**REGULATORY INFORMATION SERVICE CENTER**

Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions

**AGENCY:** Regulatory Information Service Center.

**ACTION:** Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions.

**SUMMARY:** The Regulatory Flexibility Act requires that agencies publish semiannual regulatory agendas in the *Federal Register* describing regulatory actions they are developing that may have a significant economic impact on a substantial number of small entities (5 U.S.C. 602). Executive Order 12866 “Regulatory Planning and Review,” signed September 30, 1993 (58 FR 51735), and Office of Management and Budget memoranda implementing section 4 of that Order establish minimum standards for agencies’ agendas, including specific types of information for each entry.

The *Unified Agenda of Federal Regulatory and Deregulatory Actions* (Unified Agenda) helps agencies fulfill these requirements. All Federal regulatory agencies have chosen to publish their regulatory agendas as part of the Unified Agenda.

Editions of the Unified Agenda prior to fall 2007 were printed in their entirety in the *Federal Register*. Beginning with the fall 2007 edition, the Internet is the basic means for conveying regulatory agenda information to the maximum extent legally permissible. The complete Unified Agenda for fall 2011, which contains the regulatory agendas for 59 Federal agencies, is available to the public at [http://reginfo.gov](http://reginfo.gov).

The fall 2011 Unified Agenda publication appearing in the *Federal Register* consists of agency regulatory flexibility agendas, in accordance with the publication requirements of the Regulatory Flexibility Act. Agency regulatory flexibility agendas contain only those Agenda entries for rules that are
likely to have a significant economic impact on a substantial number of small entities and entries that have been selected for periodic review under section 610 of the Regulatory Flexibility Act.

**ADDRESSES:** Regulatory Information Service Center (MI), General Services Administration, One Constitution Square, 1275 First Street NE., 651A, Washington, DC 20417.

**FOR FURTHER INFORMATION CONTACT:** For further information about specific regulatory actions, please refer to the agency contact listed for each entry.

To provide comment on or to obtain further information about this publication, contact: John C. Thomas, Executive Director, Regulatory Information Service Center (MI), General Services Administration, One Constitution Square, 1275 First Street NE., 642, Washington, DC 20417, (202) 482-7340. You may also send comments to us by e-mail at:

RISC@gsa.gov

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Introduction to the Fall 2011 Regulatory Plan

AGENCY REGULATORY PLANS

Cabinet Departments

Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Homeland Security
Department of Housing and Urban Development
Department of the Interior
Department of Justice
Department of Labor
Department of Transportation
Department of the Treasury
Department of Veterans Affairs

Other Executive Agencies

Architectural and Transportation Barriers Compliance Board
Environmental Protection Agency
Equal Employment Opportunity Commission
Financial Stability Oversight Council
General Services Administration
National Aeronautics and Space Administration
National Archives and Records Administration
Office of Personnel Management
Pension Benefit Guaranty Corporation
Small Business Administration
Social Security Administration

Independent Regulatory Agencies

Consumer Financial Protection Bureau
Consumer Product Safety Commission
Federal Trade Commission
National Indian Gaming Commission
Nuclear Regulatory Commission

AGENCY AGENDAS

Cabinet Departments

Department of Agriculture
Department of Commerce
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Homeland Security
Department of the Interior
Department of Justice
Department of Labor
INTRODUCTION TO THE UNIFIED AGENDA OF FEDERAL REGULATORY AND Deregulatory ACTIONS

I. What Is the Unified Agenda?

The Unified Agenda provides information about regulations that the Government is considering or reviewing. The Unified Agenda has appeared in the Federal Register twice each year since 1983 and has been available online since 1995. To further the objective of using modern technology to deliver better
service to the American people for lower cost, beginning with the fall 2007 edition, the Internet is the basic means for conveying regulatory agenda information to the maximum extent legally permissible. The complete Unified Agenda is available to the public at http://reginfo.gov. The online Unified Agenda offers flexible search tools and will soon offer access to the entire historic Unified Agenda database.

The fall 2011 Unified Agenda publication appearing in the Federal Register consists of agency regulatory flexibility agendas, in accordance with the publication requirements of the Regulatory Flexibility Act. Agency regulatory flexibility agendas contain only those Agenda entries for rules that are likely to have a significant economic impact on a substantial number of small entities and entries that have been selected for periodic review under section 610 of the Regulatory Flexibility Act. Printed entries display only the fields required by the Regulatory Flexibility Act. Complete agenda information for those entries appears, in a uniform format, in the online Unified Agenda at http://reginfo.gov.

These publication formats meet the publication mandates of the Regulatory Flexibility Act and Executive Order 12866, as well as move the Agenda process toward the goal of e-Government, at a substantially reduced printing cost compared with prior editions. The current format does not reduce the amount of information available to the public, but it does limit most of the content of the Agenda to online access. The complete online edition of the Unified Agenda includes regulatory agendas from 59 Federal agencies. Agencies of the United States Congress are not included.

The following agencies have no entries identified for inclusion in the printed regulatory flexibility agenda. An asterisk (*) indicates agencies that appear in The Regulatory Plan. The regulatory agendas of these agencies are available to the public at http://reginfo.gov.

Department of Housing and Urban Development*
Department of State
Department of Veterans Affairs*
Agency for International Development
Commission on Civil Rights
Committee for Purchase From People Who Are Blind or Severely Disabled
Corporation for National and Community Service
Court Services and Offender Supervision Agency for the District of Columbia
Equal Employment Opportunity Commission*
Federal Mediation and Conciliation Service
Financial Stability Oversight Council*
Institute of Museum and Library Services

National Archives and Records Administration*
National Endowment for the Humanities
National Science Foundation
Office of Government Ethics
Office of Management and Budget
Office of Personnel Management*
Peace Corps
Pension Benefit Guaranty Corporation*
Railroad Retirement Board
Selective Service System
Social Security Administration*

Commodity Futures Trading Commission
Consumer Product Safety Commission*
Farm Credit Administration
Federal Energy Regulatory Commission
Federal Housing Finance Agency
Federal Maritime Commission
Federal Trade Commission*
National Credit Union Administration
National Indian Gaming Commission*
National Labor Relations Board
Postal Regulatory Commission
Surface Transportation Board

The Regulatory Information Service Center (the Center) compiles the Unified Agenda for the Office of Information and Regulatory Affairs (OIRA), part of the Office of Management and Budget. OIRA is responsible for overseeing the Federal Government’s regulatory, paperwork, and information resource management activities, including implementation of Executive Order 12866. The Center also provides information about Federal regulatory activity to the President and his Executive Office, the Congress, agency managers, and the public.

The activities included in the Agenda are, in general, those that will have a regulatory action within the next 12 months. Agencies may choose to include activities that will have a longer timeframe than 12 months. Agency agendas also show actions or reviews completed or withdrawn since the last Unified Agenda. Executive Order 12866 does not require agencies to include regulations concerning military or foreign affairs functions or regulations related to agency organization, management, or personnel matters.
Agencies prepared entries for this publication to give the public notice of their plans to review, propose, and issue regulations. They have tried to predict their activities over the next 12 months as accurately as possible, but dates and schedules are subject to change. Agencies may withdraw some of the regulations now under development, and they may issue or propose other regulations not included in their agendas. Agency actions in the rulemaking process may occur before or after the dates they have listed. The Unified Agenda does not create a legal obligation on agencies to adhere to schedules in this publication or to confine their regulatory activities to those regulations that appear within it.

II. Why Is the Unified Agenda Published?

The Unified Agenda helps agencies comply with their obligations under the Regulatory Flexibility Act and various Executive orders and other statutes.

Regulatory Flexibility Act

The Regulatory Flexibility Act requires agencies to identify those rules that may have a significant economic impact on a substantial number of small entities (5 U.S.C. 602). Agencies meet that requirement by including the information in their submissions for the Unified Agenda. Agencies may also indicate those regulations that they are reviewing as part of their periodic review of existing rules under the Regulatory Flexibility Act (5 U.S.C. 610). Executive Order 13272 entitled “Proper Consideration of Small Entities in Agency Rulemaking,” signed August 13, 2002 (67 FR 53461), provides additional guidance on compliance with the Act.

Executive Order 12866

Executive Order 12866 entitled “Regulatory Planning and Review,” signed September 30, 1993 (58 FR 51735), requires covered agencies to prepare an agenda of all regulations under development or review. The Order also requires that certain agencies prepare annually a regulatory plan of their “most important significant regulatory actions,” which appears as part of the fall Unified Agenda. Executive
Order 13497, signed January 30, 2009 (74 FR 6113), revoked the amendments to Executive Order 12866 that were contained in Executive Order 13258 and Executive Order 13422.

Executive Order 13132

Executive Order 13132 entitled “Federalism,” signed August 4, 1999 (64 FR 43255), directs agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have “federalism implications” as defined in the Order. Under the Order, an agency that is proposing a regulation with federalism implications, which either preempt State law or impose nonstatutory unfunded substantial direct compliance costs on State and local governments, must consult with State and local officials early in the process of developing the regulation. In addition, the agency must provide to the Director of the Office of Management and Budget a federalism summary impact statement for such a regulation, which consists of a description of the extent of the agency’s prior consultation with State and local officials, a summary of their concerns and the agency’s position supporting the need to issue the regulation, and a statement of the extent to which those concerns have been met. As part of this effort, agencies include in their submissions for the Unified Agenda information on whether their regulatory actions may have an effect on the various levels of government and whether those actions have federalism implications.

Executive Order 13563

Executive Order 13563 entitled “Improving Regulation and Regulatory Review,” signed January 18, 2011, supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review that were established in Executive Order 12866, which includes the general principles of regulation and public participation, and orders integration and innovation in coordination across agencies; flexible approaches where relevant, feasible, and consistent with regulatory approaches;
scientific integrity in any scientific or technological information and processes used to support the agencies’ regulatory actions; and retrospective analysis of existing regulations.

*Unfunded Mandates Reform Act of 1995*

The *Unfunded Mandates Reform Act of 1995* (Pub. L. 104-4, title II) requires agencies to prepare written assessments of the costs and benefits of significant regulatory actions “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 . . . in any 1 year . . . .” The requirement does not apply to independent regulatory agencies, nor does it apply to certain subject areas excluded by section 4 of the Act. Affected agencies identify in the Unified Agenda those regulatory actions they believe are subject to title II of the Act.

*Executive Order 13211*

*Executive Order 13211* entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” signed May 18, 2001 (66 FR 28355), directs agencies to provide, to the extent possible, information regarding the adverse effects that agency actions may have on the supply, distribution, and use of energy. Under the Order, the agency must prepare and submit a Statement of Energy Effects to the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, for “those matters identified as significant energy actions.” As part of this effort, agencies may optionally include in their submissions for the Unified Agenda information on whether they have prepared or plan to prepare a Statement of Energy Effects for their regulatory actions.

*Small Business Regulatory Enforcement Fairness Act*

The *Small Business Regulatory Enforcement Fairness Act* (Pub. L. 104-121, title II) established a procedure for congressional review of rules (5 U.S.C. 801 et seq.), which defers, unless exempted, the
effective date of a “major” rule for at least 60 days from the publication of the final rule in the Federal Register. The Act specifies that a rule is “major” if it has resulted, or is likely to result, in an annual effect on the economy of $100 million or more or meets other criteria specified in that Act. The Act provides that the Administrator of OIRA will make the final determination as to whether a rule is major.

III. How Is the Unified Agenda Organized?

Agency regulatory flexibility agendas are printed in a single daily edition of the Federal Register. A regulatory flexibility agenda is printed for each agency whose agenda includes entries for rules which are likely to have a significant economic impact on a substantial number of small entities or rules that have been selected for periodic review under section 610 of the Regulatory Flexibility Act. Each printed agenda appears as a separate part. The parts are organized alphabetically in four groups: Cabinet departments; other executive agencies; the Federal Acquisition Regulation, a joint authority; and independent regulatory agencies. Agencies may in turn be divided into subagencies. Each agency’s part of the Agenda contains a preamble providing information specific to that agency. Each printed agency agenda has a table of contents listing the agency’s printed entries that follow.

The online, complete Unified Agenda contains the preambles of all participating agencies. Unlike the printed edition, the online Agenda has no fixed ordering. In the online Agenda, users can select the particular agencies whose agendas they want to see. Users have broad flexibility to specify the characteristics of the entries of interest to them by choosing the desired responses to individual data fields. To see a listing of all of an agency’s entries, a user can select the agency without specifying any particular characteristics of entries.

Each entry in the Agenda is associated with one of five rulemaking stages. The rulemaking stages are:

1. Prerule Stage -- actions agencies will undertake to determine whether or how to initiate rulemaking. Such actions occur prior to a Notice of Proposed Rulemaking (NPRM) and may
include Advance Notices of Proposed Rulemaking (ANPRMs) and reviews of existing regulations.

2. **Proposed Rule Stage** -- actions for which agencies plan to publish a Notice of Proposed Rulemaking as the next step in their rulemaking process or for which the closing date of the NPRM Comment Period is the next step.

3. **Final Rule Stage** -- actions for which agencies plan to publish a final rule or an interim final rule or to take other final action as the next step.

4. **Long-Term Actions** -- items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of this edition of the Unified Agenda. Some of the entries in this section may contain abbreviated information.

5. **Completed Actions** -- actions or reviews the agency has completed or withdrawn since publishing its last agenda. This section also includes items the agency began and completed between issues of the Agenda.

Long-Term Actions are rulemakings reported during the publication cycle that are outside of the required 12-month reporting period for which the Agenda was intended. Completed Actions in the publication cycle are rulemakings that are ending their lifecycle either by Withdrawal or completion of the rulemaking process. Therefore, the Long-Term and Completed RINs do not represent the ongoing, forward-looking nature intended for reporting developing rulemakings in the Agenda pursuant to Executive Order 12866, section 4(b) and 4(c). To further differentiate these two stages of rulemaking in the Unified Agenda from active rulemakings, Long-Term and Completed Actions are reported separately from active rulemakings, which can be any of the first three stages of rulemaking listed above. A separate search function is provided on reginfo.gov to search for Completed and Long-Term Actions apart from each other and active RINs.
A bullet (●) preceding the title of an entry indicates that the entry is appearing in the Unified Agenda for the first time.

In the printed edition, all entries are numbered sequentially from the beginning to the end of the publication. The sequence number preceding the title of each entry identifies the location of the entry in this edition. The sequence number is used as the reference in the printed table of contents. Sequence numbers are not used in the online Unified Agenda because the unique Regulation Identifier Number (RIN) is able to provide this cross-reference capability.

Editions of the Unified Agenda prior to fall 2007 contained several indexes, which identified entries with various characteristics. These included regulatory actions for which agencies believe that the Regulatory Flexibility Act may require a Regulatory Flexibility Analysis, actions selected for periodic review under section 610(c) of the Regulatory Flexibility Act, and actions that may have federalism implications as defined in Executive Order 13132 or other effects on levels of government. These indexes are no longer compiled, because users of the online Unified Agenda have the flexibility to search for entries with any combination of desired characteristics. The online edition retains the Unified Agenda’s subject index based on the Federal Register Thesaurus of Indexing Terms. In addition, online users have the option of searching Agenda text fields for words or phrases.

IV. What Information Appears for Each Entry?

All entries in the online Unified Agenda contain uniform data elements including, at a minimum, the following information:

*Title of the Regulation* -- a brief description of the subject of the regulation. In the printed edition, the notation “Section 610 Review” following the title indicates that the agency has selected the rule for its periodic review of existing rules under the Regulatory Flexibility Act (5 U.S.C. 610(c)). Some agencies
have indicated completions of section 610 reviews or rulemaking actions resulting from completed section 610 reviews. In the online edition, these notations appear in a separate field.

Priority -- an indication of the significance of the regulation. Agencies assign each entry to one of the following five categories of significance.

(1) Economically Significant

As defined in Executive Order 12866, a rulemaking action that will have an annual effect on the economy of $100 million or more or will adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. The definition of an “economically significant” rule is similar but not identical to the definition of a “major” rule under 5 U.S.C. 801 (Pub. L. 104-121). (See below.)

(2) Other Significant

A rulemaking that is not Economically Significant but is considered Significant by the agency. This category includes rules that the agency anticipates will be reviewed under Executive Order 12866 or rules that are a priority of the agency head. These rules may or may not be included in the agency’s regulatory plan.

(3) Substantive, Nonsignificant

A rulemaking that has substantive impacts but is neither Significant, nor Routine and Frequent, nor Informational/Administrative/Other.

(4) Routine and Frequent

A rulemaking that is a specific case of a multiple recurring application of a regulatory program in the Code of Federal Regulations and that does not alter the body of the regulation.

(5) Informational/Administrative/Other
A rulemaking that is primarily informational or pertains to agency matters not central to accomplishing the agency's regulatory mandate but that the agency places in the Unified Agenda to inform the public of the activity.

**Major** – whether the rule is “major” under 5 U.S.C. 801 (Pub. L. 104-121) because it has resulted or is likely to result in an annual effect on the economy of $100 million or more or meets other criteria specified in that Act. The Act provides that the Administrator of the Office of Information and Regulatory Affairs will make the final determination as to whether a rule is major.

**Unfunded Mandates** -- whether the rule is covered by section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). The Act requires that, before issuing an NPRM likely to result in a mandate that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector of more than $100 million in 1 year, agencies, other than independent regulatory agencies, shall prepare a written statement containing an assessment of the anticipated costs and benefits of the Federal mandate.

**Legal Authority** -- the section(s) of the United States Code (U.S.C.) or Public Law (Pub. L.) or the Executive order (E.O.) that authorize(s) the regulatory action. Agencies may provide popular name references to laws in addition to these citations.

**CFR Citation** -- the section(s) of the Code of Federal Regulations that will be affected by the action.

**Legal Deadline** -- whether the action is subject to a statutory or judicial deadline, the date of that deadline, and whether the deadline pertains to an NPRM, a Final Action, or some other action.

**Abstract** -- a brief description of the problem the regulation will address; the need for a Federal solution; to the extent available, alternatives that the agency is considering to address the problem; and potential costs and benefits of the action.
Timetable -- the dates and citations (if available) for all past steps and a projected date for at least the next step for the regulatory action. A date displayed in the form 12/00/11 means the agency is predicting the month and year the action will take place but not the day it will occur. In some instances, agencies may indicate what the next action will be, but the date of that action is “To Be Determined.” “Next Action Undetermined” indicates the agency does not know what action it will take next.

Regulatory Flexibility Analysis Required -- whether an analysis is required by the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because the rulemaking action is likely to have a significant economic impact on a substantial number of small entities as defined by the Act.

Small Entities Affected -- the types of small entities (businesses, governmental jurisdictions, or organizations) on which the rulemaking action is likely to have an impact as defined by the Regulatory Flexibility Act. Some agencies have chosen to indicate likely effects on small entities even though they believe that a Regulatory Flexibility Analysis will not be required.

Government Levels Affected -- whether the action is expected to affect levels of government and, if so, whether the governments are State, local, tribal, or Federal.

International Impacts -- whether the regulation is expected to have international trade and investment effects, or otherwise may be of interest to the Nation’s international trading partners.

Federalism -- whether the action has “federalism implications” as defined in Executive Order 13132. This term refers to actions “that have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” Independent regulatory agencies are not required to supply this information.
Included in the Regulatory Plan -- whether the rulemaking was included in the agency’s current regulatory plan published in fall 2010.

Agency Contact -- the name and phone number of at least one person in the agency who is knowledgeable about the rulemaking action. The agency may also provide the title, address, fax number, e-mail address, and TDD for each agency contact.

Some agencies have provided the following optional information:

RIN Information URL -- the Internet address of a site that provides more information about the entry.

Public Comment URL -- the Internet address of a site that will accept public comments on the entry. Alternatively, timely public comments may be submitted at the Governmentwide e-rulemaking site, http://www.regulations.gov.

Additional Information -- any information an agency wishes to include that does not have a specific corresponding data element.

Compliance Cost to the Public -- the estimated gross compliance cost of the action.

Affected Sectors -- the industrial sectors that the action may most affect, either directly or indirectly. Affected sectors are identified by North American Industry Classification System (NAICS) codes.

Energy Effects -- an indication of whether the agency has prepared or plans to prepare a Statement of Energy Effects for the action, as required by Executive Order 13211 “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,” signed May 18, 2001 (66 FR 28355).

Related RINs -- one or more past or current RIN(s) associated with activity related to this action, such as merged RINs, split RINs, new activity for previously completed RINs, or duplicate RINs.
Some agencies that participated in the fall 2010 edition of The Regulatory Plan have chosen to include the following information for those entries that appeared in the Plan:

**Statement of Need** -- a description of the need for the regulatory action.

**Summary of the Legal Basis** -- a description of the legal basis for the action, including whether any aspect of the action is required by statute or court order.

**Alternatives** -- a description of the alternatives the agency has considered or will consider as required by section 4(c)(1)(B) of Executive Order 12866.

**Anticipated Costs and Benefits** -- a description of preliminary estimates of the anticipated costs and benefits of the action.

**Risks** -- a description of the magnitude of the risk the action addresses, the amount by which the agency expects the action to reduce this risk, and the relation of the risk and this risk reduction effort to other risks and risk reduction efforts within the agency’s jurisdiction.

V. Abbreviations

The following abbreviations appear throughout this publication:

**ANPRM** -- An Advance Notice of Proposed Rulemaking is a preliminary notice, published in the Federal Register, announcing that an agency is considering a regulatory action. An agency may issue an ANPRM before it develops a detailed proposed rule. An ANPRM describes the general area that may be subject to regulation and usually asks for public comment on the issues and options being discussed. An ANPRM is issued only when an agency believes it needs to gather more information before proceeding to a notice of proposed rulemaking.
CFR -- The Code of Federal Regulations is an annual codification of the general and permanent regulations published in the Federal Register by the agencies of the Federal Government. The Code is divided into 50 titles, each title covering a broad area subject to Federal regulation. The CFR is keyed to and kept up to date by the daily issues of the Federal Register.

EO -- An Executive order is a directive from the President to Executive agencies, issued under constitutional or statutory authority. Executive orders are published in the Federal Register and in title 3 of the Code of Federal Regulations.

FR -- The Federal Register is a daily Federal Government publication that provides a uniform system for publishing Presidential documents, all proposed and final regulations, notices of meetings, and other official documents issued by Federal agencies.

FY -- The Federal fiscal year runs from October 1 to September 30.

NPRM -- A Notice of Proposed Rulemaking is the document an agency issues and publishes in the Federal Register that describes and solicits public comments on a proposed regulatory action. Under the Administrative Procedure Act (5 U.S.C. 553), an NPRM must include, at a minimum:

- a statement of the time, place, and nature of the public rulemaking proceeding;
- a reference to the legal authority under which the rule is proposed; and
- either the terms or substance of the proposed rule or a description of the subjects and issues involved.

