notify both the individuals designated under § 1311.125 or § 1311.130 and the Administration within one business day of discovery that one or more prescriptions that were issued under a DEA registration held by that practitioner were prescriptions the practitioner had not signed or were not consistent with the prescriptions he signed.

(k) The practitioner has the same responsibilities when issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription. Nothing in this subpart relieves a practitioner of his responsibility to dispense controlled substances only for a legitimate medical purpose while acting in the usual course

of his professional practice. If an agent enters information at the practitioner's direction prior to the practitioner reviewing and approving the information and signing and authorizing the transmission of that information, the practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.

§ 1311.105 Requirements for obtaining an authentication credential—Individual practitioners.

(a) An individual practitioner must obtain a two-factor authentication credential from one of the following:

(1) A credential service provider that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets the requirements of Assurance Level 3 or above as specified in NIST SP 800–63–1 as incorporated by reference in § 1311.08.

(2) For digital certificates, a certification authority that is cross-certified with the Federal Bridge certification authority and that operates at a Federal Bridge Certification Authority basic assurance level or above.

(b) The practitioner must submit identity proofing information to the credential service provider or certification authority as specified by the credential service provider or certification authority.

(c) The credential service provider or certification authority must issue the authentication credential using two channels (*e.g.,* e-mail, mail, or telephone call). If one of the factors used in the authentication protocol is a biometric, or if the practitioner has a hard token that is being enabled to sign controlled substances prescriptions, the credential service provider or certification authority must issue two pieces of information used to generate or activate the authentication credential using two channels.

§ 1311.110 Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner.

(a) For any registrant or person exempted from the requirement of registration under § 1301.22(c) of this chapter who is eligible to use the institutional practitioner's electronic prescription application to sign prescriptions for controlled substances, the entity within a DEA-registered institutional practitioner that grants that individual practitioner privileges at the institutional practitioner (*e.g.,* a hospital credentialing office) may conduct identity proofing and authorize the issuance of the authentication credential. That entity must do the following:

(1) Ensure that photographic identification issued by the Federal Government or a State government matches the person presenting the identification.

(2) Ensure that the individual practitioner's State authorization to practice and, where applicable, State authorization to prescribe controlled substances, is current and in good standing.

(3) Either ensure that the individual practitioner's DEA registration is current and in good standing or ensure that the institutional practitioner has granted the individual practitioner exempt from the requirement of registration under § 1301.22 of this chapter privileges to prescribe controlled substances using the institutional practitioner's DEA registration number.

(4) If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of Veterans Affairs pursuant to 38 U.S.C. 7401–7408.

(5) If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, confirm that the individual practitioner meets the criteria for eligibility for appointment under 38 U.S.C. 7401–7408 and is prescribing controlled substances under the registration of such facility.

(b) An institutional practitioner that elects to conduct identity proofing must provide authorization to issue the authentication credentials to a separate entity within the institutional practitioner or to an outside credential Service provider or certification authority that meets the requirements of § 1311.105(a).

(c) When an institutional practitioner is conducting identity proofing and submitting information to a credential service provider or certification authority to authorize the issuance of authentication credentials, the institutional practitioner must meet any requirements that the credential service provider or certification authority imposes on entities that serve as trusted agents.

(d) An institutional practitioner that elects to conduct identity proofing and authorize the issuance of the authentication credential as provided in paragraphs (a) through (c) of this section must do so in a manner consistent with the institutional practitioner's general obligation to maintain effective controls against diversion. Failure to meet this obligation may result in remedial action consistent with § 1301.36 of this chapter.

(e) An institutional practitioner that elects to conduct identity proofing must retain a record of the identity-proofing. An institutional practitioner that elects to issue the two-factor authentication credential must retain a record of the issuance of the credential.

§ 1311.115 Additional requirements for two-factor authentication.

(a) To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors:

(1) Something only the practitioner knows, such as a password or response to a challenge question.

(2) Something the practitioner is, biometric data such as a fingerprint or iris scan.

(3) Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.

(b) If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140–2 Security Level 1, as incorporated by reference in § 1311.08, for cryptographic modules or one-time-password devices.

(c) If one factor is a biometric, the biometric subsystem must comply with the requirements of § 1311.116.

§ 1311.116 Additional requirements for biometrics.

(a) If one of the factors used to authenticate to the electronic prescription application is a biometric as described in § 1311.115, it must comply with the following requirements.

(b) The biometric subsystem must operate at a false match rate of 0.001 or lower.

(c) The biometric subsystem must use matching software that has demonstrated performance at the operating point corresponding with the false match rate described in paragraph (b) of this section, or a lower false match rate. Testing to demonstrate performance must be conducted by the National Institute of Standards and Technology or another DEA-approved

government or nongovernment laboratory. Such testing must comply with the requirements of paragraph (h) of this section.

(d) The biometric subsystem must conform to Personal Identity Verification authentication biometric acquisition specifications, pursuant to NIST SP 800–76–1 as incorporated by reference in § 1311.08, if they exist for the biometric modality of choice.

(e) The biometric subsystem must either be co-located with a computer or PDA that the practitioner uses to issue electronic prescriptions for controlled substances, where the computer or PDA is located in a known, controlled location, or be built directly into the practitioner's computer or PDA that he uses to issue electronic prescriptions for controlled substances.

(f) The biometric subsystem must store device ID data at enrollment (i.e., biometric registration) with the biometric data and verify the device ID at the time of authentication to the electronic prescription application.

(g) The biometric subsystem must protect the biometric data (raw data or templates), match results, and/or non-match results when authentication is not local. If sent over an open network, biometric data (raw data or templates), match results, and/or non-match results must be:

(1) Cryptographically source authenticated;

(2) Combined with a random challenge, a nonce, or a time stamp to prevent replay;

(3) Cryptographically protected for integrity and confidentiality; and

(4) Sent only to authorized systems.

(h) Testing of the biometric subsystem must have the following characteristics:

(1) The test is conducted by a laboratory that does not have an interest in the outcome (positive or negative) of performance of a submission or biometric.