PL (or Pub. L.) -- A public law is a law passed by Congress and signed by the President or enacted over his veto. It has general applicability, unlike a private law that applies only to those persons or entities specifically designated. Public laws are numbered in sequence throughout the 2-year life of each Congress; for example, PL 112-4 is the fourth public law of the 112th Congress.
RFA -- A Regulatory Flexibility Analysis is a description and analysis of the impact of a rule on small entities, including small businesses, small governmental jurisdictions, and certain small not-for-profit organizations. The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires each agency to prepare an initial RFA for public comment when it is required to publish an NPRM and to make available a final RFA when the final rule is published, unless the agency head certifies that the rule would not have a significant economic impact on a substantial number of small entities.

RIN -- The Regulation Identifier Number is assigned by the Regulatory Information Service Center to identify each regulatory action listed in the Unified Agenda, as directed by Executive Order 12866 (section 4(b)). Additionally, OMB has asked agencies to include RINs in the headings of their Rule and Proposed Rule documents when publishing them in the Federal Register, to make it easier for the public and agency officials to track the publication history of regulatory actions throughout their development.

Seq. No. -- The sequence number identifies the location of an entry in the printed edition of the Unified Agenda. Note that a specific regulatory action will have the same RIN throughout its development but will generally have different sequence numbers if it appears in different printed editions of the Unified Agenda. Sequence numbers are not used in the online Unified Agenda.

USC -- The United States Code is a consolidation and codification of all general and permanent laws of the United States. The USC is divided into 50 titles, each title covering a broad area of Federal law.

VI. How Can Users Get Copies of the Agenda?

Copies of individual agency materials may be available directly from the agency or may be found on the agency’s website. Please contact the particular agency for further information.

All editions of The Regulatory Plan and the Unified Agenda of Federal Regulatory and Deregulatory Actions since fall 1995 are available in electronic form at http://reginfo.gov, along with flexible search tools.

In accordance with regulations for the Federal Register, the Government Printing Office’s GPO FDsys website contains copies of the Agendas and Regulatory Plans that have been printed in the Federal Register. These documents are available at http://www.fdsys.gov.

Dated: December 19, 2011.

NAME: John C. Thomas,
Director.
[FR Doc. Filed 12–16–11;8:45 am]

BILLING CODE

INTRODUCTION TO THE FALL 2011 REGULATORY PLAN

Executive Order 12866, issued in 1993, requires the annual production of a Unified Regulatory Agenda and Regulatory Plan. It does so to promote transparency – or in the words of the Executive Order itself, “to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order.”

The requirements of Executive Order 12866 were reaffirmed in Executive Order 13563, issued in 2011. Consistent with Executive Orders 13563 and 12866, we are now providing the Unified Regulatory Agenda and the Regulatory Plan for public scrutiny and review. Such scrutiny and review are closely connected with the general goal, central to Executive Order 13563, of promoting public participation in the rulemaking process.

It is important to understand that the Agenda and Plan are intended merely to serve as a preliminary statement, for public understanding and assessment, of regulatory and deregulatory
policies and priorities that are now under contemplation. This preliminary statement often includes a number of rules that are not issued in the following year and that may well not be issued at all. This year, we have taken several new steps to clarify the purposes and uses of the Agenda and Plan and to improve its presentation. Among other things, we have narrowed the list of “active rulemakings” to rules that are not merely under some form of contemplation but that also have at least some possibility of issuance over the next year. We have also made it easier to understand which rules are active rulemakings rather than long-term actions or completed actions. But it remains true that rules on this list, designed among other things “to involve the public and its State, local, and tribal officials in regulatory planning,” must undergo serious internal and external scrutiny before they are issued -- and that there are rules on the list that may never be issued.

In this light, it should be clear that this preliminary statement of policies and priorities has extremely important limitations. No regulatory action can be made effective until it has gone through legally required processes, including those that involve public scrutiny and review. For this reason, the inclusion of a regulatory action here does not necessarily mean that it will be finalized or even proposed. Any proposed or final action must satisfy the requirements of relevant statutes, Executive Orders, and Presidential Memoranda. Those requirements, public comments, and new information may or may not lead an agency to go forward with an action that is currently under contemplation and that is included here. For example, the directives of Executive Order 13563, emphasizing the importance of careful consideration of costs and benefits, may lead an agency to decline to proceed with a regulatory action that is presented here.

It is also important to note that under Executive Order 12866, whether a regulation counts as “economically significant” is not an adequate measure of whether it imposes high costs on the private sector. Economically significant actions may impose small costs or even no costs. For example, regulations may count as economically significant not because they impose significant costs, but because they confer large benefits. Moreover, many regulations count as economically significant not because they impose significant regulatory costs on the private sector, but because they involve transfer payments as required or authorized by law.

It should be observed that the number of economically significant actions listed as under active consideration here – 138 – is lower than the corresponding figure for Spring 2011 (149) and for Fall 2010 (140). It is notable that the number of such rules has not grown even taking account of rules implementing the Affordable Care Act and the Wall Street Reform and Consumer Protection Act. We also note that the net benefits of regulation were unusually high in Fiscal Year 2011 (well over $50 billion for the year alone). In addition, the aggregate costs for that year (under $8 billion) were lower than in Fiscal Year 2010 and were not out of line with those in recent years, including during the Bush Administration.

With these notes and qualifications, the Regulatory Plan provides a list of important regulatory actions that are now under contemplation for issuance in proposed or final form during the upcoming fiscal year. In contrast, the Unified Agenda is a more inclusive list, including numerous ministerial actions and routine rulemakings, as well as long-term initiatives that agencies do not plan to complete in the coming year.
We hope that public scrutiny of the Regulatory Plan and the Unified Agenda might help ensure, in the words of Executive Order 13563, a regulatory system that protects “public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.”

As discussed below, a large number of significant recent steps have been taken, consistent with Executive Order 13563, to reduce regulatory costs and ensure that our regulatory system is consistent with promoting growth and job creation. At the same time, a number of steps have been taken to promote public health, welfare, safety, and our environment. It is important to emphasize that the net benefits of recent rules, including the monetized benefits, are high – over the first two fiscal years of this Administration, in excess of $35 billion. Rules have been issued and initiatives have been undertaken that are saving lives on the highways and in workplaces; reducing air and water pollution, preventing thousands of deaths in the process; increasing fuel economy, thus saving money while reducing pollution; making both trains and planes safer; increasing energy efficiency, saving billions of dollars while increasing energy security; combating childhood obesity; and creating a “race to the top” in education. Consider, as merely one example, the fact that in 2010, the rates of roadway fatalities and injuries fell to their lowest recorded levels and to their lowest numbers since 1949. The decrease is attributable, in part, to a range of regulatory actions and to private-public partnerships that have increased safety.

Since President Reagan’s Executive Order 12291, issued in 1981, a principal focus of the Office of Information and Regulatory Affairs, and of regulatory policy in general, has been on maximizing net benefits. In this Administration, agencies and OMB have worked together to issue a number of rules for which the benefits exceed the costs, and by a large margin. Consider the following figure:
These figures reflect the numbers for 2009 and 2010. As noted, the net benefits for 2011 are expected to be unusually high (in excess of $50 billion); they will be discussed in detail in the 2012 Report to Congress on the Benefits and Costs of Federal Regulations.

The recent steps build on a great deal of new learning about regulation. As a result of conceptual and empirical advances, we know far more than during the New Deal and the Great Society. We have also learned much since the 1980s and 1990s. These lessons have informed the Administration’s efforts to protect public health and safety while also promoting economic growth and job creation. Eight points are particularly important:

1. We are now equipped with state-of-the-art techniques for anticipating, cataloguing, and monetizing the consequences of regulation, including both benefits and costs.
2. We know that risks are part of systems, and that efforts to reduce a certain risk may increase other risks, perhaps even deadly ones, thus producing ancillary harms—and that efforts to reduce a certain risk may reduce other risks, perhaps even deadly ones, thus producing ancillary benefits.
3. We know that flexible, innovative approaches, maintaining freedom of choice and respecting heterogeneity and the fact that one size may not fit all, are often desirable, both because they preserve liberty and because they frequently cost less.
4. We know that large benefits can come from seemingly modest and small steps, including simplification of regulatory requirements, provision of information, and sensible default rules, such as automatic enrollment for retirement savings.

5. We know, more clearly than ever before, that it is important to allow public participation in the design of rules, because members of the public have valuable information about likely effects, existing problems, creative solutions, and possible unintended consequences.

6. We know that if carefully designed, disclosure policies can promote informed choices and save both money and lives.

7. We know that intuitions and anecdotes are unreliable, and that advance testing of the effects of rules, as through pilot programs or randomized controlled experiments, can be highly illuminating.

8. We know that it is important to explore the effects of regulation in the real world, to learn whether they are having beneficial consequences or producing unintended harm. We need to consult, and to learn from, those who are affected by rules.

Executive Order 13563 draws on these understandings and emphasizes the importance of protecting “public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” Executive Order 13563 explicitly points to the need for predictability and for certainty, and for use of the least burdensome tools for achieving regulatory ends. It indicates that agencies “must take into account benefits and costs, both quantitative and qualitative.” It explicitly draws attention to the need to measure and to improve “the actual results of regulatory requirements” – a clear reference to the importance of retrospective evaluation.

Executive Order 13563 reaffirms the principles, structures, and definitions in Executive Order 12866, which has long governed regulatory review. In addition, it endorses, and quotes, a number of provisions of that Executive Order that specifically emphasize the importance of considering costs – including the requirement that to the extent permitted by law, agencies should not proceed in the absence of a reasoned determination that the benefits justify the costs. Importantly, Executive Order 13563 directs agencies “to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible.” This direction reflects a strong emphasis on quantitative analysis as a means of improving regulatory choices and increasing transparency.

Among other things, Executive Order 13563 sets out five sets of requirements to guide regulatory decision making:

- **Public participation.** Agencies are directed to promote public participation, in part by making supporting documents available on Regulations.gov in order to promote transparency and public comment. Executive Order 13563 also directs agencies, where feasible and appropriate, to engage the public, including affected stakeholders, before rulemaking is initiated.

- **Integration and innovation.** Agencies are directed to attempt to reduce “redundant, inconsistent, or overlapping” requirements, in part by working with one another to simplify and harmonize rules. This important provision is designed to reduce confusion, redundancy, and excessive cost. An important goal of simplification and harmonization is to promote rather than
to hamper innovation, which is a foundation of both growth and job creation. Different offices within the same agency might work together to harmonize their rules; different agencies might work together to achieve the same objective. Such steps can also promote predictability and certainty.

- **Flexible approaches.** Agencies are directed to identify and consider flexible approaches to regulatory problems, including warnings, appropriate default rules, and disclosure requirements. Such approaches may “reduce burdens and maintain flexibility and freedom of choice for the public.” In certain settings, they may be far preferable to mandates and bans, precisely because they maintain freedom of choice and reduce costs. The reference to “appropriate default rules” signals the possibility that important social goals can be obtained through simplification – as, for example, in the form of automatic enrollment, direct certification, or reduced paperwork burdens.

- **Science.** Agencies are directed to promote scientific integrity, and in a way that ensures a clear separation between judgments of science and judgments of policy.

- **Retrospective analysis of existing rules.** Agencies are directed to produce preliminary plans to engage in retrospective analysis of existing significant regulations to determine whether they should be modified, streamlined, expanded, or repealed.

Executive Order 13563 addresses both the “flow” of new regulations that are under development and the “stock” of existing regulations that are already in place. Executive Order 13563 emphasizes the importance of promoting predictability, of carefully considering costs, of choosing the least burdensome approach, and of selecting the most flexible, least costly tools. In addition, Executive Order 13563 calls for careful reassessment, based on empirical analysis. It is understood that the prospective analysis required by Executive Order 13563 may depend on a degree of speculation and that the actual costs and benefits of a regulation may be lower or higher than what was anticipated when the rule was originally developed. It is also understood that circumstances may change in a way that requires reconsideration of regulatory requirements. After retrospective analysis has been undertaken, agencies will be in a position to reevaluate existing rules and to streamline, modify, or eliminate those that do not make sense in their current form.

In August 2011, over two dozen agencies released final plans to remove what the President has called unjustified rules and “absurd and unnecessary paperwork requirements that waste time and money.” Over the next five years, billions of dollars in savings are anticipated from just a few initiatives from the Department of Transportation, the Department of Labor, the Department of Health and Human Services, and the Environmental Protection Agency. And all in all, the plans’ initiatives will save tens of millions of hours in annual paperwork burdens on individuals, businesses, and state and local governments.

The plans span over 800 pages and offer more than 500 proposals. Some plans list well over 50 reforms. Many of the proposals focus on small business. Indeed, a number of the initiatives are specifically designed to reduce burdens on small business and to enable them to do what they do best, which is to create jobs. Some of the proposed initiatives represent a fundamental rethinking of how things have long been done – as, for example, with numerous efforts to move
from paper to electronic reporting. For both private and public sectors, those efforts can save a
great deal of money. Over the next five years, the Department of Treasury’s paperless initiative
will be saving $400 million and 12 million pounds of paper.

Many of the reforms will have a significant economic impact:

■ The Occupational Safety and Health Administration has announced a final rule that will
remove over 1.9 million annual hours of redundant reporting burdens on employers and save
more than $40 million in annual costs. Businesses will no longer be saddled with the obligation
to fill out unnecessary government forms, meaning that their employees will have more time to
be productive and do their real work.

■ To eliminate unjustified economic burdens on railroads, the Department of Transportation
is reconsidering parts of a rule that requires railroads to install equipment on trains. DOT has
proposed to refine the requirements so that the equipment is installed only where it is really
needed on grounds of safety. DOT expects initial savings of up to $325 million, with total 20-
year savings of up to $755 million.

■ EPA has proposed to eliminate the obligation for many states to require air pollution vapor
recovery systems at local gas stations, on the ground that modern vehicles already have effective
air pollution control technologies. The anticipated annual savings are $87 million.

■ The Departments of Commerce and State are undertaking a series of steps to eliminate
unnecessary barriers to exports, including duplicative and unnecessary regulatory requirements,
thus reducing the cumulative burden and uncertainty faced by American companies and their
trading partners. These steps will make it a lot easier for American companies to reach new
markets, increasing our exports while creating jobs here at home.

■ To promote flexibility, the Department of Health and Human Services has proposed two
rules, and finalized another, to reduce burdensome regulatory requirements now placed on
hospitals and doctors. These reforms are expected to save more than $1 billion annually.

The regulatory lookback is not merely a one-time exercise. Regular reporting, about recent
progress and coming initiatives, is required. The goal is to change the regulatory culture to
ensure that rules on the books are reevaluated and are effective, cost-justified, and based on the
best available science. By creating regulatory review teams at agencies, we will continue to
examine what is working and what is not and to eliminate unjustified and outdated regulations.

In addition to looking back at existing regulations, we are looking forward to ensure that
future regulations are well-justified. Executive Order 13563 provides critical guidance with its
emphasis on careful consideration of costs and benefits, public participation, integration and
innovation, flexible approaches, and science. These requirements are meant to produce a
regulatory system that draws on recent learning, that is driven by evidence, and that is suited to
the distinctive circumstances of the twenty-first century.
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Statement of Regulatory Priorities

USDA’s focus in 2012 will be on programs that create/save jobs, particularly in rural America, while identifying and taking action on those programs that could be modified, streamlined, and simplified, or reporting burdens reduced, particularly with the public's access to USDA programs. In addition, USDA’s regulatory efforts in the coming year will be focused on achieving the Department’s goals identified in the Department’s Strategic Plan for 2010 to 2015.

• Assist rural communities to create prosperity so they are self-sustaining, re-populating, and economically thriving. USDA is the leading advocate for rural America. The Department supports rural communities and enhances quality of life for rural residents by improving their economic opportunities, community infrastructure, environmental health, and the sustainability of agricultural production. The common goal is to help create thriving rural communities with good jobs where people want to live and raise families, and where children have economic opportunities and a bright future.

• Ensure that all of America’s children have access to safe, nutritious, and balanced meals. A plentiful supply of safe and nutritious food is essential to the well-being of every family and the healthy development of every child in America. USDA provides nutrition assistance to children and low-income people who need it and works to improve the healthy eating habits of all Americans, especially children. In addition, the Department safeguards the quality and wholesomeness of meat, poultry, and egg products and addresses and prevents loss and damage from pests and disease outbreaks.

• Ensure our national forests and private working lands are conserved, restored, and made more resilient to climate change, while enhancing our water resources. America’s prosperity is inextricably linked to the health of our lands and natural resources. Forests, farms, ranches, and grasslands offer enormous environmental benefits as a source of clean air, clean and abundant water, and wildlife
habitat. These lands generate economic value by supporting the vital agriculture and forestry sectors, attracting tourism and recreation visitors, sustaining green jobs, and producing ecosystem services, food, fiber, timber and non-timber products, and energy. They are also of immense social importance, enhancing rural quality of life, sustaining scenic and culturally important landscapes, and providing opportunities to engage in outdoor activity and reconnect with the land.

- Help America promote agricultural production and biotechnology exports as America works to increase food security. A productive agricultural sector is critical to increasing global food security. For many crops, a substantial portion of domestic production is bound for overseas markets. USDA helps American farmers and ranchers use efficient, sustainable production, biotechnology, and other emergent technologies to enhance food security around the world and find export markets for their products.

Important regulatory activities supporting the accomplishment of these goals in 2012 will include the following:

- Rural Development and Renewable Energy. USDA priority regulatory actions for the Rural Development mission will be to revise regulations for the Business and Industry Guaranteed Loan Program, Rural Development’s flagship job creation and capital expansion business program, and finalize regulations for the bioenergy programs.

- USDA will continue to promote sustainable economic opportunities to create jobs in rural communities through the purchase and use of biobased products through the BioPreferred® program. USDA will continue to designate groups of biobased products to receive procurement preference from Federal agencies and contractors. BioPreferred has made serious efforts to minimize burdens on small business by providing a standard mechanism for product testing, an online application process, and individual assistance for small manufacturers when needed. Both the Federal preferred procurement and the certified label parts of the program are voluntary, and both are designed to assist biobased
• Nutrition Assistance. As changes are made to the nutrition assistance programs, USDA will work to foster actions that ensure access to program benefits, improve program integrity, improve diets and healthy eating through nutrition education, and promote physical activity consistent with the national effort to reduce obesity. In support of these activities in 2012, the Food and Nutrition Service (FNS) plans to publish the final rule regarding the nutrition standards in the school meals programs; finalize a rule updating the WIC food packages; and establish permanent rules for the Fresh Fruit and Vegetable Program. FNS will continue to work to implement rules that minimize participant and vendor fraud in its nutrition assistance programs.

• Food Safety. In the area of food safety, USDA will continue to develop science-based regulations that improve the safety of meat, poultry, and processed egg products in the least burdensome and most cost-effective manner. Regulations will be revised to address emerging food safety challenges, streamlined to remove excessively prescriptive regulations, and updated to be made consistent with hazard analysis and critical control point principles. In 2012, the Food Safety and Inspection Service (FSIS) plans to propose regulations to establish new systems for poultry slaughter inspection, requirements for federally inspected egg product plants to develop and implement hazard analysis and critical control point systems and sanitation standard operating procedures, and finalize regulations on catfish inspection. To assist small entities to comply with food safety requirements, the FSIS will continue to collaborate with other USDA agencies and State partners in the enhanced small business outreach program.

• Farm Loans, Disaster Designation, and Environmental Compliance. USDA will work to ensure a strong U.S. agricultural system through farm income support and farm loan programs. In addition, USDA will streamline the disaster designation process and update and consolidate the environmental compliance regulations.
• Forestry and Conservation. In the conservation area, USDA plans to finalize regulations that would provide financial assistance grants to local governments, tribal governments, and nonprofit organizations to establish community forests by acquiring and protecting private forestlands.

• Marketing and Regulatory Programs. USDA will work to support the organic sector and continue regulatory work to protect the health and value of U.S. agricultural and natural resources. USDA will also implement regulations to enhance enforcement of the Packers and Stockyards Act. In addition, USDA plans to finalize acceptable animal disease traceability standards. Regarding plant health, USDA anticipates revising the permitting of movement of plant pests and biological control organisms. For the Animal Welfare Act, USDA will propose specific standards for the humane care of birds and finalize specific standards for the humane care of dogs imported for resale.

**Retrospective Review and Executive Order 13563**

In January 2011, President Obama issued Executive Order (E.O.) 13563 on Improving Regulation and Regulatory Review. As part of this E.O., agencies were asked to review existing rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them accordingly. Reducing the regulatory burden on the American people and our trading partners is a priority for USDA, and we will continually work to improve the effectiveness of our existing regulations. As a result of our regulatory review efforts in 2011, USDA will make regulatory changes in 2012, including the following:

*Labeling - Generic Approval and Regulations Consolidation.* FSIS is developing a rule that will expand the circumstances in which the labels of meat and poultry products will be deemed to be generically approved by FSIS. The rule will reduce duplication and streamline the regulations on this subject by combining them into a single part of the Code of Federal Regulations (CFR);
Electronic Export Application and Certification Fee. FSIS is planning a rule to provide for the electronic transmittal of foreign establishment certifications between FSIS and foreign governments. The rule will consolidate four inspection certificates (meat, meat by-products, poultry, and egg products) into one certificate. The rulemaking is intended, in part, to accommodate the Agency’s electronic Public Health Information System.

Environmental Compliance. The Farm Service Agency (FSA) will consolidate and update the environmental compliance regulations to ensure regulations are consistent and current for all FSA programs and remove obsolete regulations;

National Environmental Policy Act (NEPA) Streamlining. The Natural Resources and Environment mission area and the Forest Service (FS), in cooperation with the Council on Environmental Quality (CEQ), is considering a series of initiatives to improve and streamline the NEPA process as it applies to FS projects;

Rural Energy for America Program. This new program will modify the existing grant and guaranteed loan program for renewable energy system (RES) and energy efficiency improvement (EEI) projects. In addition, it would add a grant program for RES feasibility studies and a grant program for energy audits and renewable energy development assistance. This rulemaking will streamline the process for smaller grants, lessening the burden to the customer. It will also make the guaranteed portion of the rule consistent with other programs Rural Development (RD) manages and allow applications to be accepted year around;

Business and Industry Loan Guaranteed Program. RD plans to rewrite the regulations, which will result in improved efficiency and effectiveness of the program, fewer errors because the guidelines and requirements will be clearer, and items will be more easily found in a better organized volume of regulations; and
Water and Waste Loans and Grants. RD will update the operations aspects of the loan and grant program to reduce the burden on the borrower.

Reducing the Paperwork Burden on Customers and Executive Order 13563

USDA has continued to make substantial progress in realizing the goal of the Paperwork Reduction Act. For example, the Farm and Foreign Agricultural Services (FFAS) mission area will reduce the paperwork burden on program participants by consolidating the information collections required to participate in farm programs administered by FSA and the Federal crop insurance program administered by the Risk Management Agency (RMA).

FFAS will evaluate methods to simplify and standardize, to the extent practical, acreage reporting processes, program dates, and data definitions across the various USDA programs and agencies. FFAS expects to allow producers to use information from their farm-management and precision agriculture systems for reporting production, planted and harvested acreage, and other key information needed to participate in USDA programs. FFAS will also streamline the collection of producer information by FSA and RMA with the agricultural production information collected by National Agricultural Statistics Service.

These process changes will allow for program data that is common across agencies to be collected once and utilized or redistributed to Agency programs in which the producer chooses to participate. FFAS plans to implement the Acreage and Crop Reporting Streamlining Initiative (ACRSI) in an incremental approach starting in late 2012 with a pilot in Kansas for growers of winter wheat when OMB approves the information collection. Full implementation is planned for 2013. When specific changes are identified, FSA and RMA will make any required conforming changes in their respective regulations.
Increasingly, USDA is providing electronic alternatives to its traditionally paper-based customer transactions. As a result, customers increasingly have the option to electronically file forms and other documentation online, allowing them to choose when and where to conduct business with USDA.

For example, Rural Development continues to review its regulations to determine which application procedures for Business Programs, Community Facilities Programs, Energy Programs, and Water and Environmental Programs can be streamlined and its requirements synchronized. RD is approaching the exercise from the perspective of the people it serves, by communicating with stakeholders on two common areas of regulation that can provide the basis of reform.

The first area provides support for entrepreneurship and business innovation. This initiative would provide for the streamlining and reformulating of the Business & Industry Loan Guarantee Program and the Intermediary Relending Program—the first such overhauls in over 20 years. The second area would provide for streamlining programs being made available to municipalities, tribes, and non-profit organizations; specifically Water and Waste Disposal, Community Facilities, and Rural Business Enterprise Grants, plus programs such as Electric and Telecommunications loans that provide basic community needs. This regulatory reform initiative has the potential to significantly reduce the burden to respondents (lenders and borrowers).

To the extent practicable, each reform initiative will consist of a common application and uniform documentation requirements making it easier for constituency groups to apply for multiple programs. In addition, there will be associated regulations for each program that will contain program specific information.

Natural Resources Conservation Service will also improve the delivery of technical and financial assistance by simplifying customer access to NRCS’ technical and financial assistance programs, streamlining the delivery and timeliness of conservation assistance to clients, and enhancing the technical quality of its conservation planning and services. The streamlining initiatives will allow NRCS field staff to
spend more time on conservation planning in the field with customers, reduce the time needed to implement cost-share contracts, and provide more flexibility for customers to work with NRCS in different ways. NRCS estimates that this initiative has the potential to reduce the amount of time required for producers to participate in USDA’s conservation programs by almost 800,000 hours annually. This includes efficiencies from reduced paperwork, data entry by the client, and reduced travel time to and from the local office to complete forms and other administrative tasks. Improvements being considered include the following:

- Providing an online portal that will allow customers to apply for programs or services, review their plans and contracts, view and assess natural resource information specifically about their farm, evaluate the costs and benefits for various conservation treatment alternatives, notify NRCS of installed practices, and check on contract payments at their convenience;
- Creating an e-customer profile that will improve customer service by allowing the client to view, finalize, and electronically sign documents using remote electronic signature, on-site rather than at a local office;
- Providing clients with more timely and specific information on alternative conservation treatments, including the environmental benefits of their planned and applied practices;
- Accelerating payments to clients; and
- Simplifying conservation plan documents to more specifically address client needs and goals.

**Major Regulatory Priorities**

This document represents summary information on prospective significant regulations as called for in E.O.s 12866 and 13563. The following USDA agencies are represented in this regulatory plan, along with a summary of their mission and key regulatory priorities in 2012:

*Food and Nutrition Service*
Mission: FNS increases food security and reduces hunger in partnership with cooperating organizations by providing children and low-income people access to food, a healthful diet, and nutrition education in a manner that supports American agriculture and inspires public confidence.

Priorities: In addition to responding to provisions of legislation authorizing and modifying Federal nutrition assistance programs, FNS’ 2012 regulatory plan supports USDA’s Strategic Goal “Ensure that all of America’s children have access to safe, nutritious, and balanced meals,” and its two related objectives:

Access to Nutritious Food. This objective represents FNS’s efforts to improve nutrition by providing access to program benefits (food consumed at home, school meals, commodities) and distributing State administrative funds to support program operations. To advance this objective, FNS plans to publish a final rule of the 2008 Farm Bill that ensures access to SNAP benefits and addresses other eligibility, certification, employment, and training issues. An interim rule, implementing provisions of the Child Nutrition and WIC Reauthorization Act of 2004 to establish automatic eligibility for homeless children for school meals, further supports this objective.

Promote Healthy Diet and Physical Activity Behaviors. This objective represents FNS’ efforts to improve the diets of its clients through nutrition education, support the national effort to reduce obesity by promoting healthy eating and physical activity, and to ensure that program benefits meet appropriate standards to effectively improve nutrition for program participants. In support of this objective, FNS plans to publish the final rule regarding the nutrition standards in the school meals programs, finalize a rule updating the WIC food packages, and establish permanent rules for the Fresh Fruit and Vegetable Program, which currently operates in a select number of schools in each State, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.
Mission: FSIS is responsible for ensuring that meat, poultry, egg, and catfish products in interstate and foreign commerce are wholesome, not adulterated, and properly marked, labeled, and packaged.

Priorities: FSIS is committed to developing and issuing science-based regulations intended to ensure that meat, poultry, egg, and catfish products are wholesome and not adulterated or misbranded. FSIS regulatory actions support the objective to protect public health by ensuring that food is safe under USDA’s goal to ensure access to safe food. To reduce the number of foodborne illnesses and increase program efficiencies, FSIS will continue to review its existing authorities and regulations to ensure that it can address emerging food safety challenges, to streamline excessively prescriptive regulations, and to revise or remove regulations that are inconsistent with the FSIS’ hazard analysis and critical control point (HACCP) regulations. FSIS is also working with the Food and Drug Administration (FDA) to improve coordination and increase the effectiveness of inspection activities. FSIS’ priority initiatives are as follows:

- Rulemakings that support initiatives of the President’s Food Safety Working Group:
  - Poultry Slaughter Inspection. Based on the Administration’s top-to-bottom review of food safety activities, the Food Safety and Inspection Service will issue regulations that will prevent thousands of food-borne illnesses by more clearly focusing FSIS inspection activities on improving food safety, streamline poultry inspections, and reduce Government spending.
  - Revision of Egg Products Inspection Regulations. FSIS is planning to propose requirements for federally inspected egg product plants to develop and implement HACCP systems and sanitation standard operating procedures. FSIS will be proposing pathogen reduction performance standards for egg products and will remove prescriptive requirements for egg product plants.
Initiatives that provide for disclosure or that enable economic growth. FSIS plans to issue two rules to promote disclosure of information to the public or that provide flexibility for the adoption of new technologies:

- **Product Labeling; Use of the Voluntary Claim "Natural" in the Labeling of Meat and Poultry Products.** FSIS will propose to amend the meat and poultry products regulations to define the conditions under which the voluntary claim “natural” may be used on meat and poultry product labeling.

- **Food Ingredients and Sources of Radiation Listed and Approved for Use in the Production of Meat and Poultry Products.** FSIS will propose to amend its food ingredient regulations to provide for the use under certain conditions of benzoic acid, sodium propionate, or sodium benzoate.

**Notification, Documentation, and Recordkeeping Requirements for Inspected Establishments.** As authorized by the 2008 Farm Bill, FSIS will issue final regulations that will require establishments that are subject to inspection to promptly notify FSIS when an adulterated or misbranded product received by or originating from the establishment has entered into commerce. The regulations also will require the establishments to prepare and maintain current procedures for the recall of all products produced and shipped by the establishments and to document each reassessment of the establishments’ process control plans.

**Catfish Inspection.** FSIS is developing final regulations to implement provisions of the 2008 Farm Bill provisions that make catfish an amenable species under the Federal Meat Inspection Act (FMIA).

**Public Health Information System.** To support its food safety inspection activities, FSIS is implementing the Public Health Information System (PHIS). PHIS, which is user-friendly and Web-based, will replace many of FSIS’ current systems and automate many business processes. PHIS also will
improve FSIS’ ability to systematically verify the effectiveness of foreign food safety systems and enable
greater exchange of information between FSIS and other Federal agencies (such as U. S. Customs and
Border Protection) involved in tracking cross-border movement of import and export shipments of meat,
poultry, and processed egg products. To facilitate the implementation of some PHIS components, FSIS
is proposing to provide for electronic export and import application and certification processes as
alternatives to the current paper-based systems for these certifications.

Other Planned Initiatives. FSIS plans to finalize a February 2001 proposed rule to establish food
safety performance standards for all processed ready-to-eat (RTE) meat and poultry products and for
partially heat-treated meat and poultry products that are not ready-to-eat. Some provisions of the
proposal addressed post-lethality contamination of RTE products with Listeria monocytogenes. In June
2003, FSIS published an interim final rule requiring establishments to prevent L. monocytogenes
contamination of RTE products. FSIS has carefully reviewed its economic analysis of the interim final rule
and is planning to affirm the interim rule as a final rule with changes.

FSIS Small Business Implications. The great majority of businesses regulated by FSIS are small
businesses. Some of the regulations listed above substantially affect small businesses. FSIS conducts a
small business outreach program that provides critical training, access to food safety experts, and
information resources (such as compliance guidance and questions and answers on various topics) in
forms that are uniform, easily comprehended, and consistent. FSIS collaborates in this effort with other
USDA agencies and cooperating State partners. For example, FSIS makes plant owners and operators
aware of loan programs, available through USDA’s Rural Business and Cooperative programs, to help
them in upgrading their facilities. FSIS employees meet with small and very small plant operators to learn
more about their specific needs and provide joint training sessions for small and very small plants and
FSIS employees.

Animal and Plant Health Inspection Service
Mission: A major part of the mission of the Animal and Plant Health Inspection Service (APHIS) is to protect the health and value of American agricultural and natural resources. APHIS conducts programs to prevent the introduction of exotic pests and diseases into the U.S. and conducts surveillance, monitoring, control, and eradication programs for pests and diseases in this country. These activities enhance agricultural productivity and competitiveness and contribute to the national economy and the public health. APHIS also conducts programs to ensure the humane handling, care, treatment, and transportation of animals under the Animal Welfare Act.

Priorities: With respect to animal health, APHIS is continuing work to revise its regulations concerning bovine spongiform encephalopathy (BSE) to provide a more comprehensive and universally applicable framework for the importation of certain animals and products. In the area of plant health, APHIS is in the midst of a revision to its regulations for the importation and interstate movement of plant pests and biological control organisms to clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms, facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture, and address gaps in the current regulations. APHIS also plans to propose standards for the humane handling, care, treatment, and transportation of birds covered under the Animal Welfare Act.

Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

Agricultural Marketing Service

Mission: The Agricultural Marketing Service (AMS) provides marketing services to producers, manufacturers, distributors, importers, exporters, and consumers of food products. The AMS also manages the Government's food purchases, supervises food quality grading, maintains food quality standards, and supervises the Federal research and promotion programs.
Priorities: AMS’ priority items for the next year include rulemaking that impact the organic industry, as well as the wholesale pork industry. Rulemakings the Agency intends to initiate within the next 12 months include:

Sunset Review (2012)—Nutrient Vitamins and Minerals. On March 26, 2010, the National Organic Program (NOP) issued an Advanced Notice of Proposed Rulemaking (ANPRM) announcing the National Organic Standards Board’s (NOSB) sunset review of exempted and prohibited substances codified at the National List of Allowed and Prohibited Substances of the NOP regulations. This review included a listing for “Nutrient vitamins and minerals” scheduled to sunset on October 21, 2012. AMS intends to publish a proposed rule to address a recommendation submitted by the NOSB for this listing. This proposed rule would continue the exemption (use) for nutrient vitamins and minerals for 5 years after the October 21, 2012, sunset date. This proposed rule would amend the annotation for nutrient vitamins and minerals to correct an inaccurate cross reference to U.S. Food and Drug Administration (FDA) regulations as AMS determined that the current exemption for the use of nutrient vitamins and minerals in organic products in the NOP regulations is inaccurate. In effect, the proposed amendment would clarify what synthetic substances are allowed as nutrient vitamins and minerals in organic products. Further, the NOP regulations do not correctly provide for the fortification of infant formula that would meet FDA requirements. This proposed rule would incorporate the correct FDA citation with respect to the addition of required vitamins and minerals to organic infant formula.

Livestock Mandatory Reporting; Establishing Regulations for Wholesale Pork. As directed by the 2008 Farm Bill, the Secretary conducted a study to determine advantages, drawbacks, and potential implementation issues associated with adopting mandatory wholesale pork reporting. The report from this study concluded that negotiated wholesale pork price reporting is thin and becoming thinner and found some degree of support for moving to mandatory price reporting exists at every segment of the industry interviewed. That study also concluded that the benefits likely would exceed the cost of moving from a voluntary to a mandatory reporting program for wholesale pork.
Subsequently, the Mandatory Price Reporting Act of 2010 (2010 Reauthorization Act) (Pub. L. 111-239), was signed into law on September 28, 2010, and reauthorized Livestock Mandatory Reporting for 5 years and added a provision for mandatory reporting of wholesale pork cuts. The 2010 Reauthorization Act directed the Secretary to engage in negotiated rulemaking to make required regulatory changes for mandatory wholesale pork reporting.

Further, the 2010 Reauthorization Act directed the Secretary to establish a Committee that represented the spectrum of interests within the pork industry, as well as related stakeholders, to ensure all parties had input into the regulatory framework. Specifically, the statute required that the Committee include representatives from (i) organizations representing swine producers; (ii) organizations representing packers of pork, processors of pork, retailers of pork, and buyers of wholesale pork; (iii) Department of Agriculture; and (iv) interested parties that participate in swine or pork production.

The Agricultural Marketing Service (AMS) convened the Wholesale Pork Reporting Negotiated Rulemaking Committee (Committee) through notice in the Federal Register on January 26, 2011. The Committee met three times over the period February through May of 2011 to develop the regulatory framework necessary to implement a mandatory program of wholesale pork reporting.

The regulatory text developed by the Committee will serve as the primary basis for the proposed rule, consistent with both the intent of Congress and the Negotiated Rulemaking Act. It is important to note that the Committee reached consensus on all items included in the proposed rule—where consensus was defined by the Committee bylaws as being unanimous agreement. Therefore, AMS is confident the proposed rule to implement wholesale pork reporting will be met with little or no resistance from the industry members who will be required to report under the mandatory system.
**Grain Inspection, Packers, and Stockyards Administration**

Mission: The Grain Inspection, Packers, and Stockyards Administration (GIPSA) facilitates the marketing of livestock, poultry, meat, cereals, oilseeds, and related agricultural products and promotes fair and competitive trading practices for the overall benefit of consumers and American agriculture. GIPSA’s activities contribute significantly to USDA’s goal to increase prosperity in rural areas by supporting a competitive agricultural system.

Priorities: GIPSA intends to issue a final rule that will define practices or conduct that are unfair, unjustly discriminatory, or deceptive, and/or that represent the making or giving of an undue or unreasonable preference or advantage, and ensure that producers and growers can fully participate in any arbitration process that may arise relating to livestock or poultry contracts. This regulation is being finalized in accordance with the authority granted to the Secretary by the Packers and Stockyards Act of 1921 and with the requirements of sections 11005 and 11006 of the 2008 Farm Bill.

**Farm Service Agency**

Mission: FSA’s mission is to equitably serve all farmers, ranchers, and agricultural partners through the delivery of effective, efficient agricultural programs, which contributes to two USDA goals: Assist rural communities in creating prosperity so they are self-sustaining, re-populating, and economically thriving; and enhance the Nation’s natural resource base by assisting owners and operators of farms and ranches to conserve and enhance soil, water, and related natural resources. FSA supports the first goal by stabilizing farm income, providing credit to new or existing farmers and ranchers who are temporarily unable to obtain credit from commercial sources, and helping farm operations recover from the effects of disaster. FSA supports the second goal by administering several conservation programs directed toward agricultural producers. The largest program is the Conservation Reserve Program (CRP), which protects nearly 32 million acres of environmentally sensitive land.

Priorities:
Farm Loan Programs. FSA will develop and issue regulations to amend programs for farm operating loans, down payment loans, and emergency loans to include socially disadvantaged farmers, increase loan limits, loan size, funding targets, interest rates, and graduating borrowers to commercial credit. In addition, FSA will further streamline normal loan servicing activities and reduce burden on borrowers while still protecting the loan security.

Disaster Designation. FSA will revise the disaster designation process to streamline it and reduce the burden on States and tribes requesting disaster designations. One result may be fewer delays in delivering disaster assistance to help farm operations recover from the effects of disaster.

Forest Service

Mission: The mission of the Forest Service is to sustain the health, productivity, and diversity of the Nation's forests and rangelands to meet the needs of present and future generations. This includes protecting and managing National Forest System lands, providing technical and financial assistance to States, communities, and private forest landowners, and developing and providing scientific and technical assistance and scientific exchanges in support of international forest and range conservation. FS' regulatory priorities support the accomplishment of USDA's goal to ensure our national forests are conserved, restored, and made more resilient to climate change, while enhancing our water resources.

Priorities:

Special Areas; State-Specific Inventoried Roadless Area Management: Colorado. FS planned final rulemaking would establish a State-specific rule to provide management direction for conserving and managing inventoried roadless areas on National Forest System lands in the State of Colorado.

Land Management Planning Rule. FS is required to issue rulemaking for National Forest System land management planning under 16 U.S.C. 1604. The first planning rule was adopted in 1979, and amended
in 1982. FS published a new planning rule on April 21, 2008 (73 FR 21468). On June 30, 2009, the United States District Court for the Northern District of California invalidated FS’ 2008 Planning Rule published at 36 CFR 219 based on violations of NEPA and the Endangered Species Act in the rulemaking process. The District Court vacated the 2008 rule, enjoined USDA from further implementing it, and remanded it to USDA for further proceedings. USDA has determined that the 2000 planning rule is now in effect, including its transition provisions as amended in 2002 and 2003, and as clarified by interpretative rules issued in 2001 and 2004, which allows the use of the provisions of the 1982 planning rule to amend or revise plans. FS is now in the 2000 planning rule transition period. FS published a proposed planning rule on February 14, 2011 (76 FR 8480). The final rule is expected to be published December 2011. In so doing, FS plans to correct deficiencies that have been identified over two decades of forest planning and update planning procedures to reflect contemporary collaborative planning practices.

Community Forest and Open Space Conservation Program. The purpose of the Community Forest Program is to achieve community benefits through financial assistance grants to local governments, tribal governments, and nonprofit organizations to establish community forests by acquiring and protecting private forestlands. Community forest benefits are specified in the authorizing statute and include economic benefits from sustainable forest management, natural resource conservation, forest-based educational programs, model forest stewardship activities, and recreational opportunities.

Rural Business-Cooperative Service

Mission: Promoting a dynamic business environment in rural America is the goal of the Rural Business-Cooperative Service (RBS). Business Programs works in partnership with the private sector and the community-based organizations to provide financial assistance and business planning, and helps fund projects that create or preserve quality jobs and/or promote a clean rural environment. The financial resources are often leveraged with those of other public and private credit source lenders to meet business and credit needs in under-served areas. Recipients of these programs may include individuals,
corporations, partnerships, cooperatives, public bodies, nonprofit corporations, Indian tribes, and private companies. The mission of Cooperative Programs of RBS is to promote understanding and use of the cooperative form of business as a viable organizational option for marketing and distributing agricultural products.

Priorities: In support USDA’s goal to increase the prosperity of rural communities, RBS regulatory priorities will facilitate sustainable renewable energy development and enhance the opportunities necessary for rural families to thrive economically. RBS’ priority will be to publish regulations to fully implement the 2008 Farm Bill. This includes promulgating regulations for the Biorefinery Assistance Program (sec. 9003), the Repowering Assistance Program (sec. 9004), the Bioenergy Program for Advanced Biofuels (sec. 9005), and the Rural Microentrepreneur Assistance Program (RMAP). RBS has been administering sections 9003, 9004, and 9005 through the use of Notices of Funds Availability and Notices of Contract Proposals. Revisions to the Rural Energy for America Program (sec. 9007) will be made to incorporate Energy Audits and Renewable Energy Development Assistance and Feasibility Studies for Rural Energy Systems as eligible grant purposes, as well as other Farm Bill initiatives and various technical changes throughout the rule. In addition, revisions to the Business and Industry Guaranteed Loan Program will be made to implement 2008 Farm Bill provisions and other program initiatives. These rules will minimize program complexity and burden on the public while enhancing program delivery and RBS oversight.

*Rural Utilities Service*

Mission: The mission of the Rural Utilities Service (RUS) is to improve the quality of life in rural America by providing investment capital for the deployment of critical rural utilities telecommunications, electric, and water and waste disposal infrastructure. Financial assistance is provided to rural utilities, municipalities, commercial corporations, limited liability companies, public utility districts, Indian tribes, and cooperative, non-profit, limited-dividend, or mutual associations. The public-private partnership,
which is forged between RUS and these industries, results in billions of dollars in rural infrastructure development and creates thousands of jobs for the American economy.

Priorities: RUS’ regulatory priorities will be to achieve the President’s goal to bring affordable broadband to all rural Americans. To accomplish this, RUS will continue to improve the Broadband Program established by the 2002 Farm Bill. The 2002 Farm Bill authorized RUS to approve loans and loan guarantees for the costs of construction, improvement, and acquisition of facilities and equipment for broadband service in eligible rural communities. The 2008 Farm Bill significantly changed the statutory requirements of the Broadband Loan Program. As such, RUS issued an interim rule to implement the statutory changes and requested comments on the section of the rule that was not part of the proposed rule published in May 2007. Comments were received and the agency will analyze the comments and finalize the rule.

Departmental Management

Mission: Departmental Management’s mission is to provide management leadership to ensure that USDA administrative programs, policies, advice, and counsel meet the needs of USDA program organizations, consistent with laws and mandates, and provide safe and efficient facilities and services to customers.