(2) Test data are sequestered.

(3) Algorithms are provided to the testing laboratory (as opposed to scores or other information).

(4) The operating point(s) corresponding with the false match rate described in paragraph (b) of this section, or a lower false match rate, is tested so that there is at least 95% confidence that the false match and non-match rates are equal to or less than the observed value.

(5) Results of the testing are made publicly available.

§ 1311.120 Electronic prescription application requirements.

(a) A practitioner may only use an electronic prescription application that meets the requirements in paragraph (b) of this section to issue electronic controlled substance prescriptions.

(b) The electronic prescription application must meet the requirements of this subpart including the following:

(1) The electronic prescription application must do the following:

(i) Link each registrant, by name, to at least one DEA registration number.

(ii) Link each practitioner exempt from registration under § 1301.22(c) of this chapter to the institutional practitioner's DEA registration number and the specific internal code number required under § 1301.22(c)(5) of this chapter.

(2) The electronic prescription application must be capable of the setting of logical access controls to limit permissions for the following functions:

(i) Indication that a prescription is ready for signing and signing controlled substance prescriptions.

(ii) Creating, updating, and executing the logical access controls for the functions specified in paragraph (b)(2)(i) of this section.

(3) Logical access controls must be set by individual user name or role. If the application sets logical access control by role, it must not allow an individual to be assigned the role of registrant unless that individual is linked to at least one DEA registration number as provided in paragraph (b)(1) of this section.

(4) The application must require that the setting and changing of logical access controls specified under paragraph (b)(2) of this section involve the actions of two individuals as specified in §§ 1311.125 or 1311.130. Except for institutional practitioners, a practitioner authorized to sign controlled substance prescriptions must approve logical access control entries.

(5) The electronic prescription application must accept two-factor authentication that meets the requirements of § 1311.115 and require its use for signing controlled substance prescriptions and for approving data that set or change logical access controls related to reviewing and signing controlled substance prescriptions.

(6) The electronic prescription application must be capable of recording all of the applicable information required in part 1306 of this chapter for the controlled substance prescription.

(7) If a practitioner has more than one DEA registration number, the electronic prescription application must require the practitioner or his agent to select the DEA registration number to be included on the prescription.

(8) The electronic prescription application must have a time application that is within five minutes of the official National Institute of Standards and Technology time source.

(9) The electronic prescription application must present for the practitioner's review and approval all of the following data for each controlled substance prescription:

(i) The date of issuance.

(ii) The full name of the patient.

(iii) The drug name.

(iv) The dosage strength and form, quantity prescribed, and directions for use.

(v) The number of refills authorized, if applicable, for prescriptions for Schedule III, IV, and V controlled substances.

(vi) For prescriptions written in accordance with the requirements of § 1306.12(b) of this chapter, the earliest date on which a pharmacy may fill each prescription.

(vii) The name, address, and DEA registration number of the prescribing practitioner.

(viii) The statement required under § 1311.140(a)(3).

(10) The electronic prescription application must require the prescribing practitioner to indicate that each controlled substance prescription is ready for signing. The electronic prescription application must not permit alteration of the DEA elements after the practitioner has indicated that a controlled substance prescription is ready to be signed without requiring another review and indication of readiness for signing. Any controlled substance prescription not indicated as ready to be signed shall not be signed or transmitted.

(11) While the information required by paragraph (b)(9) of this section and the statement required by § 1311.140(a)(3) remain displayed, the electronic prescription application must prompt the prescribing practitioner to authenticate to the application, using two-factor authentication, as specified in § 1311.140(a)(4), which will constitute the signing of the prescription by the practitioner for purposes of § 1306.05(a) and (e) of this chapter.

(12) The electronic prescription application must not permit a practitioner other than the prescribing practitioner whose DEA number (or institutional practitioner DEA number and extension data for the individual practitioner) is listed on the prescription as the prescribing practitioner and who has indicated that the prescription is ready to be signed to sign the prescription.

(13) Where a practitioner seeks to prescribe more than one controlled substance at one time for a particular

patient, the electronic prescription application may allow the practitioner to sign multiple prescriptions for a single patient at one time using a single invocation of the two-factor authentication protocol provided the following has occurred: The practitioner has individually indicated that each controlled substance prescription is ready to be signed while the information required by paragraph (b)(9) of this section for each such prescription is displayed along with the statement required by § 1311.140(a)(3).

(14) The electronic prescription application must time and date stamp the prescription when the signing function is used.

(15) When the practitioner uses his two-factor authentication credential as specified in § 1311.140(a)(4), the electronic prescription application must digitally sign at least the information required by part 1306 of this chapter and electronically archive the digitally signed record. If the practitioner signs the prescription with his own private key, as provided in § 1311.145, the electronic prescription application must electronically archive a copy of the digitally signed record, but need not apply the application's digital signature to the record.

(16) The digital signature functionality must meet the following requirements:

(i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter must be at least FIPS 140–2 Security Level 1 validated. FIPS 140–2 is incorporated by reference in § 1311.08.

(ii) The digital signature application and hash function must comply with FIPS 186–3 and FIPS 180–3, as incorporated by reference in § 1311.08.

(iii) The electronic prescription application's private key must be stored encrypted on a FIPS 140–2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm. FIPS 140–2 is incorporated by reference in § 1311.08.

(iv) For software implementations, when the signing module is deactivated, the application must clear the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key.

(17) Unless the digital signature created by an individual practitioner's private key is being transmitted to the pharmacy with the prescription, the electronic prescription application must include in the data file transmitted an indication that the prescription was signed by the prescribing practitioner.

(18) The electronic prescription application must not transmit a controlled substance prescription unless the signing function described in § 1311.140(a)(4) has been used.

(19) The electronic prescription application must not allow alteration of any of the information required by part 1306 of this chapter after the prescription has been digitally signed. Any alteration of the information required by part 1306 of this chapter after the prescription is digitally signed must cancel the prescription.