Priorities: In support of the Department’s goal to increase rural prosperity, USDA’s departmental management will finalize regulations to revise the BioPreferred program guidelines to continue adding designated product categories to the preferred procurement program, including intermediates and feedstocks and finished products made of intermediates and feedstocks.

Aggregate Costs and Benefits
USDA will ensure that its regulations provide benefits that exceed costs but is unable to provide an estimate of the aggregated impacts of its regulations. Problems with aggregation arise due to differing baselines, data gaps, and inconsistencies in methodology and the type of regulatory costs and benefits considered. Some benefits and costs associated with rules listed in the regulatory plan cannot currently be quantified as the rules are still being formulated. For 2012, USDA's focus will be to implement the changes to programs in such a way as to provide benefits while minimizing program complexity and regulatory burden for program participants.

USDA—Agricultural Marketing Service (AMS)  PROPOSED RULE STAGE

1. WHOLESALE PORK REPORTING PROGRAM

Priority:
Other Significant

Legal Authority:
7 USC 1635 to 1636

CFR Citation:
7 CFR 59

Legal Deadline:

With the passage of S. 3656, the Mandatory Price Reporting Act of 2010, the Secretary of Agriculture is required to amend chapter 3 of subtitle B of the Agricultural Marketing Act of 1946 by adding a new section for mandatory reporting of wholesale pork cuts. To make these amendments, the Secretary was directed to promulgate a final rule no later than 1 1/2 years after the date of the enactment of the Act. Accordingly, a final rule will be promulgated by March 28, 2012.

Abstract:

On September 15, 2010, Congress passed the Mandatory Price Reporting Act of 2010 reauthorizing Livestock Mandatory Reporting for 5 years and adding a provision for mandatory reporting of wholesale pork cuts. The Act was signed by the President on September 28, 2010. Congress directed the Secretary
to engage in negotiated rulemaking to make required regulatory changes for mandatory wholesale pork reporting. Further, Congress required that the negotiated rulemaking committee include representatives from (i) organizations representing swine producers; (ii) organizations representing packers of pork, processors of pork, retailers of pork, and buyers of wholesale pork; (iii) the Department of Agriculture; and (iv) interested parties that participate in swine or pork production.

**Statement of Need:**

Implementation of mandatory pork reporting is required by Congress. Congress delegated responsibility to the Secretary for determining what information is necessary and appropriate. The Food, Conservation, and Energy Act of 2008 (Pub. L. 110-234) directed the Secretary to conduct a study to determine advantages, drawbacks, and potential implementation issues associated with adopting mandatory wholesale pork reporting. The report from this study generally concluded that voluntary wholesale pork price reporting is thin and becoming thinner, and some degree of support for moving to mandatory price reporting exists at every segment of the industry interviewed. The report was delivered to Congress on March 25, 2010.

**Summary of Legal Basis:**

Livestock Mandatory Reporting is authorized under the Agricultural Marketing Act (7 U.S.C. 1635 to 1636). The Livestock and Seed Program of USDA's Agricultural Marketing Service has day-to-day responsibility for collecting and disseminating LMR data.

**Alternatives:**

There are no alternatives, as this rulemaking is a matter of law based on the Mandatory Price Reporting Act of 2010.

**Anticipated Cost and Benefits:**

Estimation of costs will follow the previous methodology used in earlier Livestock Mandatory Reporting rulemaking. The focus of the cost estimation is the burden placed on reporting companies in providing pork marketing data to the Livestock and Seed Program. Previous rulemaking cost estimates of boxed beef reporting of similar data found the burden to be an annual total of 65 hours in additional reporting requirements per firm. Because no official USDA grade standards are used in the marketing of pork, and
there are fewer cutting styles, the burden for pork reporting firms in comparison with beef reporting firms could be lower. However, the impact is not truly known at this stage.

**Risks:**

Implementing wholesale pork reporting presents few risks to the Agency and the impacted industry. Members of the industry who served on the negotiated rulemaking committee expressed some concern with reporting prices under a different reporting basis than what is used for voluntary pork reporting. However, ultimately the committee reached consensus on having prices reporting on both an FOB Omaha and FOB Plant basis in order to reduce market volatility.

**Timetable:**

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<td>11/24/10</td>
<td>75 FR 71568</td>
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<td>01/26/11</td>
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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Agency Contact:**

Michael P. Lynch

Department of Agriculture

Agricultural Marketing Service

14th and Independence Avenue SW

Washington, DC 20250
2. NATIONAL ORGANIC PROGRAM: SUNSET REVIEW FOR NUTRIENT VITAMINS AND MINERALS (NOP–10–0083)

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

7 USC 6501

CFR Citation:

7 CFR 205

Legal Deadline:

None

Abstract:

This proposed rule would address a recommendation submitted to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB) on April 29, 2011. The recommendation pertains to the 2012 Sunset Review of the listing for nutrient vitamins and minerals on the U.S. Department of Agriculture's (USDA) National List of Allowed and Prohibited Substances (National List). As recommended by the NOSB, the proposed rule would continue the exemption (use) for nutrient vitamins and minerals for 5 years after the October 21, 2012, sunset date. In addition, the proposed rule would amend the annotation to correct an inaccurate cross reference to U.S. Food and Drug Administration regulations. The proposed amendment to the annotation would clarify what synthetic substances are allowed as nutrient vitamins and minerals in organic products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

Statement of Need:
The Agricultural Marketing Service (AMS) has determined that the current exemption for the use of nutrient vitamins and minerals in organic products in the National Organic Program (NOP) regulations (7 CFR part 205) is inaccurate. The proposed rule would amend the annotation for nutrient vitamins and minerals to correct an inaccurate cross reference to U.S. Food and Drug Administration (FDA) regulations. In effect, the proposed amendment would clarify what synthetic substances are allowed as nutrient vitamins and minerals in organic products. Further, the NOP regulations do not correctly provide for the fortification of infant formula that would meet FDA requirements. This proposed rule would incorporate the correct FDA citation with respect to the addition of required vitamins and minerals to organic infant formula.

Summary of Legal Basis:

This proposed rule would address a recommendation submitted to the Secretary of Agriculture by the National Organic Standards Board (NOSB) on April 29, 2011, to continue the exemption for nutrient vitamins and minerals in organic products as provided by the NOP National List of Allowed and Prohibited Substances (National List). The Organic Foods Production Act of 1990 (OFPA) authorizes the Secretary to amend the National List based on proposed amendments developed by the NOSB. The Sunset Provision, in section 6517(e) of the OFPA, provides that no exemption or prohibition on the National List will remain valid after 5 years unless the exemption or prohibition has been reviewed and the Secretary renews the listing. The exemption for nutrient vitamins and minerals is scheduled to sunset on October 21, 2012.

Alternatives:

AMS considered two alternatives to this proposed rulemaking: (1) Renew the existing listing for nutrient vitamins and minerals or (2), in lieu of a rule, issue guidance stating NOP's intent to interpret the current listing for nutrient vitamins and minerals as proposed in this action. AMS determined that neither alternative is viable as both would retain a regulatory provision that is inaccurate and remains vulnerable to misinterpretations of what substances are permitted in organic products.

Anticipated Cost and Benefits:

This proposed rule would establish a finite list of essential and required vitamins and minerals for use in organic food and infant formula. The action addresses the requests of a broad spectrum of public
commenters for clarification on the parameters for adding nutrient vitamins and minerals to organic products and is expected to reduce the submission of consumer complaints alleging the unlawful addition of substances to organic products. This proposed rule would also provide more certainty to certifying agents and organic operations in determining whether substances are acceptable for use in organic products. Further, this proposed action also would foster greater transparency by ensuring that exemptions for the use of vitamins, minerals, and other nutrients are subject to National Organic Standards Board (NOSB) evaluation in accordance with the criteria established in OFPA.

This action could directly impact a subset of certified organic operations, which add substances to organic products that are not essential vitamins and minerals for human nutrition (21 CFR 101.9) or required vitamins and minerals for infant formula (21 CFR 107.100 or 107.10), as enumerated by FDA regulation. AMS believes the impacts will be concentrated within five categories of organic products in which nutrient supplementation has been more prevalent: Infant formula, baby food, milk, breakfast cereal, and pet food. The proposed rule could indirectly impact producers who supply organic agricultural commodities to affected product categories. However, AMS expects that there will be opportunities for producers to divert organic agricultural products to other purchasers to buffer the impact of any disruption to the manufacture of certain processed organic products as a result of this proposed action.

There are several impact mitigation factors which are expected to reduce the costs of complying with this proposed action. AMS is proposing a 2-year implementation phase, which is intended to provide time for NOSB to consider petitions for substances that are affected by this action and for AMS to conclude any rulemaking to add substances to the National List. The implementation phase would also provide entities the time to explore reformulation of affected products. Further, if some products are discontinued as a result of this proposed rule, AMS anticipates that some consumers will purchase, as an alternative, an organic product within the same category rather than a nonorganic product.

**Risks:**

For the 2-year implementation phase to function as a mitigation measure, the timeframe may be tight to complete the review of petitions received by publication of this proposed rule and for any rulemaking
action recommended by NOSB. Therefore, AMS has requested comments on the length of the
implementation phase as part of this proposed rule.

Timetable:

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Regulatory Flexibility Analysis Required:
Undetermined

Government Levels Affected:
Local, State

Agency Contact:
Melissa R. Bailey
Director, Standards Division
Department of Agriculture
Agricultural Marketing Service
Washington, DC 20250
Phone: 202 720–3252
Fax: 202 205–7808
Email: melissa.bailey@usda.gov

Related RIN: Split from 0581–AC96
RIN: 0581–AD17
Other Significant Legal Authority:
7 USC 2131 to 2159
CFR Citation:
9 CFR 1 to 3
Legal Deadline:
None
Abstract:
APHIS intends to establish standards for the humane handling, care, treatment, and transportation of birds other than birds bred for use in research.

Statement of Need:
The Farm Security and Rural Investment Act of 2002 amended the definition of animal in the Animal Welfare Act (AWA) by specifically excluding birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research. While the definition of animal in the regulations contained in 9 CFR part 1 has excluded rats of the genus Rattus and mice of the genus Mus bred for use in research, that definition has also excluded all birds (i.e., not just those birds bred for use in research). In line with this change to the definition of animal in the AWA, APHIS intends to establish standards in 9 CFR part 3 for the humane handling, care, treatment, and transportation of birds other than those birds bred for use in research and to revise the regulations in 9 CFR parts 1 and 2 to make them applicable to birds.

Summary of Legal Basis:
The Animal Welfare Act (AWA) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, operators of auction sales, and carriers and immediate handlers. Animals covered by the AWA include birds that are not bred for use in research.

Alternatives:
To be identified.

Anticipated Cost and Benefits:
Benefits of the rule would stem from improvements in the humane handling and care of birds by affected dealers, exhibitors, carriers, and intermediate handlers. At a minimum, these entities would be required to satisfy certain reporting provisions and undergo periodic compliance inspections by APHIS—measures that they are not subject to now with respect to birds. Regulated entities, therefore, may incur certain costs because of the proposed rule. Most facilities that use birds in research, such as pharmaceutical companies, universities, and research institutes, would not be affected. Retail pet stores could be affected to the extent that regulatory costs are passed on to them by breeders and other suppliers.

Most entities affected by the proposal are likely to be small in size, based on Small Business Administration standards. We have not been able to conduct a comprehensive analysis of the rule’s potential economic impact because of the paucity of available data on the affected industries. APHIS welcomes public comment that would permit a more complete assessment of the proposed rule’s impact.

Risks:
Not applicable.

Timetable:

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Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Businesses

Government Levels Affected:
Undetermined

Additional Information:
Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

Agency Contact:
4. PLANT PEST REGULATIONS; UPDATE OF GENERAL PROVISIONS

Priority:
Other Significant

Legal Authority:
7 USC 450; 7 USC 2260; 7 USC 7701 to 7772; 7 USC 7781 to 7786; 7 USC 8301 to 8817; 19 USC 136;
21 USC 111; 21 USC 114a; 21 USC 136 and 136a; 31 USC 9701; 42 USC 4331 and 4332

CFR Citation:
7 CFR 318 and 319; 7 CFR 330; 7 CFR 352

Legal Deadline:
None

Abstract:
We are proposing to revise our regulations regarding the movement of plant pests. We are proposing to
regulate the movement of, not only plant pests, but also biological control organisms and associated
articles. We are proposing risk-based criteria regarding the movement of biological control organisms and
are proposing to exempt certain types of plant pests from permitting requirements for their interstate
movement and movement for environmental release. We are also proposing to revise our regulations
regarding the movement of soil and to establish regulations governing the biocontainment facilities in
which plant pests, biological control organisms, and associated articles are held. This proposed rule replaces a previously published proposed rule, which we are withdrawing as part of this document. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms, facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture, and address gaps in the current regulations.

**Statement of Need:**
APHIS is preparing a proposed rule to revise its regulations regarding the movement of plant pests. The revised regulations would address the importation and interstate movement of plant pests, biological control organisms, and associated articles, and the release into the environment of biological control organisms. The revision would also address the movement of soil and establish regulations governing the biocontainment facilities in which plant pests, biological control organisms, and associated articles are held. This proposal would clarify the factors that would be considered when assessing the risks associated with the movement of certain organisms, facilitate the movement of regulated organisms and articles in a manner that also protects U.S. agriculture, and address gaps in the current regulations.

**Summary of Legal Basis:**
Under section 411(a) of the Plant Protection Act (PPA), no person shall import, enter, export, or move in interstate commerce any plant pest, unless the importation, entry, exportation, or movement is authorized under a general or specific permit and in accordance with such regulations as the Secretary of Agriculture may issue to prevent the introduction of plant pests into the United States or the dissemination of plant pests within the United States.

Under section 412 of the PPA, the Secretary may restrict the importation or movement in interstate commerce of biological control organisms by requiring the organisms to be accompanied by a permit authorizing such movement and by subjecting the organisms to quarantine conditions or other remedial measures deemed necessary to prevent the spread of plant pests or noxious weeds. That same section of the PPA also gives the Secretary explicit authority to regulate the movement of associated articles.

**Alternatives:**
The alternatives we considered were taking no action at this time or implementing a comprehensive risk reduction plan. This latter alternative would be characterized as a broad risk mitigation strategy that could involve various options such as increased inspection, regulations specific to a certain organism or group of related organisms, or extensive biocontainment requirements.

We decided against the first alternative because leaving the regulations unchanged would not address the needs identified immediately above. We decided against the latter alternative, because available scientific information, personnel, and resources suggest that it would be impracticable at this time.

**Anticipated Cost and Benefits:**
To be determined.

**Risks:**

Unless we issue such a proposal, the regulations will not provide a clear protocol for obtaining permits that authorize the movement and environmental release of biological control organisms. This, in turn, could impede research to explore biological control options for various plant pests and noxious weeds known to exist within the United States, and could indirectly lead to the further dissemination of such pests and weeds.

Moreover, unless we revise the soil regulations, certain provisions in the regulations will not adequately address the risk to plants, plant parts, and plant products within the United States that such soil might present.

**Timetable:**

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Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Businesses, Organizations

Government Levels Affected:
Local, State, Tribal

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Additional Information:
Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

Agency Contact:
Shirley Wager–Page
Chief, Pest Permitting Branch, Plant Health Programs, PPQ
Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road, Unit 131
Riverdale, MD 20737–1236
Phone: 301 734–8453
RIN: 0579–AC98

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USDA—APHIS | FINAL RULE STAGE
---|---
5. IMPORTATION OF LIVE DOGS

Priority:
Other Significant

Legal Authority:
7 USC 2148

**CFR Citation:**
9 CFR 1 and 2

**Legal Deadline:**
None

**Abstract:**
This rulemaking would amend the Animal Welfare Act (AWA) regulations to regulate dogs imported for resale as required by a recent amendment to the AWA. Importation of dogs for resale would be prohibited unless the dogs are in good health, have all necessary vaccinations, and are 6 months of age or older. This proposal would also reflect the exemptions provided in the amendment to the AWA for dogs imported for research purposes or veterinary treatment and for dogs legally imported into the State of Hawaii from the British Isles, Australia, Guam, or New Zealand.

**Statement of Need:**
The Food, Conservation, and Energy Act of 2008 mandates that the Secretary of Agriculture promulgate regulations to implement and enforce new provisions of the Animal Welfare Act (AWA) regarding the importation of dogs for resale. In line with the changes to the AWA, APHIS intends to amend the regulations in 9 CFR parts 1 and 2 to regulate the importation of dogs for resale.

**Summary of Legal Basis:**
The Food, Conservation, and Energy Act of 2008 (Pub. L. 110-246, signed into law on Jun. 18, 2008) added a new section to the Animal Welfare Act (7 U.S.C. 2147) to restrict the importation of live dogs for resale. As amended, the AWA now prohibits the importation of dogs into the United States for resale unless the Secretary of Agriculture determines that the dogs are in good health, have received all necessary vaccinations, and are at least 6 months of age. Exceptions are provided for dogs imported for research purposes or veterinary treatment. An exception to the 6-month age requirement is also provided for dogs that are lawfully imported into Hawaii for resale purposes from the British Isles, Australia, Guam, or New Zealand in compliance with the applicable regulations of Hawaii, provided the dogs are vaccinated, are in good health, and are not transported out of Hawaii for resale purposes at less than 6 months of age.
Alternatives:
To be identified.

Anticipated Cost and Benefits:
To be determined.

Risks:
Not applicable.

Timetable:

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Regulatory Flexibility Analysis Required:
Undetermined

Government Levels Affected:
None

Additional Information:
Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

Agency Contact:
Gerald Rushin
Veterinary Medical Officer, Animal Care
Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road, Unit 84
Riverdale, MD 20737–1234
Phone: 301 734–0954

RIN: 0579–AD23
6. ANIMAL DISEASE TRACEABILITY

Priority:
Other Significant

Legal Authority:
7 USC 8305

CFR Citation:
9 CFR 90

Legal Deadline:
None

Abstract:
This rulemaking would establish a new part in the Code of Federal Regulations containing minimum national identification and documentation requirements for livestock moving interstate. The proposed regulations specify approved forms of official identification for each species covered under this rulemaking but would allow such livestock to be moved interstate with another form of identification, as agreed upon by animal health officials in the shipping and receiving States or tribes. The purpose of the new regulations is to improve our ability to trace livestock in the event that disease is found.

Statement of Need:
Preventing and controlling animal disease is the cornerstone of protecting American animal agriculture. While ranchers and farmers work hard to protect their animals and their livelihoods, there is never a guarantee that their animals will be spared from disease. To support their efforts, USDA has enacted regulations to prevent, control, and eradicate disease, and to increase foreign and domestic confidence in the safety of animals and animal products. Traceability helps give that reassurance. Traceability does not prevent disease, but knowing where diseased and at-risk animals are, where they have been, and when, is indispensable in emergency response and in ongoing disease programs. The primary objective of these proposed regulations is to improve our ability to trace livestock in the event that disease is found in a manner that continues to ensure the smooth flow of livestock in interstate commerce.
**Summary of Legal Basis:**
Under the Animal Health Protection Act (7 U.S.C. 8301 et seq.), the Secretary of Agriculture may prohibit or restrict the interstate movement of any animal to prevent the introduction or dissemination of any pest or disease of livestock, and may carry out operations and measures to detect, control, or eradicate any pest or disease of livestock. The Secretary may promulgate such regulations as may be necessary to carry out the Act.

**Alternatives:**
As part of its ongoing efforts to safeguard animal health, APHIS initiated implementation of the National Animal Identification System (NAIS) in 2004. More recently, the Agency launched an effort to assess the level of acceptance of NAIS through meetings with the Secretary, listening sessions in 14 cities, and public comments. Although there was some support for NAIS, the vast majority of participants were highly critical of the program and of USDA's implementation efforts. The feedback revealed that NAIS has become a barrier to achieving meaningful animal disease traceability in the United States in partnership with America's producers.

The option we are proposing pertains strictly to interstate movement and gives States and tribes the flexibility to identify and implement the traceability approaches that work best for them.

**Anticipated Cost and Benefits:**
A workable and effective animal traceability system would enhance animal health programs, leading to more secure market access and other societal gains. Traceability can reduce the cost of disease outbreaks, minimizing losses to producers and industries by enabling current and previous locations of potentially exposed animals to be readily identified. Trade benefits can include increased competitiveness in global markets generally, and when outbreaks do occur, the mitigation of export market losses through regionalization. Markets benefit through more efficient and timely epidemiological investigation of animal health issues.

Other societal benefits include improved animal welfare during natural disasters.
The main economic effect of the rule is expected to be on the beef and cattle industry. For other species such as horses and other equine species, poultry, sheep and goats, swine, and captive cervids, APHIS would largely maintain and build on the identification requirements of existing disease program regulations.

Costs of an animal traceability system would include those for tags and interstate certificates of veterinary inspection (ICVIs) or other movement documentation, for animals moved interstate. Incremental costs incurred are expected to vary depending upon a number of factors, including whether an enterprise does or does not already use eartags to identify individual cattle. For many operators, costs of official animal identification and ICVIs would be similar, respectively, to costs associated with current animal identification practices and the in-shipment documentation currently required by individual States. To the extent that official animal identification and ICVIs would simply replace current requirements, the incremental costs of the rule for private enterprises would be minimal.

Risks:
This rulemaking is being undertaken to address the animal health risks posed by gaps in the existing regulations concerning identification of livestock being moved interstate. The current lack of a comprehensive animal traceability program is impairing our ability to trace animals that may be infected with disease.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
Businesses

Government Levels Affected:
Additional Information:

Additional information about APHIS and its programs is available on the Internet at http://www.aphis.usda.gov.

Agency Contact:

Neil Hammerschmidt
Program Manager, Animal Disease Traceability, VS
Department of Agriculture
Animal and Plant Health Inspection Service
4700 River Road, Unit 46
Riverdale, MD 20737–1231
Phone: 301 734–5571

RIN: 0579–AD24

7. SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM: FARM BILL OF 2008 RETAILER SANCTIONS

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
PL 110–246

CFR Citation:
7 CFR 276

Legal Deadline:
None

Abstract:
This proposed rule would implement provisions under section 4132 of the Food, Conservation, and Energy Act of 2008, also referred to as the Farm Bill of 2008. Under section 4132, the Department of Agriculture's Food and Nutrition Service (FNS) is provided with greater authority and flexibility when sanctioning retail or wholesale food stores that violate Supplemental Nutrition Assistance Program (SNAP) rules. Specifically, the Department is authorized to assess a civil penalty and to disqualify a retail or wholesale food store authorized to participate in SNAP. Previously, the Department could assess a civil penalty or disqualification, but not both. Section 4132 also eliminates the minimum disqualification period, which was previously set at 6 months.

Statement of Need:
This proposed rule would implement provisions under section 4132 of the Food, Conservation, and Energy Act of 2008, also referred to as the Farm Bill of 2008. Under section 4132, the Department of Agriculture’s Food and Nutrition Service (FNS) is provided with greater authority and flexibility when sanctioning retail or wholesale food stores that violate Supplemental Nutrition Assistance Program (SNAP) rules. Specifically, the Department is authorized to assess a civil penalty and to disqualify a retail or wholesale food store authorized to participate in SNAP. Previously, the Department could assess a civil penalty or disqualification, but not both. Section 4132 also eliminates the minimum disqualification period, which was previously set at 6 months. In addition to implementing statutory provisions, this rule proposes to provide a clear administrative penalty when an authorized retailer or wholesale food store redeems a SNAP participant's program benefits without the knowledge of the participant. All program benefits are issued through the Electronic Benefits Transfer (EBT) system. The EBT system establishes data that may be used to identify fraud committed by retail food stores. While stealing program benefits could be prosecuted under current statute, program regulations do not provide a clear penalty for these thefts. The proposed rule would establish an administrative penalty for such thefts equivalent to the penalty for trafficking in program benefits, which is the permanent disqualification of a retailer or wholesale food store from SNAP participation. Finally, the Department proposes to identify additional administrative retail violations and the associated sanction that would be imposed against the retail food store for committing the violation. For instance, to maintain integrity, FNS requires retail and wholesale food stores to key enter EBT card data in the presence of the actual EBT card. The proposed rule would
codify this requirement and identify the specific sanction that would be imposed if retail food stores are found to be in violation.

**Summary of Legal Basis:**


**Alternatives:**

Because this proposed rule is under development, alternatives are not yet articulated.

**Anticipated Cost and Benefits:**

Because this proposed rule is under development, anticipated costs and benefits have not yet been articulated.

**Risks:**

The risk that retail or wholesale food stores will violate SNAP rules, or continue to violate SNAP rules, is expected to be reduced by refining program sanctions for participating retailers and wholesalers.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:**

Undetermined

**Additional Information:**

Note: This RIN replaces the previously issued RIN 0584-AD78.

**Agency Contact:**

James F. Herbert

Regulatory Review Specialist

Department of Agriculture

Food and Nutrition Service
USDA—FNS

8. NATIONAL SCHOOL LUNCH AND SCHOOL BREAKFAST PROGRAMS: NUTRITION

STANDARDS FOR ALL FOODS SOLD IN SCHOOL, AS REQUIRED BY THE HEALTHY, HUNGER-FREE KIDS ACT OF 2010

Priority:
Other Significant

Unfunded Mandates:
Undetermined

Legal Authority:
PL 111–296

CFR Citation:
7 CFR 210; 7 CFR 220

Legal Deadline:
None

Abstract:
This proposed rule would codify the following provisions of the Healthy, Hunger-Free Kids Act (Pub. L. 111-296; the Act) as appropriate, under 7 CFR parts 210 and 220.
Section 203 requires schools participating in the National School Lunch Program to make available to children free of charge, as nutritionally appropriate, potable water for consumption in the place where meals are served during meal service.

Section 208 requires the Secretary to promulgate proposed regulations to establish science-based nutrition standards for all foods sold in schools not later than December 13, 2011. The nutrition standards would apply to all food sold outside the school meal programs, on the school campus, and at any time during the school day. (11-004)

**Statement of Need:**

This proposed rule would codify the following provisions of the Healthy, Hunger-Free Kids Act (Pub. L. 111-296; the Act) as appropriate, under 7 CFR parts 210 and 220.

Section 203 requires schools participating in the National School Lunch Program to make available to children free of charge, as nutritionally appropriate, potable water for consumption in the place where meals are served during meal service.

Section 208 requires the Secretary to promulgate proposed regulations to establish science-based nutrition standards for all foods sold in schools not later than December 13, 2011. The nutrition standards would apply to all food sold outside the school meal programs, on the school campus, and at any time during the school day.

**Summary of Legal Basis:**

There is no existing regulatory requirement to make water available where meals are served. Regulations at 7 CFR parts 210.11 direct State agencies and school food authorities to establish such rules or regulations necessary to control the sale of foods in competition with lunches served under the NSLP. Such rules or regulations shall prohibit the sale of foods of minimal nutritional value in the food service areas during the lunch periods. The sale of other competitive foods may, at the discretion of the State agency and school food authority, be allowed in the food service area during the lunch period only if all income from the sale of such foods accrues to the benefit of the nonprofit school food service or the
school or student organizations approved by the school. State agencies and school food authorities may impose additional restrictions on the sale of and income from all foods sold at any time throughout schools participating in the Program.

Alternatives:

None.

Anticipated Cost and Benefits:

Expected Costs Analysis and Budgetary Effects Statement:

The Congressional Budget Office determined these provisions would incur no Federal costs.

Expected Benefits of the Proposed Action:

The provisions in this proposed rulemaking would result in better nutrition for all school children.

Risks:

None known.

Timetable:

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Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

Local, State

Agency Contact:

James F. Herbert

Regulatory Review Specialist

Department of Agriculture

Food and Nutrition Service

10th Floor
USDA—FNS

9. • WIC: ELECTRONIC BENEFIT TRANSFER (EBT) IMPLEMENTATION

Priority:
Other Significant

Unfunded Mandates:
Undetermined

Legal Authority:
PL 111–296

CFR Citation:
7 CFR 246

Legal Deadline:
NPRM, Statutory, October 1, 2020, Require all WIC State agencies to implement EBT Statewide.

Abstract:
This proposed rule would revise and expand regulations regarding WIC EBT at 7 CFR 246 and implement statutory provisions related to EBT as defined in the Healthy, Hunger-Free Kids Act of 2010, Public Law 11-296. The EBT requirements addressed in the proposed rule would promote improved access to Program benefits, standardize EBT operations, and establish implementation guidelines and timeframes.

Statement of Need:
This proposed rule would revise and expand regulations regarding WIC EBT at 7 CFR 246 and implement statutory provisions related to EBT as defined in the Healthy, Hunger-Free Kids Act of 2010,
Public Law 11-296. The EBT requirements addressed in the proposed rule would promote improved access to program benefits, standardize EBT operations, and establish implementation guidelines and timeframes.

WIC EBT has been an ongoing effort within the WIC community for several years. The proposed rule would address the following:

* Set forth the definition of EBT.

* Require all WIC State agencies to implement EBT statewide by October 1, 2020.

* Require State agencies to submit status reports demonstrating their progress toward Statewide EBT implementation.

* Revise the current provision regarding the imposition of EBT costs to vendors to include: 1) The formation of cost-sharing criteria associated with any equipment or system not solely dedicated to EBT; 2) the allowance of the payment of fees imposed by a third-party processor for EBT transactions; 3) the disallowance of the payment of interchange fees; 4) clarification of EBT cost impositions after Statewide implementation; 5) elimination of the requirement for State agencies to fund ongoing maintenance costs for vendors using multi-function EBT equipment; and 6) require vendors to demonstrate the capability to accept program benefits electronically prior to authorization after Statewide implementation of EBT.

* Establish minimum lane coverage guidelines for vendor equipment, as set forth in the operating rules, and require State agencies to provide the necessary EBT-only equipment if vendors do not wish to acquire multi-function equipment.

* Require that EBT technical standards and operating rules be established and adhered to by State agencies.
* Require all State agencies to use the universal product code database.

**Summary of Legal Basis:**


**Alternatives:**

None.

**Anticipated Cost and Benefits:**

Expected Costs Analysis and Budgetary Effects Statement:

FNS estimates costs of approximately $30 to $60 million per fiscal year (as reflected in the program's budget) for State agencies to comply with the mandate. The costs will vary depending on implementation activity and are expected to decline as more State agencies adopt WIC EBT.

Expected Benefits of the Proposed Action:

The EBT requirements addressed in the proposed rule would promote improved access to program benefits, standardize EBT operations, and establish implementation guidelines and timeframes.

**Risks:**

None known.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:**

Undetermined
10. NUTRITION STANDARDS IN THE NATIONAL SCHOOL LUNCH AND SCHOOL BREAKFAST PROGRAMS

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
PL 108–265, sec 103

CFR Citation:
7 CFR 210; 7 CFR 220

Legal Deadline:
None

Abstract:
Public Law 108-265 requires the Secretary to issue regulations that reflect specific recommendations for increased consumption of foods and food ingredients in school nutrition programs based on the most recent Dietary Guidelines for Americans.
The current regulations require that reimbursable meals offered by schools meet the applicable recommendations of the Dietary Guidelines for Americans. This rule would revise the regulations on meal patterns and nutrition standards to ensure that school meals reflect the 2005 Dietary Guidelines for Americans (04-017).

**Statement of Need:**
This final rule will implement the requirement in section 201 of the Healthy, Hunger-Free Kids Act of 2010 (Pub. L. 111-296) (the Act) that USDA promulgate regulations to update the meal patterns and nutrition standards for school lunches and breakfasts based on recommendations made by the Institute of Medicine (IOM). USDA issued a proposed rule on January 13, 2011. The Act requires USDA to issue interim or final regulations not later than 18 months after promulgation of the proposed regulation.

This final rule will implement meal patterns and nutrition standards recommended by IOM in its report “School Meals: Building Blocks for Healthy Children.” In addition, the final rule will address the comments submitted by the public in response to USDA’s proposed rule.

**Summary of Legal Basis:**
The meal patterns and nutrition standards for school lunches and breakfast are established in 7 CFR 210.10 and 7 CFR 220.8, respectively. State agencies monitor compliance with the meal patterns and nutrition standards through program reviews authorized in 7 CFR 210.19.

**Alternatives:**
None.

**Anticipated Cost and Benefits:**
Expected Costs Analysis and Budgetary Effects Statement:

While there are no increased Federal costs associated with implementation of this final rule, the Act provides schools that comply with the new meal requirements with an increased Federal reimbursement. The Act also provides Federal funding for training, technical assistance, certification, and oversight
activities related to compliance with this rule. It is expected that the total costs of compliance with the final rule will exceed $100 million per year.

Expected Benefits of the Proposed Action:

The final rule is projected to make substantial improvements to the meals served daily in over 101,000 schools nationwide to more than 31 million children. It will align school meals with national nutrition guidelines and help safeguard the health of school children.

Risks:

None known.

Timetable:

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Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Local, State

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

James F. Herbert
Regulatory Review Specialist
Department of Agriculture
Food and Nutrition Service
USDA—FNS

11. DIRECT CERTIFICATION OF CHILDREN IN FOOD STAMP HOUSEHOLDS AND CERTIFICATION OF HOMELESS, MIGRANT, AND RUNAWAY CHILDREN FOR FREE MEALS

Priority:
Other Significant. Major under 5 USC 801.

Legal Authority:
PL 108–265, sec 104

CFR Citation:

Legal Deadline:
None

Abstract:
In response to Public Law 108-265, which amended the Richard B. Russell National School Lunch Act, 7 CFR 245, Determining Eligibility for Free and Reduced Price Meals and Free Milk in Schools, is amended to establish categorical (automatic) eligibility for free meals and free milk upon documentation that a child is (1) homeless as defined by the McKinney-Vento Homeless Assistance Act; (2) a runaway served by grant programs under the Runaway and Homeless Youth Act; or (3) migratory as defined in section 1309(2) of the Elementary and Secondary Education Act. The rule also requires phase-in of mandatory direct certification for children who are members of households receiving benefits from the Supplemental...
Nutrition Assistance Program and continues discretionary direct certification for other categorically eligible children (04-018).

**Statement of Need:**

The changes made to the Richard B. Russell National School Lunch Act concerning direct certification are intended to improve program access, reduce paperwork, and improve the accuracy of the delivery of free meal benefits. This regulation will implement the statutory changes and provide State agencies and local educational agencies with the policies and procedures to conduct mandatory and discretionary direct certification.

**Summary of Legal Basis:**

These changes are being made in response to provisions in Public Law 108-265.

**Alternatives:**

None; statutory requirements.

**Anticipated Cost and Benefits:**

This regulation will reduce paperwork, target benefits more precisely, and will improve program access of eligible school children.

**Risks:**

This regulation may require adjustments to existing computer systems to more readily share information between schools and assistance agencies.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**
No

**Government Levels Affected:**
Local, State

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**Related RIN:** Merged with 0584–AD62
**RIN:** 0584–AD60

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**USDA—FNS**

**12. ELIGIBILITY, CERTIFICATION, AND EMPLOYMENT AND TRAINING PROVISIONS OF THE FOOD, CONSERVATION, AND ENERGY ACT OF 2008**

**Priority:**
Economically Significant. Major under 5 USC 801.

**Legal Authority:**
PL 110–246; PL 104–121

**CFR Citation:**
7 CFR 273

**Legal Deadline:**
None
Abstract: This proposed rule would amend the regulations governing the Supplemental Nutrition Assistance Program (SNAP) to implement provisions from the Food, Conservation, and Energy Act of 2008 (Pub. L. 110-246) (FCEA) concerning the eligibility and certification of SNAP applicants and participants and SNAP employment and training. In addition, this proposed rule would revise the SNAP regulations throughout 7 CFR part 273 to change the program name from the Food Stamp Program to SNAP and to make other nomenclature changes as mandated by the FCEA. The statutory effective date of these provisions was October 1, 2008. Food and Nutrition Service (FNS) is also proposing two discretionary revisions to SNAP regulations to provide State agencies options that are currently available only through waivers. These provisions would allow State agencies to average student work hours and to provide telephone interviews in lieu of face-to-face interviews. FNS anticipates that this rule would impact the associated paperwork burdens (08-006).

Statement of Need: This proposed rule would amend the regulations governing SNAP to implement provisions from the FCEA concerning the eligibility and certification of SNAP applicants and participants and SNAP employment and training. In addition, this proposed rule would revise the SNAP regulations throughout 7 CFR part 273 to change the program name from the Food Stamp Program to SNAP and to make other nomenclature changes as mandated by the FCEA. The statutory effective date of these provisions was October 1, 2008. FNS is also proposing two discretionary revisions to SNAP regulations to provide State agencies options that are currently available only through waivers. These provisions would allow State agencies to average student work hours and to provide telephone interviews in lieu of face-to-face interviews. FNS anticipates that this rule would impact the associated paperwork burdens.


Alternatives: Most aspects of the rule are non-discretionary and tie to explicit, specific requirements for SNAP in the FCEA. However, FNS did consider alternatives in implementing section 4103 of the FCEA, Elimination of Dependent Care Deduction Caps. FNS considered whether to limit deductible expenses to costs paid
directly to the care provider or whether to permit households to deduct other expenses associated with dependent care in addition to the direct costs. FNS chose to allow households to deduct the cost of transportation to and from the dependent care provider and the cost of separately identified activity fees that are associated with dependent care. Section 4103 signaled an important shift in congressional recognition that dependent care costs constitute major expenses for working households. In addition, it was noted during the floor discussion in both houses of Congress prior to passage of the FCEA that some States already counted transportation costs as part of dependent care expenditures.

**Anticipated Cost and Benefits:**

The estimated total SNAP costs to the Government of the FCEA provisions implemented in the rule are estimated to be $831 million in FY 2010 and $5.619 billion over the 5 years FY 2010 through FY 2014. These impacts are already incorporated into the President's budget baseline.

There are many potential societal benefits of this rule. Some provisions may make some households newly eligible for SNAP benefits. Other provisions may increase SNAP benefits for certain households. Certain provisions in the rule will reduce the administrative burden for households and State agencies.

**Risks:**

The statutory changes and discretionary ones under consideration would streamline program operations. The changes are expected to reduce the risk of inefficient operations.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Government Levels Affected:**

Local, State

**Agency Contact:**
USDA—FNS

13. • SUPPLEMENTAL NUTRITION ASSISTANCE PROGRAM: NUTRITION EDUCATION AND OBESITY PREVENTION GRANT

Priority:
Other Significant

Legal Authority:
PL 111–296

CFR Citation:
7 CFR 272

Legal Deadline:

Abstract:

[Pub. L. 111-296, The Healthy, Hunger-Free Kids Act of 2001, title II; Reducing Childhood Obesity and Improving the Diets of Children, subtitle D; Miscellaneous, sec. 241.] The Nutrition Education and Obesity Prevention Grant Program amends the Food and Nutrition Act of 2008 to replace the current nutrition education program under the Act with a program providing grants to States for the implementation of a
nutrition education and obesity prevention program that promotes healthy food choices consistent with
the most recent Dietary Guidelines for Americans.

Statement of Need:
The Nutrition Education and Obesity Prevention Grant Program rule amends the Food and Nutrition Act
of 2008 to replace the current nutrition education program under the Act with a program providing grants
to States for the implementation of a nutrition education and obesity prevention program that promotes
healthy food choices consistent with the most recent Dietary Guidelines for Americans. This rule will
implement all requirements of the law. It makes eligible for program participation: (1) Supplemental
Nutrition Assistance Program (SNAP) participants, (2) participants in the school lunch or breakfast
programs, and (3) individuals who reside in low-income communities or are low-income individuals. The
rule continues commitment to serving low-income populations while focusing on the issue of obesity, a
priority of this Administration. It ensures that interventions implemented as part of State nutrition
education plans recognize the constrained resources of the eligible population.

The rule requires activities be science-based and outcome-driven and provides for accountability and
transparency through State plans. It will require coordination and collaboration among Federal agencies
and stakeholders, including the Centers for Disease Control and Prevention, the public health community,
the academic and research communities, nutrition education practitioners, representatives of State and
local governments, and community organizations that serve the low-income populations. The rule allows
for 100 percent Federal funding, and States will not have to provide matching funds. The grant funding
will be based on 2009 expenditures. For 3 years after enactment, States will receive grant funds based on
their level of funds expended for the 2009 base year with funds indexed for inflation thereafter. The new
funding structure is phased in over a 7-year period. From fiscal year 2014 forward, funds will be allocated
based on a formula that considers participation.

Summary of Legal Basis:

Alternatives:
None.
**Anticipated Cost and Benefits:**

**Expected Costs Analysis and Budgetary Effects Statement:**

The action allows for 100 percent Federal funding which gives States more flexibility to target services where they can be most effective without the constraints of a State match. For 3 years after enactment, States will receive grant funds based on their level of funds expended for the 2009 base year with funds indexed for inflation thereafter. The new funding structure is phased in over a 7-year period. From fiscal year 2014 forward, funds will be allocated based on a formula that considers participation.

**Expected Benefits of the Proposed Action:**

This regulatory action seeks to improve the effectiveness of the program and make it easier for the States to administer, while still allowing funding to grow. It allows for 100 percent Federal funding, which gives States more flexibility to target services where they can be most effective without the constraints of a State match. It allows grantees to adopt individual and group-based nutrition education, as well as community and public health approaches. It allows coordinated services to be provided to participants in all the Federal food assistance programs and to other low-income persons.

**Risks:**

None known.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

State
USDA—Food Safety and Inspection Service (FSIS)  |  PROPOSED RULE STAGE

14. PRIOR LABELING APPROVAL SYSTEM: GENERIC LABEL APPROVAL

Priority:
Other Significant

Legal Authority:
21 USC 451 to 470; 21 USC 601 to 695

CFR Citation:
9 CFR 317; 9 CFR 327; 9 CFR 381; 9 CFR 412

Legal Deadline:
None

Abstract:
This rulemaking will continue an effort initiated several years ago by amending FSIS' regulations to expand the types of labeling that are generically approved. FSIS plans to propose that the submission of labeling for approval prior to use be limited to certain types of labeling, as specified in the regulations. In
addition, FSIS plans to reorganize and amend the regulations by consolidating the nutrition labeling rules that currently are stated separately for meat and poultry products (in part 317, subpart B, and part 381, subpart Y, respectively) and by amending their provisions to set out clearly various circumstances under which these products are misbranded.

**Statement of Need:**
Expanding the types of labeling that are generically approved would permit Agency personnel to focus their resources on evaluating only those claims or special statements that have health and safety or economic implications. This would essentially eliminate the time needed for FSIS personnel to evaluate labeling features and allocate more time for staff to work on other duties and responsibilities. A major advantage of this proposal is that it is consistent with FSIS’ current regulatory approach, which separates industry and Agency responsibilities.

**Summary of Legal Basis:**

**Alternatives:**
FSIS considered several options. The first was to expand the types of labeling that would be generically approved and consolidate into one part all of the labeling regulations applicable to products regulated under the FMIA and PPIA and the policies currently contained in FSIS Directive 7220.1, Revision 3. The second option FSIS considered was to consolidate only the meat and poultry regulations that are similar and to expand the types of generically approved labeling that can be applied by Federal and certified foreign establishments. The third option, and the one favored by FSIS, was to amend the prior labeling approval system in an incremental three-phase approach.

**Anticipated Cost and Benefits:**
The proposed rule would permit the Agency to realize an estimated discounted cost savings of $2.9 million over 10 years. The proposed rule would be beneficial because it would streamline the generic labeling process, while imposing no additional cost burden on establishments. Consumers would benefit because industry would have the ability to introduce products into the marketplace more quickly.

**Risks:**
None
Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
Businesses

Government Levels Affected:
None

Agency Contact:
Jeff Canavan
Labeling and Program Delivery Division
Department of Agriculture
Food Safety and Inspection Service
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Washington, DC 20250–5273
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Email: jeff.canavan@fsis.usda.gov

RIN: 0583–AC59

15. PRODUCT LABELING: USE OF THE VOLUNTARY CLAIM “NATURAL” ON THE LABELING OF MEAT AND POULTRY PRODUCTS

Priority:
Other Significant Legal Authority:
21 USC 601 et seq; 21 USC 451 et seq

CFR Citation:
9 CFR 317; 9 CFR 381

Legal Deadline:
None

Abstract:
The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry products inspection regulations to define the conditions under which it will permit the voluntary claim “natural” to be used in the labeling of meat and poultry products. FSIS is also proposing that label approval requests for labels that contain “natural” claims include documentation to demonstrate that the products meet the criteria to bear a “natural” claim. FSIS is proposing to require that meat or poultry products meet these conditions to qualify for a “natural” claim to make the claim more meaningful to consumers.

Statement of Need:
A codified “natural” claim definition will reduce uncertainty about which products qualify to be labeled as “natural” and will increase consumer confidence in the claim. A codified “natural” definition that clearly articulates the criteria that meat and poultry products must meet to qualify to be labeled as “natural” will make the Agency’s approval of “natural” claims more transparent and will allow the Agency to review labels that contain “natural” claims in a more efficient and consistent manner. A codified “natural” definition will also make the claim more meaningful to consumers.