(20) The electronic prescription application must not allow transmission of a prescription that has been printed.

(21) The electronic prescription application must allow printing of a prescription after transmission only if the printed prescription is clearly labeled as a copy not for dispensing. The electronic prescription application may allow printing of prescription information if clearly labeled as being for informational purposes. The electronic prescription application may transfer such prescription information to medical records.

(22) If the transmission of an electronic prescription fails, the electronic prescription application may print the prescription. The prescription must indicate that it was originally transmitted electronically to, and provide the name of, a specific pharmacy, the date and time of transmission, and that the electronic transmission failed.

(23) The electronic prescription application must maintain an audit trail of all actions related to the following:

(i) The creation, alteration, indication of readiness for signing, signing, transmission, or deletion of a controlled substance prescription.

(ii) Any setting or changing of logical access control permissions related to the issuance of controlled substance prescriptions.

(iii) Notification of a failed transmission.

(iv) Auditable events as specified in § 1311.150.

(24) The electronic prescription application must record within each audit record the following information:

(i) The date and time of the event.

(ii) The type of event.

(iii) The identity of the person taking the action, where applicable.

(iv) The outcome of the event (success or failure).

(25) The electronic prescription application must conduct internal audits and generate reports on any of the events specified in § 1311.150 in a format that is readable by the practitioner. Such internal audits may be automated and need not require human intervention to be conducted.

(26) The electronic prescription application must protect the stored audit records from unauthorized deletion. The electronic prescription application shall prevent modifications to the audit records.

(27) The electronic prescription application must do the following:

(i) Generate a log of all controlled substance prescriptions issued by a practitioner during the previous calendar month and provide the log to the practitioner no later than seven calendar days after that month.

(ii) Be capable of generating a log of all controlled substance prescriptions issued by a practitioner for a period specified by the practitioner upon request. Prescription information available from which to generate the log must span at least the previous two years.

(iii) Archive all logs generated.

(iv) Ensure that all logs are easily readable or easily rendered into a format that a person can read.

(v) Ensure that all logs are sortable by patient name, drug name, and date of issuance of the prescription.

(28) Where the electronic prescription application is required by this part to archive or otherwise maintain records, it must retain such records electronically for two years from the date of the record's creation and comply with all other requirements of § 1311.305.

§ 1311.125 Requirements for establishing logical access control—Individual practitioner.

(a) At each registered location where one or more individual practitioners wish to use an electronic prescription application meeting the requirements of this subpart to issue controlled substance prescriptions, the registrant(s) must designate at least two individuals to manage access control to the application. At least one of the designated individuals must be a registrant who is authorized to issue controlled substance prescriptions and who has obtained a two-factor authentication credential as provided in § 1311.105.

(b) At least one of the individuals designated under paragraph (a) of this section must verify that the DEA registration and State authorization(s) to practice and, where applicable, State authorization(s) to dispense controlled substances of each registrant being granted permission to sign electronic prescriptions for controlled substances are current and in good standing.

(c) After one individual designated under paragraph (a) of this section

enters data that grants permission for individual practitioners to have access to the prescription functions that indicate readiness for signature and signing or revokes such authorization, a second individual designated under paragraph (a) of this section must use his two-factor authentication credential to satisfy the logical access controls. The second individual must be a DEA registrant.

(d) A registrant's permission to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date the occurrence is discovered:

(1) A hard token or any other authentication factor required by the two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.

(2) The individual practitioner's DEA registration expires, unless the registration has been renewed.

(3) The individual practitioner's DEA registration is terminated, revoked, or suspended.

(4) The individual practitioner is no longer authorized to use the electronic prescription application (*e.g.,* when the individual practitioner leaves the practice).

§ 1311.130 Requirements for establishing logical access control—Institutional practitioner.

(a) The entity within an institutional practitioner that conducts the identity proofing under § 1311.110 must develop a list of individual practitioners who are permitted to use the institutional practitioner's electronic prescription application to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions. The list must be approved by two individuals.

(b) After the list is approved, it must be sent to a separate entity within the institutional practitioner that enters permissions for logical access controls into the application. The institutional practitioner must authorize at least two individuals or a role filled by at least two individuals to enter the logical access control data. One individual in the separate entity must authenticate to the application and enter the data to grant permissions to individual practitioners to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions. A second individual must authenticate to the application to execute the logical access controls.

(c) The institutional practitioner must retain a record of the individuals or roles that are authorized to conduct identity proofing and logical access control data entry and execution.

(d) Permission to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date the occurrence is discovered:

(1) An individual practitioner's hard token or any other authentication factor required by the practitioner's two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.

(2) The institutional practitioner's or, where applicable, individual practitioner's DEA registration expires, unless the registration has been renewed.

(3) The institutional practitioner's or, where applicable, individual practitioner's DEA registration is terminated, revoked, or suspended.

(4) An individual practitioner is no longer authorized to use the institutional practitioner's electronic prescription application (*e.g.,* when the individual practitioner is no longer associated with the institutional practitioner.)

§ 1311.135 Requirements for creating a controlled substance prescription.

(a) The electronic prescription application may allow the registrant or his agent to enter data for a controlled substance prescription, provided that only the registrant may sign the prescription in accordance with §§ 1311.120(b)(11) and 1311.140.

(b) If a practitioner holds multiple DEA registrations, the practitioner or his agent must select the appropriate registration number for the prescription being issued in accordance with the requirements of § 1301.12 of this chapter.

(c) If required by State law, a supervisor's name and DEA number may be listed on a prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

§ 1311.140 Requirements for signing a controlled substance prescription.

(a) For a practitioner to sign an electronic prescription for a controlled substance the following must occur:

(1) The practitioner must access a list of one or more controlled substance prescriptions for a single patient. The list must display the information required by § 1311.120(b)(9).

(2) The practitioner must indicate the prescriptions that are ready to be signed.

(3) While the prescription information required in § 1311.120(b)(9) is displayed, the following statement or its substantial equivalent is displayed: "By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above."

(4) While the prescription information required in § 1311.120(b)(9) and the statement required by paragraph (a)(3) of this section remain displayed, the practitioner must be prompted to complete the two-factor authentication protocol.

(5) The completion by the practitioner of the two-factor authentication protocol in the manner provided in paragraph (a)(4) of this section will constitute the signing of the prescription by the practitioner for purposes of § 1306.05(a) and (e) of this chapter.

(6) Except as provided under § 1311.145, the practitioner's completion of the two-factor authentication protocol must cause the application to digitally sign and electronically archive the information required under part 1306 of this chapter.

(b) The electronic prescription application must clearly label as the signing function the function that prompts the practitioner to execute the two-factor authentication protocol using his credential.

(c) Any prescription not signed in the manner required by this section shall not be transmitted.

§ 1311.145 Digitally signing the prescription with the individual practitioner's private key.

(a) An individual practitioner who has obtained a digital certificate as provided in § 1311.105 may digitally sign a controlled substance prescription using the private key associated with his digital certificate.

(b) The electronic prescription application must require the individual practitioner to complete a two-factor authentication protocol as specified in § 1311.140(a)(4) to use his private key.

(c) The electronic prescription application must digitally sign at least all information required under part 1306 of this chapter.

(d) The electronic prescription application must electronically archive the digitally signed record.

(e) A prescription that is digitally signed with a practitioner's private key

may be transmitted to a pharmacy without the digital signature.

(f) If the electronic prescription is transmitted without the digital signature, the electronic prescription application must check the certificate revocation list of the certification authority that issued the practitioner's digital certificate. If the digital certificate is not valid, the electronic prescription application must not transmit the prescription. The certificate revocation list may be cached until the certification authority issues a new certificate revocation list.

(g) When the individual practitioner digitally signs a controlled substance prescription with the private key associated with his own digital certificate obtained as provided under § 1311.105, the electronic prescription application is not required to digitally sign the prescription using the application's private key.

§ 1311.150 Additional requirements for internal application audits.

(a) The application provider must establish and implement a list of auditable events. Auditable events must, at a minimum, include the following:

(1) Attempted unauthorized access to the electronic prescription application, or successful unauthorized access where the determination of such is feasible.

(2) Attempted unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any information or records required by this part where the determination of such is feasible.

(3) Interference with application operations of the prescription application.

(4) Any setting of or change to logical access controls related to the issuance of controlled substance prescriptions.

(5) Attempted or successful interference with audit trail functions.

(6) For application service providers, attempted or successful creation, modification, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider.

(b) The electronic prescription application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event.

(c) Any person designated to set logical access controls under §§ 1311.125 or 1311.130 must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the electronic prescription application provider and the Administration within one business day.

§ 1311.170 Transmission requirements.

(a) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner.

(b) The electronic prescription application may print a prescription that has been transmitted only if an intermediary or the designated pharmacy notifies a practitioner that an electronic prescription was not successfully delivered to the designated pharmacy. If this occurs, the electronic prescription application may print the prescription for the practitioner's manual signature. The printed prescription must include information noting that the prescription was originally transmitted electronically to [name of the specific pharmacy] on [date/time] and that transmission failed.

(c) The electronic prescription application may print copies of the transmitted prescription if they are clearly labeled: "Copy only—not valid for dispensing." Data on the prescription may be electronically transferred to medical records, and a list of prescriptions written may be printed for patients if the list indicates that it is for informational purposes only and not for dispensing.

(d) The electronic prescription application must not allow the transmission of an electronic prescription if an original prescription was printed prior to attempted transmission.

(e) The contents of the prescription required by part 1306 of this chapter must not be altered during transmission between the practitioner and pharmacy. Any change to the content during transmission, including truncation or removal of data, will render the electronic prescription invalid. The electronic prescription data may be converted from one software version to another between the electronic prescription application and the pharmacy application; conversion includes altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data.

(f) An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (*e.g.,* facsimile) for transmission.

§ 1311.200 Pharmacy responsibilities.

(a) Before initially using a pharmacy application to process controlled substance prescriptions, the pharmacy must determine that the third-party auditor or certification organization has found that the pharmacy application does the following accurately and consistently:

(1) Import, store, and display the information required for prescriptions under § 1306.05(a) of this chapter.

(2) Import, store, and display the indication of signing as required by § 1311.120(b)(17).

(3) Import, store, and display the number of refills as required by § 1306.22 of this chapter.

(4) Import, store, and verify the practitioner's digital signature, as provided in § 1311.210(c), where applicable.

(b) If the third-party auditor or certification organization has found that a pharmacy application does not accurately and consistently import, store, and display other information required for prescriptions under this chapter, the pharmacy must not process electronic prescriptions for controlled substances that are subject to the additional information requirements.

(c) If a pharmacy application provider notifies a pharmacy that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies it that the application provider has identified an issue that makes the application non-compliant, the pharmacy must immediately cease to process controlled substance prescriptions using the application.

(d) A pharmacy that receives a notification that the pharmacy application is not in compliance with the requirements of this part must not use the application to process controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.

(e) The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions (to the extent such alterations are permitted under this chapter). The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions.

(f) When a pharmacist fills a prescription in a manner that would require, under part 1306 of this chapter, the pharmacist to make a notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or in linked files. When a prescription is received electronically, the prescription and all required annotations must be retained electronically.

(g) When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist must check its records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.

(h) When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy must mark the electronic version as void or canceled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

(i) Nothing in this part relieves a pharmacy and pharmacist of the responsibility to dispense controlled substances only pursuant to a prescription issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice.

§ 1311.205 Pharmacy application requirements.

(a) The pharmacy may only use a pharmacy application that meets the requirements in paragraph (b) of this section to process electronic controlled substance prescriptions.

(b) The pharmacy application must meet the following requirements:

(1) The pharmacy application must be capable of setting logical access controls to limit access for the following functions:

(i) Annotation, alteration, or deletion of prescription information.

(ii) Setting and changing the logical access controls.

(2) Logical access controls must be set by individual user name or role.