Summary of Legal Basis:

Alternatives:
The Agency has considered not proceeding with rulemaking and maintaining the existing policy guidance on “natural” claims and using that policy guidance to evaluate “natural” claims on a case-by-case basis. The Agency has also considered alternative definitions of “natural” and establishing separate codified
definitions of “natural,” “natural. . .minimally processed,” and “natural. . .minimally processed/all natural ingredients.”

**Anticipated Cost and Benefits:**

FSIS anticipates that a clear and simple definition of “natural” will minimize cognitive costs to consumers. FSIS also anticipates benefits from a consistent USDA policy on “natural” claims. FSIS anticipates costs to establishments to change their labels or change their production practices.

**Risks:**

None

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Agency Contact:**

Rosalyn Murphy–Jenkins

Director, Labeling and Program Delivery Division

Department of Agriculture

Food Safety and Inspection Service

Patriots Plaza 3, 8th Floor, Room 8–148, Stop 5273

1400 Independence Avenue SW

Washington, DC 20250–5273
16. NEW POULTRY SLAUGHTER INSPECTION

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
21 USC 451 et seq

CFR Citation:
9 CFR 381.66; 9 CFR 381.67; 9 CFR 381.76; 9 CFR 381.83; 9 CFR 381.91; 9 CFR 381.94

Legal Deadline:
None

Abstract:
FSIS is proposing a new inspection system for young poultry slaughter establishments that would facilitate public health-based inspection. This new system would be available initially only to young chicken and turkey slaughter establishments. Establishments that slaughter broilers, fryers, roasters, and Cornish game hens (as defined in 9 CFR 381.170) would be considered as “young chicken establishments.” FSIS is also proposing to revoke the provisions that allow young chicken slaughter establishments to operate under the current Streamlined Inspection System (SIS) or the New Line Speed (NELS) Inspection System, and to revoke the New Turkey Inspection System (NTIS). FSIS anticipates that this proposed rule would provide the framework for action to provide public health-based inspection in all establishments that slaughter amenable poultry species.
Under the proposed new system, young chicken slaughter establishments would be required to sort chicken carcasses and to conduct other activities to ensure that carcasses are not adulterated before they enter the chilling tank.

**Statement of Need:**
Because of the risk to the public health associated with pathogens on young chicken carcasses, FSIS is proposing a new inspection system that would allow for more effective inspection of young chicken carcasses, would allow the Agency to more effectively allocate its resources, would encourage industry to more readily use new technology, and would include new performance standards to reduce pathogens.

This proposed rule is an example of regulatory reform because it would facilitate technological innovation in young chicken slaughter establishments. It would likely result in more cost-effective dressing of young chickens that are ready to cook or ready for further processing. Similarly, it would likely result in more efficient and effective use of Agency resources.

**Summary of Legal Basis:**

**Alternatives:**
FSIS considered the following options in developing this proposal:

1) No action.

2) Propose to implement HACCP-based Inspection Models Pilot in regulations.

3) Propose to establish a mandatory, rather than a voluntary, new inspection system for young chicken slaughter establishments.

**Anticipated Cost and Benefits:**
Not publicly available at this time.

**Risks:**
Salmonella and other pathogens are present on a substantial portion of poultry carcasses inspected by FSIS. Foodborne salmonella cause a large number of human illnesses that at times lead to hospitalization and even death. There is an apparent relationship between human illness and prevalence levels for salmonella in young chicken carcasses. FSIS believes that through better allocation of
inspection resources and the use of performance standards, it would be able to better address the prevalence of salmonella and other pathogens in young chickens.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Agency Contact:**

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**RIN:** 0583–AD32

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**USDA—FSIS**

17. ELECTRONIC IMPORTED PRODUCT INSPECTION APPLICATION AND CERTIFICATION OF IMPORTED PRODUCT AND FOREIGN ESTABLISHMENTS; AMENDMENTS TO FACILITATE THE PUBLIC HEALTH INFORMATION SYSTEM (PHIS)
Priority:
Other Significant

Legal Authority:
Federal Meat Inspection Act (FMIA) (21 USC 601 to 695), the Poultry Products Inspection Act (PPIA) (21 USC 451 to 470); Egg Products Inspection Act (EPIA) (21 USC 1031 to 1056)

CFR Citation:
9 CFR 304.3; 9 CFR 327.2 and 327.4; 9 CFR 381.196 to 381.198; 9 CFR 590.915 and 590.920

Legal Deadline:
None

Abstract:
FSIS is proposing to amend the meat, poultry, and egg products import inspection regulations to provide for an electronic import inspection application, and electronic imported product foreign inspection and foreign establishment certification system. FSIS is also proposing to delete the “streamlined” import inspection procedures for Canadian product. In addition, the Agency is proposing that official import inspection establishment must develop, implement, and maintain written Sanitation SOPs, as provided in 9 CFR 416.11 through 416.17. FSIS is also announcing that it is discontinuing its practice of conducting imported product reinspection based on a foreign government's guarantee.

Statement of Need:
FSIS is proposing these regulations to provide for the electronic import system, which will be available through the Agency's Public Health Information System (PHIS), a computerized, Web-based inspection information system. The import system will enable applicants to electronically submit and track import inspection applications that are required for all commercial entries of FSIS-regulated products imported into the U.S. FSIS inspection program personnel will be able to access the PHIS system to assign appropriate imported product inspection activities. The electronic import system will also facilitate the imported product foreign inspection and annual foreign establishment certifications by providing immediate and direct electronic government-to-government exchange of information. The Agency is proposing to delete the Canadian streamlined import inspection procedures because they have not been in use since 1990 and are obsolete. Sanitation SOPs are written procedures establishments develop,
implement, and maintain to prevent direct contamination or adulteration of meat or poultry products. To ensure that imported meat and poultry products do not become contaminated while undergoing reinspection prior to entering the U.S., FSIS is proposing to clarify that official import inspection establishments must develop written Sanitation SOPs.

**Summary of Legal Basis:**


**Alternatives:**

The use of the electronic import system is voluntary. The Agency will continue to accept and process paper import inspection applications, and foreign establishment and imported product foreign inspection certificates. The Canadian streamlined import inspection procedures are not currently in use. Proposing Sanitation SOPs in official import inspection establishments will prevent direct contamination or adulteration of product. Therefore, no alternatives were considered.

**Anticipated Cost and Benefits:**

Under this proposed rule, the industry will have the option of filing inspection applications electronically and submitting electronic imported foreign inspection product and establishment certificates through the PHIS. Since the electronic option is voluntary, applicants and the foreign countries that choose to file electronically will do so only if the benefits outweigh the cost. Sanitation SOPs are a condition of approval for official import inspection establishments and as a requirement for official import inspection establishments to continue to operate under Federal inspection. The proposed rule will clarify that official import inspection establishments must have developed written Sanitation SOPs before being granted approval and that existing official import inspection establishments must meet Sanitation SOP requirements. Since, in practice, FSIS has always expected official import inspection establishments to maintain Sanitation SOPs during the reinspection of imported products, the proposed amendment for these sanitation requirements will have little, if any, cost impact on the industry.

**Risks:**

None.

**Timetable:**

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Regulatory Flexibility Analysis Required: No

Small Entities Affected: Businesses

Government Levels Affected: None

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:
Mary Stanley
Director, International Policy Division Office of Policy and Program
Department of Agriculture
Food Safety and Inspection Service
Room 2125
1400 Independence Avenue SW
Washington, DC 20250
Phone: 202 720–0287

RIN: 0583–AD39

18. ELECTRONIC EXPORT APPLICATION AND CERTIFICATION AS A REIMBURSABLE SERVICE AND FLEXIBILITY IN THE REQUIREMENTS FOR OFFICIAL EXPORT INSPECTION MARKS, DEVICES, AND CERTIFICATES

Priority: Other Significant
Legal Authority:
Federal Meat Inspection Act (FMIA) (21 USC 601 to 695); Poultry Products Inspection Act (PPIA) (21 USC 451 to 470); Egg Products Inspection Act (EPIA) (21 USC 1031 to 1056)

CFR Citation:
9 CFR 312.8; 9 CFR 322.1 and 322.2; 9 CFR 350.7; 9 CFR 362.5; 9 CFR 381.104 to 381.106; 9 CFR 590.407; 9 CFR 592.20 and 592.500

Legal Deadline:
None

Abstract:
The Food Safety and Inspection Service (FSIS) is proposing to amend the meat, poultry, and egg product inspection regulations to provide an electronic export application and certification system. The electronic export application and certification system will be a component of the Agency’s Public Health Information System (PHIS). The export component of PHIS will be available as an alternative to the paper-based application and certification process. FSIS is proposing to charge users for the use of the proposed system. FSIS is proposing to establish a formula for calculating the fee. FSIS is also proposing to provide establishments that export meat, poultry, and egg products with flexibility in the official export inspection marks, devices, and certificates. In addition, FSIS is proposing egg product export regulations that parallel the meat and poultry export regulations.

Statement of Need:
FSIS is proposing these regulations to facilitate the electronic processing of export applications and certificates through the Public Health Information System (PHIS), a computerized, Web-based inspection information system. The current export application and certification regulations provide only for a paper-based process. This proposed rule will provide this electronic export system as a reimbursable certification service charged to the exporter.

Summary of Legal Basis:

Alternatives:
The electronic export applications and certification system is being proposed as a voluntary service; therefore, exporters have the option of continuing to use the current paper-based system. Therefore, no alternatives were considered.

**Anticipated Cost and Benefits:**

FSIS is proposing to charge exporters an application fee for the electronic system. Automating the export application and certification process will facilitate the exportation of U.S. meat, poultry, and egg products by streamlining and automating the processes that are in use while ensuring that foreign regulatory requirements are met. The cost to an exporter would depend on the number of electronic applications submitted. An exporter that submits only a few applications per year would not be likely to experience a significant economic impact. Under this proposal, inspection personnel workload is reduced through the elimination of the physical handling and processing of applications and certificates. When an electronic government-to-government system interface or data exchange is used, fraudulent transactions, such as false alterations and reproductions, will be significantly reduced, if not eliminated. The electronic export system is designed to ensure authenticity, integrity, and confidentiality. Exporters will be provided a more efficient and effective application and certification process. The proposed egg product export regulations provide the same export requirements across all products regulated by FSIS and consistency in the export application and certification process. The total annual paperwork burden to egg processing industry to fill out the paper-based export application is approximately $32,340 per year for a total of 924 hours a year. The average establishment burden would be 11 hours, and $385.00 per establishment.

**Risks:**

None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses
Government Levels Affected:
None

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:
Dr. Ron Jones
Assistant Administrator, Office of International Affairs
Department of Agriculture
Food Safety and Inspection Service
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Phone: 202 720–3473
RIN: 0583–AD41
Abstract:
FSIS has proposed to establish pathogen reduction performance standards for all ready-to-eat (RTE) and partially heat-treated meat and poultry products, and measures, including testing, to control Listeria monocytogenes in RTE products. The performance standards spell out the objective level of pathogen reduction that establishments must meet during their operations in order to produce safe products, but allow the use of customized, plant-specific processing procedures other than those prescribed in the earlier regulations. With HACCP, food safety performance standards give establishments the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls, while providing objective, measurable standards that can be verified by Agency inspectional oversight. This set of performance standards will include and be consistent with standards already in place for certain ready-to-eat meat and poultry products.

Statement of Need:
Although FSIS routinely samples and tests some ready-to-eat products for the presence of pathogens prior to distribution, there are no specific regulatory pathogen reduction requirements for most of these products. The proposed performance standards are necessary to help ensure the safety of these products; give establishments the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls; and provide objective, measurable standards that can be verified by Agency oversight.

Summary of Legal Basis:

Alternatives:
As an alternative to all of the proposed requirements, FSIS considered taking no action. As alternatives to the proposed performance standard requirements, FSIS considered end-product testing and requiring “use-by” date labeling on ready-to-eat products.

Anticipated Cost and Benefits:
Benefits are expected to result from fewer contaminated products entering commercial food distribution channels as a result of improved sanitation and process controls and in-plant verification. FSIS believes
that the benefits of the rule would exceed the total costs of implementing its provisions. FSIS currently estimates net benefits from the 2003 interim final rule at $470 to $575 million, with annual recurring costs at $150.4 million, if FSIS discounts the capital cost at 7 percent. FSIS is continuing to analyze the potential impact of the other provisions of the proposal.

The other main provisions of the proposed rule are: Lethality performance standards for Salmonella and E. coli O157:H7 and stabilization performance standards for C. perfringens that firms must meet when producing RTE meat and poultry products. Most of the costs of these requirements would be associated with one-time process performance validation in the first year of implementation of the rule and with revision of HACCP plans. Benefits are expected to result from the entry into commercial food distribution channels of product with lower levels of contamination resulting from improved in-plant process verification and sanitation. Consequently, there will be fewer cases of foodborne illness.

**Risks:**

Before FSIS published the proposed rule, FDA and FSIS had estimated that each year L. monocytogenes caused 2,540 cases of foodborne illness, including 500 fatalities. The Agencies estimated that about 65.3 percent of these cases, or 1660 cases and 322 deaths per year, were attributable to RTE meat and poultry products. The analysis of the interim final rule on control of L. monocytogenes conservatively estimated that implementation of the rule would lead to an annual reduction of 27.3 deaths and 136.7 illnesses at the median. FSIS is continuing to analyze data on production volume and Listeria controls in the RTE meat and poultry products industry and is using the FSIS risk assessment model for L. monocytogenes to determine the likely risk reduction effects of the rule. Preliminary results indicate that the risk reductions being achieved are substantially greater than those estimated in the analysis of the interim rule.

FSIS is also analyzing the potential risk reductions that might be achieved by implementing the lethality and stabilization performance standards for products that would be subject to the proposed rule. The risk reductions to be achieved by the proposed rule and that are being achieved by the interim rule are intended to contribute to the Agency's public health protection effort.
Timetable:

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Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

Agency Contact:

Dr. Daniel L. Engeljohn

Assistant Administrator, Office of Policy and Program Development
20. NOTIFICATION, DOCUMENTATION, AND RECORDKEEPING REQUIREMENTS FOR INSPECTED ESTABLISHMENTS

Priority:
Other Significant

Legal Authority:
21 USC 612 to 613; 21 USC 459

CFR Citation:
9 CFR 417.4; 9 CFR 418

Legal Deadline:
None

Abstract:
The Food Safety and Inspection Service (FSIS) has proposed to require establishments subject to inspection under the Federal Meat Inspection Act and the Poultry Products Inspection Act to promptly notify the Secretary of Agriculture that an adulterated or misbranded product received by or originating from the establishment has entered into commerce, if the establishment believes or has reason to believe that this has happened. FSIS has also proposed to require these establishments to: (1) Prepare and
maintain current procedures for the recall of all products produced and shipped by the establishment and
(2) document each reassessment of the process control plans of the establishment.

Statement of Need:
Farm Bill, amended the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act
(PPIA) to require establishments subject to inspection under these Acts to promptly notify the Secretary
that an adulterated or misbranded product received by or originating from the establishment has entered
into commerce, if the establishment believes or has reason to believe that this has happened. Section
11017 also requires establishments subject to inspection under the FMIA and PPIA to: (1) Prepare and
maintain current procedures for the recall of all products produced and shipped by the establishment and
(2) document each reassessment of the process control plans of the establishment.

Summary of Legal Basis:

Alternatives:
The option of no rulemaking is unavailable.

Anticipated Cost and Benefits:
Approximate costs: $5.0 million for labor and costs; $5.2 million for first-year costs; $0.7 million average
costs adjusted with a 3.0 percent inflation rate for following years. Total approximate costs: $10.2 million.
The average cost of this final rule to small entities is expected to be less than 1/10 of 1 cent of meat and
poultry food products per annum. Therefore, FSIS has determined that this rule will not have a significant
economic impact on a substantial number of small entities.

Approximate benefits: Benefits have not been monetized because quantified data on benefits attributable
to this final rule are not available. Non-monetary benefits include improved protection of the public health,
improved HACCP plans, and improved recall effectiveness.

Risks:
In preparing regulations on the shipment of adulterated meat and poultry products by meat and poultry
establishments, the preparation and maintenance of procedures for recalled products produced and
shipped by establishments, and the documentation of each reassessment of the process control plans by
the establishment, the Agency considered any risks to public health or other pertinent risks associated with these actions.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Agency Contact:**

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**RIN:** 0583–AD34

**BILLING CODE 3410–90–S**

DEPARTMENT OF COMMERCE (DOC)

Statement of Regulatory and Deregulatory Priorities
Established in 1903, the Department of Commerce is one of the oldest Cabinet-level agencies in the Federal Government. The Department’s mission is to create the conditions for economic growth and opportunity by promoting innovation, entrepreneurship, competitiveness, and environmental stewardship. Commerce has 12 operating units, which are responsible for managing a diverse portfolio of programs and services, ranging from trade promotion and economic development assistance to broadband and the National Weather Service.

The Department touches Americans daily, in many ways—making possible the daily weather reports and survey research; facilitating technology that all of us use in the workplace and in the home each day; supporting the development, gathering, and transmission of information essential to competitive business; enabling the diversity of companies and goods found in America’s and the world’s marketplace; and supporting environmental and economic health for the communities in which Americans live.

Commerce has a clear and compelling vision for itself, for its role in the Federal Government, and for its roles supporting the American people, now and in the future. To achieve this vision, the Department works in partnership with businesses, universities, communities, and workers to:

- **Innovate** by creating new ideas through cutting-edge science and technology from advances in nanotechnology, to ocean exploration, to broadband deployment, and by protecting American innovations through the patent and trademark system;

- **Support entrepreneurship and commercialization** by enabling community development and strengthening minority businesses and small manufacturers;

- Maintain U.S. economic **competitiveness** in the global marketplace by promoting exports, ensuring a level playing field for U.S. businesses, and ensuring that technology transfer is consistent with our Nation’s economic and security interests;

- Provide effective management and **stewardship** of our Nation’s resources and assets to ensure sustainable economic opportunities; and
• Make informed policy decisions and enable better understanding of the economy by providing accurate economic and demographic data.

The Department is a vital resource base, a tireless advocate, and Cabinet-level voice for job creation.

The Regulatory Plan tracks the most important regulations that implement these policy and program priorities, several of which involve regulation of the private sector by the Department.

Responding to the Administration's Regulatory Philosophy and Principles

The vast majority of the Department's programs and activities do not involve regulation. Of the Department's 12 primary operating units, only the National Oceanic and Atmospheric Administration (NOAA) will be planning actions that are considered the "most important" significant preregulatory or regulatory actions for FY 2012. During the next year, NOAA plans to publish four rulemaking actions that are designated as regulatory plan actions. The Bureau of Industry and Security (BIS) will also publish rulemaking actions designated as regulatory plan actions. Further information on these actions is provided below.

The Department has a long-standing policy to prohibit the issuance of any regulation that discriminates on the basis of race, religion, gender, or any other suspect category and requires that all regulations be written so as to be understandable to those affected by them. The Secretary also requires that the Department afford the public the maximum possible opportunity to participate in departmental rulemakings, even where public participation is not required by law.

National Oceanic and Atmospheric Administration

NOAA establishes and administers Federal policy for the conservation and management of the Nation's oceanic, coastal, and atmospheric resources. It provides a variety of essential environmental and climate services vital to public safety and to the Nation's economy, such as weather forecasts, drought forecasts, and storm warnings. It is a source of objective information on the state of the environment. NOAA plays the lead role in achieving the Departmental goal of promoting stewardship by providing assessments of the global environment.
Recognizing that economic growth must go hand-in-hand with environmental stewardship, the Department, through NOAA, conducts programs designed to provide a better understanding of the connections between environmental health, economics, and national security. Commerce's emphasis on "sustainable fisheries" is designed to boost long-term economic growth in a vital sector of the U.S. economy while conserving the resources in the public trust and minimizing any economic dislocation necessary to ensure long-term economic growth. The Department is where business and environmental interests intersect, and the classic debate on the use of natural resources is transformed into a "win-win" situation for the environment and the economy.

Three of NOAA's major components, the National Marine Fisheries Services (NMFS), the National Ocean Service (NOS), and the National Environmental Satellite, Data, and Information Service (NESDIS), exercise regulatory authority.

NMFS oversees the management and conservation of the Nation's marine fisheries, protects threatened and endangered marine and anadromous species and marine mammals, and promotes economic development of the U.S. fishing industry. NOS assists the coastal States in their management of land and ocean resources in their coastal zones, including estuarine research reserves; manages the national marine sanctuaries; monitors marine pollution; and directs the national program for deep-seabed minerals and ocean thermal energy. NESDIS administers the civilian weather satellite program and licenses private organizations to operate commercial land-remote sensing satellite systems.

The Department, through NOAA, has a unique role in promoting stewardship of the global environment through effective management of the Nation's marine and coastal resources and in monitoring and predicting changes in the Earth's environment, thus linking trade, development, and technology with environmental issues. NOAA has the primary Federal responsibility for providing sound scientific observations, assessments, and forecasts of environmental phenomena on which resource management, adaptation, and other societal decisions can be made.

In the environmental stewardship area, NOAA's goals include: Rebuilding and maintaining strong U.S. fisheries by using market-based tools and ecosystem approaches to management; increasing the populations of depleted, threatened, or endangered species and marine mammals by implementing recovery plans that provide for their recovery while still allowing for economic and recreational
opportunities; promoting healthy coastal ecosystems by ensuring that economic development is managed in ways that maintain biodiversity and long-term productivity for sustained use; and modernizing navigation and positioning services. In the environmental assessment and prediction area, goals include: Understanding climate change science and impacts, and communicating that understanding to government and private sector stakeholders enabling them to adapt; continually improving the National Weather Service; implementing reliable seasonal and interannual climate forecasts to guide economic planning; providing science-based policy advice on options to deal with very long-term (decadal to centennial) changes in the environment; and advancing and improving short-term warning and forecast services for the entire environment.

**Magnuson-Stevens Fishery Conservation and Management Act**

Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) rulemakings concern the conservation and management of fishery resources in the U.S. Exclusive Economic Zone (generally 3-200 nautical miles). Among the several hundred rulemakings that NOAA plans to issue in FY 2012, a number of the preregulatory and regulatory actions will be significant. The exact number of such rulemakings is unknown, since they are usually initiated by the actions of eight regional Fishery Management Councils (FMCs) that are responsible for preparing fishery management plans (FMPs) and FMP amendments, and for drafting implementing regulations for each managed fishery. NOAA issues regulations to implement FMPs and FMP amendments. Once a rulemaking is triggered by an FMC, the Magnuson-Stevens Act places stringent deadlines upon NOAA by which it must exercise its rulemaking responsibilities. FMPs and FMP amendments for Atlantic highly migratory species, such as bluefin tuna, swordfish, and sharks, are developed directly by NOAA, not by FMCs.