(3) The pharmacy application must digitally sign and archive a prescription on receipt or be capable of receiving and archiving a digitally signed record.

(4) For pharmacy applications that digitally sign prescription records upon receipt, the digital signature functionality must meet the following requirements:

(i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter must be at least FIPS 140–2 Security Level 1 validated. FIPS 140–2 is incorporated by reference in § 1311.08.

(ii) The digital signature application and hash function must comply with FIPS 186–3 and FIPS 180–3, as incorporated by reference in § 1311.08.

(iii) The pharmacy application's private key must be stored encrypted on a FIPS 140–2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm. FIPS 140–2 is incorporated by reference in § 1311.08.

(iv) For software implementations, when the signing module is deactivated, the pharmacy application must clear the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key.

(v) The pharmacy application must have a time application that is within five minutes of the official National Institute of Standards and Technology time source.

(5) The pharmacy application must verify a practitioner's digital signature (if the pharmacy application accepts prescriptions that were digitally signed with an individual practitioner's private key and transmitted with the digital signature).

(6) If the prescription received by the pharmacy application has not been digitally signed by the practitioner and transmitted with the digital signature, the pharmacy application must either:

(i) Verify that the practitioner signed the prescription by checking the data field that indicates the prescription was signed; or

(ii) Display the field for the pharmacist's verification.

(7) The pharmacy application must read and retain the full DEA number including the specific internal code number assigned to individual practitioners authorized to prescribe controlled substances by the hospital or other institution as provided in § 1301.22(c) of this chapter.

(8) The pharmacy application must read and store, and be capable of displaying, all information required by part 1306 of this chapter.

(9) The pharmacy application must read and store in full the information required under § 1306.05(a) of this chapter. The pharmacy application must either verify that such information is present or must display the information for the pharmacist's verification.

(10) The pharmacy application must provide for the following information to be added or linked to each electronic controlled substance prescription record for each dispensing:

(i) Number of units or volume of drug dispensed.

(ii) Date dispensed.

(iii) Name or initials of the person who dispensed the prescription.

(11) The pharmacy application must be capable of retrieving controlled substance prescriptions by practitioner name, patient name, drug name, and date dispensed.

(12) The pharmacy application must allow downloading of prescription data into a database or spreadsheet that is readable and sortable.

(13) The pharmacy application must maintain an audit trail of all actions related to the following:

(i) The receipt, annotation, alteration, or deletion of a controlled substance prescription.

(ii) Any setting or changing of logical access control permissions related to the dispensing of controlled substance prescriptions.

(iii) Auditable events as specified in § 1311.215.

(14) The pharmacy application must record within each audit record the following information:

(i) The date and time of the event.

(ii) The type of event.

(iii) The identity of the person taking the action, where applicable.

(iv) The outcome of the event (success or failure).

(15) The pharmacy application must conduct internal audits and generate reports on any of the events specified in § 1311.215 in a format that is readable by the pharmacist. Such an internal audit may be automated and need not require human intervention to be conducted.

(16) The pharmacy application must protect the stored audit records from unauthorized deletion. The pharmacy application shall prevent modifications to the audit records.

(17) The pharmacy application must back up the controlled substance prescription records daily.

(18) The pharmacy application must retain all archived records electronically for at least two years from the date of their receipt or creation and comply

with all other requirements of § 1311.305.

§ 1311.210 Archiving the initial record.

(a) Except as provided in paragraph (c) of this section, a copy of each electronic controlled substance prescription record that a pharmacy receives must be digitally signed by one of the following:

(1) The last intermediary transmitting the record to the pharmacy must digitally sign the prescription immediately prior to transmission to the pharmacy.

(2) The first pharmacy application that receives the electronic prescription must digitally sign the prescription immediately on receipt.

(b) If the last intermediary digitally signs the record, it must forward the digitally signed copy to the pharmacy.

(c) If a pharmacy receives a digitally signed prescription that includes the individual practitioner's digital signature, the pharmacy application must do the following:

(1) Verify the digital signature as provided in FIPS 186–3, as incorporated by reference in § 1311.08.

(2) Check the validity of the certificate holder's digital certificate by checking the certificate revocation list. The pharmacy may cache the CRL until it expires.

(3) Archive the digitally signed record. The pharmacy record must retain an indication that the prescription was verified upon receipt. No additional digital signature is required.

§ 1311.215 Internal audit trail.

(a) The pharmacy application provider must establish and implement a list of auditable events. The auditable events must, at a minimum, include the following:

(1) Attempted unauthorized access to the pharmacy application, or successful unauthorized access to the pharmacy application where the determination of such is feasible.

(2) Attempted or successful unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any information or records required by this part where the determination of such is feasible.

(3) Interference with application operations of the pharmacy application.

(4) Any setting of or change to logical access controls related to the dispensing of controlled substance prescriptions.

(5) Attempted or successful interference with audit trail functions.

(6) For application service providers, attempted or successful annotation, alteration, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider.

(b) The pharmacy application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event.

(c) The pharmacy must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the pharmacy application service provider, if applicable, and the Administration within one business day.

§ 1311.300 Application provider requirements—Third-party audits or certifications.

(a) Except as provided in paragraph (e) of this section, the application provider of an electronic prescription application or a pharmacy application must have a third-party audit of the application that determines that the application meets the requirements of this part at each of the following times:

(1) Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.

(2) Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

(b) The third-party audit must be conducted by one of the following:

(1) A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.

(2) A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.

(c) An audit for installed applications must address processing integrity and determine that the application meets the requirements of this part.

(d) An audit for application service providers must address processing integrity and physical security and determine that the application meets the requirements of this part.

(e) If a certifying organization whose certification process has been approved by DEA verifies and certifies that an electronic prescription or pharmacy application meets the requirements of this part, certification by that organization may be used as an alternative to the audit requirements of paragraphs (b) through (d) of this section, provided that the certification that determines that the application meets the requirements of this part occurs at each of the following times:

(1) Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.

(2) Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

(f) The application provider must make the audit or certification report available to any practitioner or pharmacy that uses the application or is considering use of the application. The electronic prescription or pharmacy application provider must retain the most recent audit or certification results and retain the results of any other audits or certifications of the application completed within the previous two years.

(g) Except as provided in paragraphs (h) and (i) of this section, if the third-party auditor or certification organization finds that the application does not meet one or more of the requirements of this part, the application must not be used to create, sign, transmit, or process electronic controlled substance prescriptions. The application provider must notify registrants within five business days of the issuance of the audit or certification report that they should not use the application for controlled substance prescriptions. The application provider must also notify the Administration of the adverse audit or certification report and provide the report to the Administration within one business day of issuance.

(h) For electronic prescription applications, the third-party auditor or certification organization must make the following determinations:

(1) If the information required in § 1306.05(a) of this chapter, the indication that the prescription was signed as required by § 1311.120(b)(17) or the digital signature created by the practitioner's private key, if transmitted, and the number of refills as required by § 1306.22 of this chapter, cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.

(2) If other information required under this chapter cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to create, sign, and transmit prescriptions that require the additional information.

(i) For pharmacy applications, the third-party auditor or certification

organization must make the following determinations:

(1) If the information required in § 1306.05(a) of this chapter, the indication that the prescription was signed as required by § 1311.205(b)(6), and the number of refills as required by § 1306.22 of this chapter, cannot be consistently and accurately imported, stored, and displayed, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.

(2) If the pharmacy application accepts prescriptions with the practitioner's digital signature, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part if the application does not consistently and accurately import, store, and verify the digital signature.

(3) If other information required under this chapter cannot be consistently and accurately imported, stored, and displayed, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to process electronic prescriptions that require the additional information.

§ 1311.302 Additional application provider requirements.

(a) If an application provider identifies or is made aware of any issue with its application that make the application non-compliant with the requirements of this part, the application provider must notify practitioners or pharmacies that use the application as soon as feasible, but no later than five business days after discovery, that the application should not be used to issue or process electronic controlled substance prescriptions.

(b) When providing practitioners or pharmacies with updates to any issue that makes the application non-compliant with the requirements of this part, the application provider must indicate that the updates must be installed before the practitioner or pharmacy may use the application to issue or process electronic controlled substance prescriptions.

§ 1311.305 Recordkeeping.

(a) If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.

(b) Records required by this subpart must be maintained electronically for two years from the date of their creation or receipt. This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.

(c) Records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

(d) Records required by this part must be made available to the Administration upon request.

(e) If an application service provider ceases to provide an electronic prescription application or an electronic pharmacy application or if a registrant ceases to use an application service provider, the application service provider must transfer any records subject to this part to the registrant in a format that the registrant's applications are capable of retrieving, displaying, and printing in a readable format.

(f) If a registrant changes application providers, the registrant must ensure that any records subject to this part are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(g) If a registrant transfers its electronic prescription files to another registrant, both registrants must ensure that the records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.

(h) Digitally signed prescription records must be transferred or migrated with the digital signature.

Dated: March 22, 2010.

Michele M. Leonhart,

Deputy Administrator.

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Part III

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Cumulative List of Public Laws
111th Congress, First Session

CUMULATIVE LIST OF PUBLIC LAWS

This is the cumulative list of public laws for the 111th Congress, First Session. Other cumulative lists (1993–2009) are available online at *http://www.archives.gov/federal-register/laws/past/index.html.* Comments may be addressed to the Director, Office of the Federal Register, Washington, DC 20408 or send e-mail to info@nara.fedreg.gov.

The text of laws may be ordered in individual pamphlet form (referred to as ''slip laws'') from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402 (phone, 202–512–2470). The text will also be made available on the Internet from GPO Access at *http://www.gpoaccess.gov/plaws/index.html.*