FMPs address a variety of issues including maximizing fishing opportunities on healthy stocks, rebuilding overfished stocks, and addressing gear conflicts. One of the problems that FMPs may address is preventing overcapitalization (preventing excess fishing capacity) of fisheries. This may be resolved by market-based systems such as catch shares, which permit shareholders to harvest a quantity of fish and which can be traded on the open market. Harvest limits based on the best available scientific information, whether as a total fishing limit for a species in a fishery or as a share assigned to each vessel participant, enable stressed stocks to rebuild. Other measures include staggering fishing seasons or limiting gear
types to avoid gear conflicts on the fishing grounds and establishing seasonal and area closures to
protect fishery stocks.

The FMCs provide a forum for public debate and, using the best scientific information available, make
the judgments needed to determine optimum yield on a fishery-by-fishery basis. Optional management
measures are examined and selected in accordance with the national standards set forth in the
Magnuson-Stevens Act. This process, including the selection of the preferred management measures,
constitutes the development, in simplified form, of an FMP. The FMP, together with draft implementing
regulations and supporting documentation, is submitted to NMFS for review against the national
standards set forth in the Magnuson-Stevens Act, in other provisions of the Act, and other applicable
laws. The same process applies to amending an existing approved FMP.

*Marine Mammal Protection Act*

The Marine Mammal Protection Act of 1972 (MMPA) provides the authority for the conservation and
management of marine mammals under U.S. jurisdiction. It expressly prohibits, with certain exceptions,
the take of marine mammals. Exceptions allow for permitting the collection of wild animals for scientific
research or public display or to enhance the survival of a species or stock. NMFS initiates rulemakings
under the MMPA to establish a management regime to reduce marine mammal mortalities and injuries as
a result of interactions with fisheries. The MMPA also established the Marine Mammal Commission,
which makes recommendations to the Secretaries of the Departments of Commerce and the Interior and
other Federal officials on protecting and conserving marine mammals. The Act underwent significant
changes in 1994 to allow for takings incidental to commercial fishing operations, to provide certain
exemptions for subsistence and scientific uses, and to require the preparation of stock assessments for
all marine mammal stocks in waters under U.S. jurisdiction.

*Endangered Species Act*

The Endangered Species Act of 1973 (ESA) provides for the conservation of species that are
determined to be "endangered" or "threatened," and the conservation of the ecosystems on which these
species depend. The ESA authorizes both NMFS and the Fish and Wildlife Service (FWS) to jointly
administer the provisions of the MMPA. NMFS manages marine and "anadromous" species, and FWS
manages land and freshwater species. Together, NMFS and FWS work to protect critically imperiled
species from extinction. Of the 1,310 listed species found in part or entirely in the United States and its waters, NMFS has jurisdiction over approximately 60 species. NMFS’ rulemaking actions are focused on determining whether any species under its responsibility is an endangered or threatened species and whether those species must be added to the list of protected species. NMFS is also responsible for designating, reviewing, and revising critical habitat for any listed species. In addition, under the ESA’s procedural framework, Federal agencies consult with NMFS on any proposed action authorized, funded, or carried out by that agency that may affect one of the listed species or designated critical habitat, or is likely to jeopardize proposed species or adversely modify proposed critical habitat that is under NMFS’ jurisdiction.

**NOAA’s Regulatory Plan Actions**

While most of the rulemakings undertaken by NOAA do not rise to the level necessary to be included in the Department’s regulatory plan, NMFS is undertaking four actions that rise to the level of “most important” of the Department’s significant regulatory actions and thus are included in this year’s regulatory plan. The four actions implement provisions of the Magnuson-Stevens Fishery Conservation and Management Act, as reauthorized in 2006. The third action may be of particular interest to international trading partners as it concerns the Certification of Nations Whose Fishing Vessels are Engaged in Illegal, Unreported, and Unregulated Fishing or Bycatch of Protected Living Marine Resources. A description of the four regulatory plan actions is provided below.

1. **Fishery Management Plan for Regulating Offshore Marine Aquaculture in the Gulf of Mexico (0648-AS65):** In January 2009, the Gulf of Mexico Fishery Management Council approved the Aquaculture Fishery Management Plan, which authorizes NMFS to issue permits to culture species managed by the Council (except shrimp and corals). This was the first time a regional Fishery Management Council approved a comprehensive regulatory program for offshore aquaculture in U.S. Federal waters. On September 3, 2009, the Aquaculture Fishery Management Plan entered into effect by operation of law and Dr. Lubchenco announced that NOAA would develop a new National Aquaculture Policy, which would provide context for the Aquaculture Fishery Management Plan. On June 9, 2011, NOAA released the final National Aquaculture Policy and announced that the Agency will move forward with the rulemaking to implement the Aquaculture Fishery Management Plan. The Aquaculture Plan has received
regional and national media attention and was challenged in two lawsuits. Although the lawsuits were dismissed, additional legal challenges are anticipated when the final rule is issued. A vocal coalition of environmental, non-governmental organizations and fishermen’s groups opposed to marine aquaculture has been actively following the process. Others, including some fishing and seafood groups, support the Aquaculture Fishery Management Plan.

2. Amend the Definition of Illegal, Unreported, and Unregulated Fishing Under the High Seas Driftnet Fishing Moratorium Protection Act to Include International Provisions of the Shark Conservation Act (0648-BA89): As required under the international provisions of the Shark Conservation Act, the rule would amend the identification and certification procedures under the High Seas Driftnet Fishing Moratorium Protection to include the identification of a foreign nation whose fishing vessels engaged during the preceding calendar year in fishing activities in areas beyond any national jurisdiction that target or incidentally catch sharks if that nation has not adopted a regulatory program to provide for the conservation of sharks that is comparable to that of the United States, taking into account different conditions. NMFS also intends to amend the regulatory definition of “illegal, unreported, and unregulated (IUU) fishing” for purposes of the identification and certification procedures under the Moratorium Protection Act.

3. Critical Habitat for North Atlantic Right Whale (0648-AY54): In 1994, NMFS designated critical habitat for the northern right whale in the North Atlantic Ocean. This critical habitat designation includes portions of Cape Cod Bay and Stellwagen Bank, the Great South Channel, and waters adjacent to the coasts of Georgia and Florida. In 2008, NMFS published final determinations listing right whales in the North Atlantic and North Pacific as separate endangered species under the ESA and initiated work on new critical habitat designations triggered by these 2008 listings. On October 1, 2009, NMFS received a petition from the Center for Biological Diversity, Defenders of Wildlife, Humane Society of the United States, Ocean Conservancy, and the Whale and Dolphin Conservation Society to revise the designated critical habitat of the North Atlantic right whale. The petition seeks an expansion of the areas designated as critical feeding and calving habitats and also seeks to include a migratory corridor as part of the critical
habitat designation. On October 6, 2010, NMFS published a 90-day finding and 12-month determination stating the intent to proceed with publishing a proposed rule to revise critical habitat.

4. Reduce Disturbance to Hawaiian Spinner Dolphins from Human Interactions (0648-AU02): Spinner dolphins are being disturbed in their natural resting habitats by human activities, which may be altering the dolphins’ normal behavioral patterns. NMFS is proposing time-area closures to protect the essential resting habitat of spinner dolphins and to reduce the human activities that cause unauthorized taking of these dolphins under the Marine Mammal Protection Act and its implementing regulations. The proposed rule lists time-area closures including four bays on the island of Hawaii, and one on the island of Maui. Adaptive management strategies will be used to monitor the effectiveness of the proposed rule and allow for necessary improvements. This proposed action will set a precedent for NMFS' management of wildlife viewing activities. This proposed action represents the first proposal by NMFS to use regulated area closures to reduce harassment of non-ESA listed marine mammals resulting from activities aimed at viewing and interacting with these animals.

At this time, NOAA is unable to determine the aggregate cost of the identified Regulatory Plan actions as several of these actions are currently under development.

Bureau of Industry and Security

The Bureau of Industry and Security (BIS) advances U.S. national security, foreign policy, and economic objectives by maintaining and strengthening adaptable, efficient, and effective export control and treaty compliance systems, as well as by administering programs to prioritize certain contracts to promote the national defense and to protect and enhance the defense industrial base.

In August 2009, the President directed a broad-based interagency review of the U.S. export control system with the goal of strengthening national security and the competitiveness of key U.S. manufacturing and technology sectors by focusing on the current threats and adapting to the changing economic and technological landscape. In August 2010, the President outlined an approach under which agencies that administer export controls will apply new criteria for determining what items need to be controlled and a common set of policies for determining when an export license is required. The control list criteria are to be based on transparent rules, which will reduce the uncertainty faced by our Allies,
U.S. industry and its foreign customers, and will allow the Government to erect higher walls around the most sensitive export items in order to enhance national security.

Under the President's approach, agencies will apply the criteria and revise the lists of munitions and dual use items that are controlled for export so that they:

Are "tiered" to distinguish the types of items that should be subject to stricter or more permissive levels of control for different destinations, end-uses, and end-users;

Create a "bright line" between the two current control lists to clarify jurisdictional determinations and reduce government and industry uncertainty about whether particular items are subject to the control of the State Department or the Commerce Department; and

Are structurally aligned so that they potentially can be combined into a single list of controlled items.

BIS' current regulatory plan action is designed to implement the initial phase of the President's directive.

**Major Programs and Activities**

BIS administers four sets of regulations. The Export Administration Regulations (EAR) regulate exports and reexports to protect national security, foreign policy, and short supply interests. The EAR also regulates participation of U.S. persons in certain boycotts administered by foreign governments. The National Defense Industrial Base Regulations provide for prioritization of certain contracts and allocations of resources to promote the national defense, require reporting of foreign government-imposed offsets in defense sales, and address the effect of imports on the defense industrial base. The Chemical Weapons Convention Regulations implement declaration, reporting, and on-site inspection requirements in the private sector necessary to meet United States treaty obligations under the Chemical Weapons Convention treaty. The Additional Protocol Regulations implement similar requirements with respect to an agreement between the United States and the International Atomic Energy Agency.

BIS also has an enforcement component with eight field offices in the United States. BIS export control officers are also stationed at several U.S. embassies and consulates abroad. BIS works with other U.S. Government agencies to promote coordinated U.S. Government efforts in export controls and other programs. BIS participates in U.S. Government efforts to strengthen multilateral export control regimes and to promote effective export controls through cooperation with other governments.
BIS’ Regulatory Plan Actions

As the agency responsible for leading the administration and enforcement of the U.S. dual-use export control system, BIS plays a central role in the Administration's efforts to fundamentally reform the export control system. Changing what we control, how we control it, and how we enforce and manage our controls will help strengthen our national security by focusing our efforts on controlling the most critical products and technologies, and by enhancing the competitiveness of key U.S. manufacturing and technology sectors.

In FY 2011, BIS took several steps to implement the President’s Export Control Reform Initiative. BIS published a final rule (76 FR 35276, June 16, 2011) implementing a license exception that authorizes exports, reexports, and transfers to destinations that do not pose a national security concern, provided certain safeguards against diversion to other destinations are taken. BIS also proposed a rule that provides a framework for controlling militarily less significant defense articles, largely generic parts and components, on the Commerce Control List (CCL) rather than the United States Munitions List. In the immediate future, BIS will work with other agencies to implement transfers of such items to the CCL and to make the CCL a more positive list. Looking further ahead BIS will work with other agencies to place items on the CCL into one of three tiers, corresponding to different levels of sensitivity.

Tier 1 will include the most sensitive items. These are items that provide a critical military or intelligence advantage to the United States and are available almost exclusively from the United States, or are items that are a weapon of mass destruction.

Tier 2 will include items that are sensitive but not as sensitive, as those in Tier 1. These are items that provide a substantial military or intelligence advantage to the United States and are available almost exclusively from either the United States or our partners and allies.

Tier 3 will include items that are less sensitive than those in Tier 2. These items will be those that provide a significant military or intelligence advantage but are available more broadly. BIS will also be developing other rules to implement additional aspects of the export control reform as those aspects are identified and decided.

Retrospective Review of Existing Regulations
Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Accordingly, the Agency is reviewing these rules to determine whether action under E.O. 13563 is appropriate. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for the Agency. These rulemakings can also be found on Regulations.gov. The final Agency retrospective analysis plan can be found at:

http://open.commerce.gov/sites/default/files/Commerce%20Plan%20for%20Retrospective%20Analysis%20of%20Existing%20Rules%20-%202011-08-22%20Final.pdf

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DOC—Bureau of Industry and Security (BIS) FINAL RULE STAGE

21. REVISIONS TO THE EXPORT ADMINISTRATION REGULATIONS (EAR): CONTROL OF MILITARY VEHICLES AND RELATED ITEMS THAT THE PRESIDENT DETERMINES DO NOT WARRANT CONTROL ON THE UNITED STATES MUNITIONS LIST

Priority:

Other Significant
Legal Authority:
10 USC 7420; 10 USC 7430(e); 15 USC 1824a; 22 USC 287c; 22 USC 6004; 22 USC 7201 et seq; 22
USC 7210; 30 USC 185; 42 USC 2139a; 42 USC 2139a; 42 USC 6212; 43 USC 1354; 50 USC 1701
et seq; 50 USC 2401 et seq; 50 USC 5; EO 12058; EO 12851; EO 12938; EO 12947; EO 13026; EO
13099; EO 13222; EO 13224; 22 USC 2151 note; 22 USC 3201 et seq; EO 11912; EO 12002; EO 12214;
EO 12854; EO 12918; EO 12918; EO 12981; EO 13020; EO 13338; 30 USC 185(u)

CFR Citation:

Legal Deadline:
None

Abstract:
In August 2009, President Obama directed a fundamental review of the U.S. Export control system be
carried out. This review included a fundamental review of the two primary control lists of the U.S. Export
control system; i.e., the Commerce Control List (CCL) and the United States Munitions List (USML). In
December 2010, the Departments of Commerce and State each published an Advanced Notice of
Proposed Rulemaking (ANPRM) requesting public comments on creating more “positive” and clear
control lists and recommendations for how items listed on the two control lists could be tiered based on
criteria developed during the Export Control Reform (ECR) initiative.

An integral part of creating a “positive” USML requires a proper control structure be put into place under
the EAR to appropriately control the less significant items moved from the USML to the CCL, which is the
subject of this proposed rule. This rule outlines the control structure developed under the ECR initiative to
ensure appropriate controls are in place for these less significant items moved from the USML to the
CCL.

Statement of Need:
This rule is needed to describe how items that no longer warrant ITAR control—but, because they are
specially designed for military applications, warrant some degree of control—will be made subject to the
EAR and listed on the CCL. In particular, this rule establishes the framework within which items that are transferred from the ITAR to the EAR will be identified in and controlled by the EAR. Such ready identification is needed to allow for public understanding of the changes and to facilitate executive branch compliance with the requirements to notify Congress when items are removed from the ITAR. Such controls are needed to accomplish the national security and foreign policy objectives of controlling transfers of military items, which includes complying with statutory and international obligations to prevent the transfer of such items to certain countries, end uses, and end users.

**Summary of Legal Basis:**

The Export Administration Act of 1979, as amended, authorizes the President to prohibit or curtail exports for national security or foreign policy reasons. Section 3(1) of that Act provides that “It is the policy of the United States to minimize uncertainties in export control policy and to encourage trade with all countries with which the United States has diplomatic or trading relations, except those countries with which such trade has been determined by the President to be against the national interest.” Although the Export Administration Act of 1979 (EAA), as amended, expired on August 20, 2001, Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp., p. 783 (2002)) as extended by Notice of August 12, 2010, 75 FR 50681 (Aug. 16, 2010) continues the EAR in effect under the International Emergency Economic Powers Act (IEEPA). The EAA and the IEEPA provide the President with the discretion to tailor controls, such as through the use of license exceptions and the creation of country groups in the implementing regulations, over different types of items based on their significance or other factors relevant to the national interest.

The Arms Export Control Act (22 U.S.C. 2778) gives the President the authority to identify any item as a “defense article.” The list of “defense articles” is identified on the U.S. Munitions List (USML) of the International Traffic in Arms Regulations (ITAR). (22 CFR chapter I, subchapter M). Section 38(f) of the AECA requires the President to periodically review the list of defense articles and determine which, if any, should be removed from the list. Section 38(f) authorizes the President to remove defense articles from the USML and control them under other statutory and regulatory authorities, such as the export control regulations administered by the Commerce Department, after completing a 30-day congressional notification.
Alternatives:
BIS considered several alternative regulatory structures for the items that would be moved from the ITAR to the EAR, including creating a separate Commerce Munitions List in the EAR and attempting to insert all items transferred into the existing ECCN structure. BIS selected the “600 series” structure because it provided the best balance between ease of use and the need to readily identify items moved or to be moved from the ITAR to the EAR for congressional notification purposes. A separate Commerce Munitions List would have readily identified items moved from the ITAR, but would have required the public to consult two lists to assess whether license requirements applied to a particular item. Attempting to place all transferred items within the existing ECCN structure would have minimized the number of ECCNs to be consulted but would have unduly obscured the ITAR origin of the transferred items.

Anticipated Cost and Benefits:
The underlying policy motivation for the reform effort is not a traditional economic cost/benefit analysis. Rather, it is a national security effort. When the Administration first began to consider how the export control system should be reformed to enhance national security, it did not take into account whether there would be particular economic benefits or costs. After conducting the review, the Administration ultimately determined that our national security will be strengthened if (i) our export control system allows for more interoperability with our NATO and other close allies; (ii) our industrial base is enhanced by, for example, reducing the current incentives created by the export control rules for foreign companies to design out or avoid U.S.-origin content; and (iii) our resources are more focused on controlling or prohibiting, as needed, the items that provide at least a significant military or intelligence advantage to the United States. Items made subject to the EAR as a result of this rule generally would require a license to all destinations except Canada and exporters, reexporters and transferors would incur the costs associated with applying for such licenses. BIS would need additional resources to review the additional licenses and to handle the related compliance activities that will accompany the planned change in jurisdictional status of items. The net burden on the government and that the government imposes on industry, however, would be substantially reduced because this rule would apply to items that currently are subject to strict, generally inflexible ITAR license requirements that impose many collateral compliance burdens and costs on exporters and the U.S. Government. BIS believes that replacing such ITAR license requirements with the
more flexible EAR license requirements is not likely to result in any net increase in costs. However, the benefits of the move would be substantial, although not readily quantifiable.

**Risks:**

Not all items currently subject to the ITAR are appropriate for movement to the EAR. Care must be taken to ensure that large sophisticated weapons and other inherently military items (as opposed to items unique to defense articles merely because of a change in form or fit) are not moved to the EAR. BIS believes that the ongoing interagency review process is adequate to guard against any transfers contrary to national security and foreign policy interests. At the same time, one must consider the risks of not transferring to the EAR defense articles that no longer warrant ITAR controls. These risks include continued excessive costs to exporters in complying with unnecessarily restrictive rules, continued disincentives for defense manufacturers to use U.S. origin parts and components, and continued excessive costs associated with supplying allied armed forces with U.S. origin parts and components. BIS believes that this rule sets up a structure for controls that will allow for the appropriate balance between the risks of continuing the status quo and the risks of unwarranted relaxation of controls.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Agency Contact:**

Timothy Mooney

Export Policy Analyst
22. FISHERY MANAGEMENT PLAN FOR REGULATING OFFSHORE MARINE AQUACULTURE IN THE GULF OF MEXICO

Priority:
Other Significant

Legal Authority:
16 USC 1801 et seq

CFR Citation:
50 CFR 622

Legal Deadline:
None

Abstract:
The purpose of this fishery management plan (FMP) is to develop a regional permitting process for regulating and promoting environmentally sound and economically sustainable aquaculture in the Gulf of Mexico (Gulf) exclusive economic zone. This FMP consists of ten actions, each with an associated range of management alternatives, which would facilitate the permitting of an estimated 5 to 20 offshore
aquaculture operations in the Gulf over the next 10 years, with an estimated annual production of up to 64 million pounds. By establishing a regional permitting process for aquaculture, the Gulf of Mexico Fishery Management Council will be positioned to achieve their primary goal of increasing maximum sustainable yield and optimum yield of federal fisheries in the Gulf by supplementing harvest of wild caught species with cultured product.

Statement of Need:
Demand for protein is increasing in the United States and commercial wild-capture fisheries will not likely be adequate to meet this growing demand. Aquaculture is one method to meet current and future demands for seafood. Supplementing the harvest of domestic fisheries with cultured product will help the U.S. meet consumers' growing demand for seafood and may reduce the Nation's dependence on seafood imports.

Currently, the U.S. imports over 80 percent of the seafood consumed in the country, and the annual U.S. seafood trade deficit is at an all time high of over $9 billion.

Summary of Legal Basis:
Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 et seq.

Alternatives:
The Council's Aquaculture FMP includes 10 actions, each with an associated range of alternatives. These actions and alternatives are collectively intended to establish a regional permitting process for offshore aquaculture. Management actions in the FMP include: (1) Aquaculture permit requirements, eligibility, and transferability; (2) duration aquaculture permits are effective; (3) aquaculture application requirements, operational requirements, and restrictions; (4) species allowed for aquaculture; (5) allowable aquaculture systems; (6) marine aquaculture siting requirements and conditions; (7) restricted access zones for aquaculture facilities; (8) recordkeeping and reporting requirements; (9) biological reference points and status determination criteria; and (10) framework procedures for modifying biological reference points and regulatory measures.

Anticipated Cost and Benefits:
Environmental and social/economic costs and benefits are described in detail in the Council's Aquaculture FMP. Potential benefits include: establishing a rigorous review process for reviewing and approving/denying aquaculture permits; increasing optimum yield by supplementing the harvest of wild domestic fisheries with cultured products; and reducing the nation's dependence on imported seafood. Anticipated costs include increased administration and oversight of an aquaculture permitting process, and potential negative environmental impacts to wild marine resources. Approval of an aquaculture permitting system may also benefit fishing communities by creating new jobs or impact fishing communities if cultured products economically displace domestic seafood.

**Risks:**

National offshore aquaculture legislation has also been previously proposed by the Administration. This action may reduce the need for uniform national legislation and allow aquaculture regulations to vary by region.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Agency Contact:**

Roy E. Crabtree
Southeast Regional Administrator
Department of Commerce
23. REDUCING DISTURBANCES TO HAWAIIAN SPINNER DOLPHINS FROM HUMAN INTERACTIONS

Priority:
Other Significant

Legal Authority:
16 USC 1361 et seq

CFR Citation:
50 CFR 216

Legal Deadline:
None

Abstract:
The National Marine Fisheries Service proposes regulations to protect the essential resting habitat of wild spinner dolphins (Stenella longirostris) in the main Hawaiian Islands, and to reduce the human activities that may cause “take,” as defined in the Marine Mammal Protection Act (MMPA) and its implementing regulations, or from other actions that otherwise adversely affect the dolphins, by proposing time-area closures in four bays on the island of Hawaii, and one on the island of Maui.