Public Law	Title	Approved	123 Stat.
111–1	Ensuring that the compensation and other emoluments attached to the office of Secretary of the Interior are those which were in effect on January 1, 2005.	Jan. 16, 2009	3
111–2	Lilly Ledbetter Fair Pay Act of 2009	Jan. 29, 2009	5
111–3	Children's Health Insurance Program Reauthorization Act of 2009	Feb. 4, 2009	8
111–4	DTV Delay Act	Feb. 11, 2009	112
111–5	American Recovery and Reinvestment Act of 2009	Feb. 17, 2009	115
111–6	Making further continuing appropriations for fiscal year 2009, and for other purposes	Mar. 6, 2009	522
111–7	To designate the facility of the United States Postal Service located at 2105 East Cook Street in Springfield, Illinois, as the ''Colonel John H. Wilson, Jr. Post Office Building''.	Mar. 9, 2009	523
111–8	Omnibus Appropriations Act, 2009	Mar. 11, 2009	524
111–9	To extend certain immigration programs	Mar. 20, 2009	989
111–10	To provide for an additional temporary extension of programs under the Small Business Act and the Small Business Investment Act of 1958, and for other purposes.	Mar. 20, 2009	990
111–11	Omnibus Public Land Management Act of 2009	Mar. 30, 2009	991
111–12	Federal Aviation Administration Extension Act of 2009	Mar. 30, 2009	1457
111–13	Serve America Act	Apr. 21, 2009	1460
111–14	To designate the United States courthouse under construction at 327 South Church Street, Rockford, Illinois, as the ''Stanley J. Roszkowski United States Courthouse''.	Apr. 23, 2009	1602
111–15	Special Inspector General for the Troubled Asset Relief Program Act of 2009	Apr. 24, 2009	1603
111–16	Statutory Time-Periods Technical Amendments Act of 2009	May 7, 2009	1607
111–17	Providing for the appointment of David M. Rubenstein as a citizen regent of the Board of Regents of the Smithsonian Institution.	May 7, 2009	1610
111–18	To repeal section 10(f) of Public Law 93-531, commonly known as the ''Bennett Freeze''	May 8, 2009	1611
111–19	Civil Rights History Project Act of 2009	May 12, 2009	1612
111–20	Protecting Incentives for the Adoption of Children with Special Needs Act of 2009	May 15, 2009	1616
111–21	Fraud Enforcement and Recovery Act of 2009	May 20, 2009	1617
111–22	To prevent mortgage foreclosures and enhance mortgage credit availability	May 20, 2009	1632
111–23	Weapon Systems Acquisition Reform Act of 2009	May 22, 2009	1704
111–24	Credit Card Accountability Responsibility and Disclosure Act of 2009	May 22, 2009	1734
111–25	Ronald Reagan Centennial Commission Act	June 2, 2009	1767
111–26	To designate the facility of the United States Postal Service located at 12877 Broad Street in Sparta, Georgia, as the ''Yvonne Ingram-Ephraim Post Office Building''.	June 19, 2009	1771
111–27	To designate the facility of the United States Postal Service located at 300 East 3rd Street in Jamestown, New York, as the ''Stan Lundine Post Office Building''.	June 19, 2009	1772
111–28	To designate the facility of the United States Postal Service located at 103 West Main Street in McLain, Mississippi, as the ''Major Ed W. Freeman Post Office''.	June 19, 2009	1773
111–29	To designate the facility of the United States Postal Service located at 3245 Latta Road in Rochester, New York, as the ''Brian K. Schramm Post Office Building''.	June 19, 2009	1774
111–30	Antitrust Criminal Penalty Enhancement and Reform Act of 2004 Extension Act	June 19, 2009	1775
111–31	To protect the public health by providing the Food and Drug Administration with certain authority to regulate tobacco products, to amend title 5, United States Code, to make certain modifications in the Thrift Savings Plan, the Civil Service Retirement System, and the Federal Employees' Retirement System, and for other purposes.	June 22, 2009	1776
111–32	Supplemental Appropriations Act, 2009	June 24, 2009	1859
111–33	Native American Heritage Day Act of 2009	June 26, 2009	1922
111–34	To designate the Federal building and United States courthouse located at 306 East Main Street in Elizabeth City, North Carolina, as the ''J. Herbert W. Small Federal Building and United States Courthouse''.	June 30, 2009	1924
111–35	To designate the Federal building located at 799 United Nations Plaza in New York, New York, as the ''Ronald H. Brown United States Mission to the United Nations Building''..	June 30, 2009	1925
111–36	Webcaster Settlement Act of 2009	June 30, 2009	1926
111–37	Veterans' Compensation Cost-of-Living Adjustment Act of 2009	June 30, 2009	1927
111–38	To provide additional personnel authorities for the Special Inspector General for Afghanistan Reconstruction.	June 30, 2009	1932
111–39	To make technical corrections to the Higher Education Act of 1965, and for other purposes	July 1, 2009	1934
111–40	To award a Congressional Gold Medal to the Women Airforce Service Pilots (''WASP'')	July 1, 2009	1958
111–41	Korean War Veterans Recognition Act	July 27, 2009	1962
111–42	Approving the renewal of import restrictions contained in the Burmese Freedom and Democracy Act of 2003, and for other purposes.	July 28, 2009	1963
111–43	To provide for an additional temporary extension of programs under the Small Business Act and the Small Business Investment Act of 1958, and for other purposes.	July 31, 2009	1965
111–44	New Frontier Congressional Gold Medal Act	Aug. 7, 2009	1966
111–45	To authorize the Director of the United States Patent and Trademark Office to use funds made available under the Trademark Act of 1946 for patent operations in order to avoid furloughs and reductions-in-force, and for other purposes.	Aug. 7, 2009	1968
111–46	To restore sums to the Highway Trust Fund and for other purposes	Aug. 7, 2009	1970
111–47	Making supplemental appropriations for fiscal year 2009 for the Consumer Assistance to Recycle and Save Program.	Aug. 7, 2009	1972
111–48	Miami Dade College Land Conveyance Act	Aug. 12, 2009	1974
111–49	Judicial Survivors Protection Act of 2009	Aug. 12, 2009	1976

Public Law	Title	Approved	123 Stat.
111–50	To designate the facility of the United States Postal Service located at 46-02 21st Street in Long Island City, New York, as the ''Geraldine Ferraro Post Office Building''.	Aug. 19, 2009	1979
111–51	To designate the facility of the United States Postal Service located at 601 8th Street in Freedom, Pennsylvania, as the ''John Scott Challis, Jr. Post Office''.	Aug. 19, 2009	1980
111–52	To designate the facility of the United States Postal Service located at 2351 West Atlantic Boulevard in Pompano Beach, Florida, as the ''Elijah Pat Larkins Post Office Building''.	Aug. 19, 2009	1981
111–53	Utah Recreational Land Exchange Act of 2009	Aug. 19, 2009	1982
111–54	To designate the facility of the United States Postal Service located at 41 Purdy Avenue in Rye, New York, as the ''Caroline O'Day Post Office Building''.	Aug. 19, 2009	1989
111–55	To designate the facility of the United States Postal Service located at 431 State Street in Ogdensburg, New York, as the ''Frederic Remington Post Office Building''.	Aug. 19, 2009	1990
111–56	To designate the facility of the United States Postal Service located at 123 11th Avenue South in Nampa, Idaho, as the ''Herbert A Littleton Postal Station''.	Aug. 19, 2009	1991
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111–58	To designate the facility of the United States Postal Service located at 2300 Scenic Drive in Georgetown, Texas, as the ''Kile G. West Post Office Building''.	Aug. 19, 2009	1993
111–59	To designate the facility of the United States Postal Service located at 19190 Cochran Boulevard FRNT in Port Charlotte, Florida, as the ''Lieutenant Commander Roy H. Boehm Post Office Building''.	Aug. 19, 2009	1994
111–60	To extend the deadline for commencement of construction of a hydroelectric project	Aug. 19, 2009	1995
111–61	Recognizing the service, sacrifice, honor, and professionalism of the Noncommissioned Officers of the United States Army.	Aug. 19, 2009	1996
111–62	Granting the consent and approval of Congress to amendments made by the State of Maryland, the Commonwealth of Virginia, and the District of Columbia to the Washington Metropolitan Area Transit Regulation Compact.	Aug. 19, 2009	1998
111–63	WIPA and PABSS Reauthorization Act of 2009	Sept. 18, 2009	2001
111–64	Providing for the appointment of France A. Cordova as a citizen regent of the Board of Regents of the Smithsonian Institution.	Sept. 18, 2009	2002
111–65	To provide for the award of a gold medal on behalf of Congress to Arnold Palmer in recognition of his service to the Nation in promoting excellence and good sportsmanship in golf.	Sept. 30, 2009	2003
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111–67	Defense Production Act Reauthorization of 2009	Sept. 30, 2009	2006
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111–70	To amend the Foreign Affairs Reform and Restructuring Act of 1998 to reauthorize the United States Advisory Commission on Public Diplomacy.	Oct. 9, 2009	2057
111–71	To amend the United States International Broadcasting Act of 1994 to extend by one year the operation of Radio Free Asia, and for other purposes.	Oct. 9, 2009	2058
111–72	To amend title XVIII of the Social Security Act to delay the date on which the accreditation requirement under the Medicare Program applies to suppliers of durable medical equipment that are pharmacies.	Oct. 13, 2009	2059
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111–74	To designate the federally occupied building located at McKinley Avenue and Third Street, SW., Canton, Ohio, as the ''Ralph Regula Federal Building and United States Courthouse''.	Oct. 19, 2009	2080
111–75	To designate the United States courthouse located at 525 Magoffin Avenue in El Paso, Texas, as the ''Albert Armendariz, Sr., United States Courthouse''.	Oct. 19, 2009	2081
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111–77	To designate the Federal building located at 844 North Rush Street in Chicago, Illinois, as the ''William O. Lipinski Federal Building''.	Oct. 19, 2009	2084
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111–95	To amend title 36, United States Code, to grant a Federal charter to the Military Officers Association of America, and for other purposes.	Nov. 6, 2009	3001
111–96	To allow the funding for the interoperable emergency communications grant program established under the Digital Television Transition and Public Safety Act of 2005 to remain available until expended through fiscal year 2012, and for other purposes.	Nov. 6, 2009	3005
111–97	Military Spouses Residency Relief Act	Nov. 11, 2009	3007

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111–98	To authorize a major medical facility project at the Department of Veterans Affairs Medical Center, Walla Walla, Washington, and for other purposes.	Nov. 11, 2009	3010
111–99	To designate the facility of the United States Postal Service located at 10355 Northeast Valley Road in Rollingbay, Washington, as the ''John 'Bud' Hawk Post Office''.	Nov. 30, 2009	3011
111–100	To designate the facility of the United States Postal Service located at 37926 Church Street in Dade City, Florida, as the ''Sergeant Marcus Mathes Post Office''.	Nov. 30, 2009	3012
111–101	To name the South Central Agricultural Research Laboratory of the Department of Agriculture in Lane, Oklahoma, and the facility of the United States Postal Service located at 310 North Perry Street in Bennington, Oklahoma, in honor of former Congressman Wesley ''Wes'' Watkins.	Nov. 30, 2009	3013
111–102	To designate the facility of the United States Postal Service located at 4282 Beach Street in Akron, Michigan, as the ''Akron Veterans Memorial Post Office''.	Nov. 30, 2009	3014
111–103	To designate the facility of the United States Postal Service located at 140 Merriman Road in Garden City, Michigan, as the ''John J. Shivnen Post Office Building''.	Nov. 30, 2009	3015
111–104	To designate the facility of the United States Postal Service located at 1615 North Wilcox Avenue in Los Angeles, California, as the ''Johnny Grant Hollywood Post Office Building''.	Nov. 30, 2009	3016
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111–113	Reserve Officers Association Modernization Act of 2009	Dec. 14, 2009	3026
111–114	To permit each current member of the Board of Directors of the Office of Compliance to serve for 3 terms.	Dec. 14, 2009	3028
111–115	No Social Security Benefits for Prisoners Act of 2009	Dec. 15, 2009	3029
111–116	Fiscal Year 2010 Federal Aviation Administration Extension Act, Part II	Dec. 16, 2009	3031
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111–118	Department of Defense Appropriations Act, 2010	Dec. 19, 2009	3409
111–119	Airline Flight Crew Technical Corrections Act	Dec. 21, 2009	3476
111–120	To extend through December 31, 2010, the authority of the Secretary of the Army to accept and expend funds contributed by non-Federal public entities to expedite the processing of permits.	Dec. 22, 2009	3478
111–121	Appointing the day for the convening of the second session of the One Hundred Eleventh Congress.	Dec. 22, 2009	3479
111–122	Human Rights Enforcement Act of 2009	Dec. 22, 2009	3480
111–123	To permit continued financing of Government operations	Dec. 28, 2009	3483
111–124	To extend the Generalized System of Preferences and the Andean Trade Preference Act, and for other purposes.	Dec. 28, 2009	3484
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111–135*	To designate the facility of the United States Postal Service located at 3900 Darrow Road in Stow, Ohio, as the ''Corporal Joseph A. Tomci Post Office Building''.	Jan. 29, 2010	3494
111–137	To amend title 38, United States Code, to expand veteran eligibility for reimbursement by the Secretary of Veterans Affairs for emergency treatment furnished in a non-Department facility, and for other purposes.	Feb. 1, 2010	3495

***Note:** Public Laws 111–126, 127, and 136 will appear in the Cumulative List of Public Laws for the 111th Congress, Second Session.

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H.R. 4938/P.L. 111–150
To permit the use of previously appropriated funds to extend the Small Business Loan Guarantee Program, and for other purposes. (Mar. 26, 2010; 124 Stat. 1026)

S. 3186/P.L. 111–151
Satellite Television Extension Act of 2010 (Mar. 26, 2010; 124 Stat. 1027)

A Cumulative List of Public Laws for the first session of the 111th Congress appears in Part III of this issue.

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