Statement of Need:
NMFS is concerned about the cumulative impacts on Hawaiian spinner dolphin populations from human interactions. Human interactions with dolphins in their resting habitats has increased over the past decade, with spinner dolphins now being the target of viewing or swim-with-wild-dolphins tours on a daily basis. Because spinner dolphins routinely use the same habitats, and stay in the bays for most of the day to rest, these same animals may be disturbed multiple times per day from the multiple tours that seek these animals daily. The unauthorized taking of spinner dolphins is occurring at these bays, with many adverse impacts as a result including: behavioral changes, shorter resting periods, and displacement from primary resting habitats. By protecting the essential resting habitat of the spinner dolphins, NMFS proposes to prevent the taking of these animals.

**Summary of Legal Basis:**

All marine mammals are protected under the Marine Mammal Protection Act (MMPA). NMFS is proposing these regulations pursuant to its rulemaking authority under MMPA 16 U.S.C. 1361 et seq.; 16 U.S.C. 1372 et seq., which generally prohibits the take of any marine mammals; and 16 U.S.C. 1382 et seq.

**Alternatives:**

1. No Action
2. Regulate human behaviors and activities
3. Implement time-area closures in specified spinner dolphin resting habitats
4. Combine limits on specified human behaviors with time-area closures
5. Full closure of all identified spinner dolphin resting habitats
6. Codify the West Hawaii Voluntary Standards for Marine Tourism

**Anticipated Cost and Benefits:**

The primary benefit of this action would be to reduce the unauthorized taking of spinner dolphins in their primary resting habitat. These animals are being disturbed in an area that is significant to their health, reproduction and survival. Managing the amount of interactions humans can have with spinner dolphins will help protect the animals in their natural environment. Costs with this proposed rule would affect humans as their use of these particular bays would be limited. Commercial tour operators, kayak companies, and spiritual retreat operators may be negatively economically impacted. The public at large
would not be allowed to engage in activities in the closure areas, and they may therefore associate a cost with this proposed action.

**Risks:**

No risks to public health, safety or the environment were identified with implementation of this rule.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Agency Contact:**

Melissa Andersen

Fishery Biologist, Management

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**RIN:** 0648–AU02
24. DESIGNATION OF CRITICAL HABITAT FOR THE NORTH ATLANTIC RIGHT WHALE

Priority:
Other Significant

Legal Authority:
16 USC 1361 et seq; 16 USC 1531 to 1543

CFR Citation:
50 CFR 226; 50 CFR 229

Legal Deadline:
None

Abstract:
In June 1970, the northern right whale was listed as endangered under the Endangered Species Conservation Act, the precursor to the Endangered Species Act (ESA)(35 FR 8495; codified at 50 CFR 17.11). Subsequently, right whales were listed as endangered under the ESA in 1973, and as depleted under the Marine Mammal Protection Act (MMPA) the same year. In 1994, NMFS designated critical habitat for the northern right whale, a single species thought at the time to include right whales in both the north Atlantic and the North Pacific.

In 2006, NMFS published a comprehensive right whale status review that concluded that recent genetic data provided unequivocal support to distinguish three right whale lineages (including the southern right whale) as separate phylogenetic species (Rosenbaum et al. 2000). Rosenbaum et al. (2000), concluded that the right whale should be regarded as the following three separate species: (1) The North Atlantic right whale (Eubalaena glacialis) ranging in the North Atlantic Ocean; (2) the North Pacific right whale (Eubalaena japonica), ranging in the North Pacific Ocean; and (3) the southern right whale (Eubalaena australis), historically ranging throughout the southern hemisphere’s oceans.
Based on these findings, NMFS published a proposed and final determination listing right whales in the North Atlantic and North Pacific as separate endangered species under the ESA (71 FR 77704, Dec. 27, 2006; 73 FR 12024, Mar. 6, 2008). Based on the new listing determination, NMFS is required by the ESA to designate critical habitat separately for both the North Atlantic right whale and the North Pacific right whale.

In April 2008, a final critical habitat determination was published for the North Pacific right whale (73 FR 19000; Apr. 8, 2008). At this time, NMFS is preparing a proposal to designate critical habitat for the North Atlantic right whale.

Statement of Need:
Under section 4 of the Endangered Species Act, NOAA Fisheries is required to designate critical habitat for newly listed species.

Summary of Legal Basis:
Endangered Species Act

Alternatives:
Because this rule is presently in the beginning stages of development, no alternatives have been formulated or analyzed at this time.

Anticipated Cost and Benefits:
Because this rule is presently in the beginning stages of development, no analysis has been completed at this time to assess costs and benefits.

Risks:
Loss of critical habitat for a species listed as protected under the ESA and MMPA, as well as potential loss of right whales due to habitat loss.

Timetable:

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Regulatory Flexibility Analysis Required:
No
Small Entities Affected:
No

Government Levels Affected:
None

Agency Contact:
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RIN: 0648–AY54

25. REGULATORY AMENDMENTS TO IMPLEMENT THE SHARK CONSERVATION ACT AND REVISE THE DEFINITION OF ILLEGAL, UNREPORTED, AND UNREGULATED FISHING

Priority:
Other Significant

Legal Authority:
16 USC 1826d to 1826k

CFR Citation:
50 CFR 300

Legal Deadline:
Final, Statutory, January 4, 2012, The rule needs to be published by December 4, 2011, due to the 30-day delay in effectiveness.

Abstract:

NMFS is amending identification and certification procedures under the High Seas Driftnet Fishing Moratorium Protection Act to help achieve shark conservation in international fisheries. NMFS must identify nations whose fishing vessels have engaged in high seas fisheries targeting or incidentally catching sharks not subject to a regulatory program for the conservation of sharks comparable to that of the United States, taking into account different conditions, as required under the Shark Conservation Act (Pub. L. 111-348). NMFS would subsequently certify whether identified nations have adopted regulatory programs governing the conservation of sharks that are comparable to U.S. programs, taking into account different conditions, and established management plans for sharks. The absence of sufficient steps may lead to prohibitions on the importation of certain fisheries products into the United States and other measures.

NMFS is also amending the regulatory definition of “illegal, unreported, and unregulated fishing” under the High Seas Driftnet Fishing Moratorium Protection Act.

The procedures for identification and certification would entail a multilateral approach of consultations and negotiations with other nations to achieve shark conservation.

This action is not expected to have adverse economic impacts, and any such impacts would be well below the economic threshold of impact pursuant to E.O. 12866. In addition, there are no novel legal or policy issues associated with this action since identification and certification procedures have already been established in regulations (50 CFR part 300). However, this action is significant under the meaning of E.O. 12866 because it could lead to trade restrictive measures applied against foreign nations.

Statement of Need:

These regulatory amendments are required to implement the international provisions of the Shark Conservation Act to identify and certify nations whose vessels are engaged in shark finning and/or fishing
for sharks in a manner that is not consistent with international management efforts. Additionally, this rule would revise the definition of Illegal, Unreported, and Unregulated (IUU) Fishing in response to comments on a prior rulemaking (0648-AV51) that set out the regulatory definition of IUU fishing.

**Summary of Legal Basis:**

**Alternatives:**
This action is categorically excluded from analysis under the National Environmental Policy Act because the proposed action is the promulgation of regulations of an administrative, financial, legal, technical, or procedural nature and the environmental effects of which are too broad, speculative, or conjectural to lend themselves to meaningful analysis and for which any potential cumulative effects are negligible. Consequently, no alternatives were analyzed.

**Anticipated Cost and Benefits:**
This action is not expected to have adverse economic impacts, and any such impacts would be well below the economic threshold of impact pursuant to E.O. 12866. Potential benefits, if any, would be indirect and accrue to internationally managed fisheries by strengthening Regional Fishery Management Organizations and by restricting U.S. market access through prohibiting illegally harvested fishery products.

**Risks:**
There are no novel legal or policy issues associated with this action since identification and certification procedures have already been established in regulations (50 CFR part 300). However, this action is significant under the meaning of E.O. 12866 because it could lead to trade restrictive measures applied against foreign nations.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
No
Small Entities Affected:
No

Government Levels Affected:
None

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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RIN: 0648–BA89

BILLING CODE 3510–12–S

DEPARTMENT OF DEFENSE

Statement of Regulatory Priorities

Background
The Department of Defense (DoD) is the largest Federal department, consisting of 3 Military departments (Army, Navy, and Air Force), 10 Unified Combatant Commands, 14 Defense Agencies, and 10 DoD Field Activities. It has 1,434,450 military personnel and 782,386 civilians assigned as of March 31, 2011, and over 200 large and medium installations in the continental United States, U. S. territories, and foreign countries. The overall size, composition, and dispersion of DoD, coupled with an innovative regulatory program, presents a challenge to the management of the Defense regulatory efforts under

Because of its diversified nature, DoD is affected by the regulations issued by regulatory agencies such as the Departments of Energy, Health and Human Services, Housing and Urban Development, Labor, Transportation, and the Environmental Protection Agency. In order to develop the best possible regulations that embody the principles and objectives embedded in E.O. 12866, there must be coordination of proposed regulations among the regulatory agencies and the affected DoD components. Coordinating the proposed regulations in advance throughout an organization as large as DoD is straightforward, yet a formidable undertaking.

DoD is not a regulatory agency, but occasionally it issues regulations that have an effect on the public. These regulations, while small in number compared to the regulating agencies, can be significant as defined in E.O. 12866. In addition, some of DoD’s regulations may affect the regulatory agencies. DoD, as an integral part of its program, not only receives coordinating actions from the regulating agencies, but coordinates with the agencies that are affected by its regulations as well.

**Overall Priorities**

The Department needs to function at a reasonable cost, while ensuring that it does not impose ineffective and unnecessarily burdensome regulations on the public. The rulemaking process should be responsive, efficient, cost-effective, and both fair and perceived as fair. This is being done in DoD while reacting to the contradictory pressures of providing more services with fewer resources. The Department of Defense, as a matter of overall priority for its regulatory program, fully incorporates the provisions of the President’s priorities and objectives under Executive Order (E.O.) 12866.

**Retrospective Review of Existing Regulations**

Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review (January 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. All are of particular interest to small businesses. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on
Regulations.gov. The final agency plans can be found at: http://www.regulations.gov/exchange/topic/eo-13563

- 0750-AH19 - Accelerated Payments to Small Business (DFARS Case 2011-D008)
- 0750-AH44 - Extension of DoD Mentor-Protégé Pilot Program (DFARS Case 2011-D050)
- 0750-AH45 - Deletion of Text Implementing 10 U.S.C. 2323 (DFARS Case 2011-D038)

**Administration Priorities:**

1. **Rulemakings that are expected to have high net benefits well in excess of costs.**

   The Department plans to—
   - Finalize the DFARS rule to permit offerors to propose an alternative line item structure to reflect the offeror’s business practices for selling and billing commercial items, and initial provisioning of spares for weapon systems. This rule should prevent misalignment of line item structure in receipt documents and invoices, which causes manual intervention and can delay payment;
   - Finalize the DFARS rule to conduct discussions prior to contract award for source selections of $100 million or more. A DoD study showed a significant positive correlation between high-dollar source selections that were conducted without discussions and protests sustained. This rule should reduce the number of protests filed and their resultant costs to contractors and the Government; and
   - Finalize the DFARS rule to implement section 866 of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2011 establishing a pilot program to acquire military purpose nondevelopmental items. This pilot program is designed to test whether the streamlined procedures, similar to those available for commercial items, can serve as an effective incentive for nontraditional defense contractors to (1) channel investment and innovation into areas that are useful to DoD and (2) provide items developed exclusively at private expense to meet validated military requirements. (2011-D034)

2. **Rulemakings that promote Open Government and use disclosure as a regulatory tool.**

   The Department plans to—
   - Finalize the Federal Acquisition Regulation (FAR) to inform contractors of the statutory
requirement of section 3010 of Public Law 111-212, to make Federal Awardee Performance and Integrity Information System information, excluding past performance reviews, available to the public;

- Finalize the FAR rule that implements section 743 of Division C of the Fiscal Year 2010 Consolidated Appropriations Act, which requires agencies to develop inventories of their service contacts, including number and work location of contractor employees;

- Finalize the FAR rule to establish standard evaluation factors and rating scales for documenting contractor performance;

- Finalize the FAR rule that implements the Federal Funding Accountability and Transparency Act of 2006, which requires the Office of Management and Budget (OMB) to establish a free, public, website containing full disclosure of all Federal contract award information. This rule requires contractors to report executive compensation and first-tier subcontractor awards on unclassified contracts expected to be $25,000 or more, except contracts with individuals;

- Finalize the FAR rule that implements section 811 of the NDAA for FY 2010, which requires a written justification and approval prior to awarding a sole-source contract in an amount over $20 million under the 8(a) program; and

- Finalize the DFARS rule to implement section 814 of the NDAA for FY 2010, which imposed additional reporting requirements for awards of single task and delivery-order contracts.

3. Rulemakings that streamline regulations and reduce unjustified burdens.

The Department plans to—

- Finalize the DFARS rule to remove the requirement to use DD Forms 2626 and 2631 to report past performance information for construction and architect-engineer services and to instead provide the performance reports electronically;

- Finalize the DFARS rule to amend the definition of “qualifying country end product” to make it comparable to the change in the definition of “domestic end product” by waiving the component test for qualifying country end products;

- Finalize the DFARS rule to update appendix F, Material Inspection and Receiving Report, to incorporate procedures for using the electronic Wide Area WorkFlow (WAWF) Receiving Report,
which is required for use in most contracts in lieu of the DD Form 250. WAWF is the electronic tool for documenting receipt and acceptance of supplies and services and for electronic invoicing; and

- Finalize the rule for DFARS coverage of patents, data, and copyrights, which significantly reduces the amount of regulatory text and the number of required clauses.

4. **Efforts to minimize burdens on small businesses**

   Of interest to Small Businesses are regulations to—

   - Finalize the DFARS rule to accelerate payments to all DoD small business contractors.

5. **Rules to be modified, streamlined, expanded, or repealed to make the agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives.**

   - **DFARS Case 2011-D028**—Removes component test for COTS items that are qualifying country end products. Require only determination of country of origin of the COTS item, not the components of the COTS item.
   - **DFARS Case 2011-D013**—Only One Offer. Motivate effective competition by driving behavior to allow sufficient time for submission of offers.
   - **DFARS Case 2011-D008**—Accelerate Small Business Payments. Accelerate payments to all small businesses, not just small disadvantaged businesses.
   - **DFARS Case 2010-D018**—Responsibility and Liability for Government Property. Includes fixed-price contracts that are awarded on the basis of adequate competition on the list of contract types whereby contractors are not held liable for loss of Government property.
   - **DFARS Case 2010-D001**—Patents, Data, and Copyrights. Rewrite of DFARS part 227, Patents, Data, and Copyrights.
   - **DFARS Case 2009-D026**—Multiyear Contracting. Comprehensive review of DFARS subpart 217.1 to simplify and clarify the coverage of multiyear acquisition.

**Specific DoD Priorities:**

For this regulatory plan, there are six specific DoD priorities, all of which reflect the established regulatory principles. In those areas where rulemaking or participation in the regulatory process is
required, DoD has studied and developed policy and regulations that incorporate the provisions of the President's priorities and objectives under the Executive order.

DoD has focused its regulatory resources on the most serious environmental, health, and safety risks. Perhaps most significant is that each of the priorities described below promulgates regulations to offset the resource impacts of Federal decisions on the public or to improve the quality of public life, such as those regulations concerning acquisition, security, energy projects, education, and health affairs.

1. Defense Procurement and Acquisition Policy

The Department of Defense continuously reviews the DFARS and continues to lead Government efforts to—

- Revise the DFARS to specify circumstances under which the U.S. Government needs to obtain data other than certified cost or pricing data from Canadian contractors via the Canadian Commercial Corporation.
- Revise the DFARS to provide detailed guidance and instruction to DoD contracting officers for the use of DoD's performance-based payments analysis tool when contemplating the use of performance-based payments on new fixed-price type contracts.
- Revise the DFARS to implement a DoD Better Buying Power initiative by providing a proposal-adequacy checklist in a provision to ensure offerors take responsibility for providing thorough, accurate, and complete proposals.
- Revise the DFARS to address standards and structures for the safeguarding of unclassified DoD information.
- Revise the DFARS to implement the DoD Better Buying Power initiative to address acquisitions using competitive procedures in which only one offer is received. With some exceptions, the contracting officer must resolicit for an additional period of at least 30 days, if the solicitation allowed fewer than 30 days for receipt of proposals and only one offer is received. If a period of at least 30 days was allowed for receipt of proposals, the contracting officer must determine prices to be fair and reasonable through price or cost analysis or enter negotiations with the offeror.
- Revise the DFARS to implement a DoD Better Buying Power initiative by requiring contractors to submit annual technical descriptions for their independent research and development projects.
• Revise the DFARS to establish means for cleared contractors, who have unclassified U.S. Government information resident on or transiting through contractor information systems, to share cyber threat information.
• Revise the FAR to implement section 841 of the National Defense Authorization Act for FY 2009, which required a review of the FAR coverage on organizational conflicts of interest (OCIs).
• Finalize the DFARS rule to clarify DoD policy regarding the definition and administration of contractor business systems to improve the effectiveness of DCMA/DCAA oversight of contractor business systems;
• Finalize the DFARS rule to implement a DoD Better Buying Power initiative to increase the use of fixed-price incentive (firm target) contracts;

2. Logistics and Materiel Readiness, Department of Defense

The Department of Defense published or plans to publish rules on contractors supporting the military in contingency operations:

• Final Rule: Private Security Contractors (PSCs) Operating in Contingency Operations, Combat Operations or Other Significant Military Operations. In order to meet the mandate of section 862 of the 2008 National Defense Authorization Act (NDAA) (as amended by section 813 (b) of the 2010 NDAA and section 832 of the 2011 NDAA), this rule establishes policy, assigns responsibilities, and provides procedures for the regulation of the selection, accountability, training, equipping, and conduct of personnel performing private security functions under a covered contract during contingency operations, combat operations, or other significant military operations. It also assigns responsibilities and establishes procedures for incident reporting, use of and accountability for equipment, rules for the use of force, and a process for administrative action or the removal, as appropriate, of PSCs and PSC personnel. DoD published an interim final rule on July 17, 2009 (74 FR 34690 to 34694), with an effective date of July 17, 2009. The comment period ended August 31, 2009. DoD, in coordination with the Department of State and the United States Agency for International Development, prepared a final rule, which included the responses to the public comments, and incorporated changes to the interim final rule, where appropriate. The final rule also incorporated the legislative changes required by section 813 (b) of the 2010 NDAA and section 832 of
the 2011 NDAA. The final rule was published August 11, 2011 (76 FR 49650), with an effective date of September 12, 2011.

- Interim Final Rule: Operational Contract Support. This rule will incorporate the latest changes and lessons learned into policy and procedures for operational contract support (OCS), including OCS program management, contract support integration, and the integration of DoD contractor personnel into contingency operations outside the United States. DoD anticipates publishing the interim final rule in the first or second quarter of FY 2012.

3. Installations and Environment, Department of Defense

The Department of Defense will publish a rule regarding the process for evaluating the impact of certain types of structures on military operations and readiness:

- Interim Final Rule: This rule implements policy, assigns responsibilities, and prescribes procedures for the establishment and operation of a process for evaluation of proposed projects submitted to the Secretary of Transportation under section 44718 of title 49, United States Code. The evaluation process is established for the purpose of identifying any adverse impact of proposed projects on military operations and readiness, minimizing or mitigating such adverse impacts, and determining if any such projects pose an unacceptable risk to the national security of the United States. The rule also includes procedures for the operation of a central DoD siting clearinghouse to facilitate both informal and formal reviews of proposed projects. This rule was required by section 358 of Public Law 111-383. DoD anticipates publishing an interim final rule in fourth quarter of FY 2011.

4. Military Community and Family Policy, Department of Defense

The Department of Defense plans to publish a final rule to implement policy, assign responsibilities, and prescribe procedures for the operation of voluntary education programs within DoD:

- Final Rule: Voluntary Education Programs. In this rule, the Department of Defense (DoD) implements policy, assigns responsibilities, and prescribes procedures for the operation of voluntary education programs within DoD. Several of the subject areas in this rule include: Procedures for
Service members participating in education programs; guidelines for establishing, maintaining, and operating voluntary education programs including, but not limited to, instructor-led courses offered on-installation and off-installation, as well as via distance learning; procedures for obtaining on-base voluntary education programs and services; minimum criteria for selecting institutions to deliver higher education programs and services on military installations; the establishment of a DoD Voluntary Education Partnership Memorandum of Understanding (MOU) between DoD and educational institutions receiving tuition assistance payments; and procedures for other education programs for Service members and their adult family members. The new requirement for a signed MOU with DoD from participating educational institutions will be effective January 1, 2012. The Department published a proposed rule on August 6, 2010 (75 FR 47504 to 47514). The comment period ended October 10, 2010, which contained a total of 110 comments. Several comments from the general public were accepted, including suggestions to clarify terms such as “one single tuition rate” and a “needs assessment.” DoD anticipates publishing the final rule during the first quarter of FY 2012.

5. Health Affairs, Department of Defense

The Department of Defense is able to meet its dual mission of wartime readiness and peacetime health care by operating an extensive network of medical treatment facilities. This network includes DoD’s own military treatment facilities supplemented by civilian health care providers, facilities, and services under contract to DoD through the TRICARE program. TRICARE is a major health care program designed to improve the management and integration of DoD’s health care delivery system. The program’s goal is to increase access to health care services, improve health care quality, and control health care costs.

The TRICARE Management Activity has published or plans to publish the following rules:

- Final rule on TRICARE: Reimbursement of Sole Community Hospitals and Adjustment to Reimbursement of Critical Access Hospitals. The rule implements the statutory provision in 10 United States Code 1079(j)(2) that TRICARE payment methods for institutional care shall be determined to the extent practicable in accordance with the same reimbursement rules as those that apply to payments to providers of services of the same type under Medicare. This rule implements a
reimbursement methodology similar to that furnished to Medicare beneficiaries for services provided by sole community hospitals. It is projected that implementation of this rule will result in a health care savings of $31 million per year with proposed phase-in period and an estimated initial start-up cost of $200,000. Any on-going administrative costs would be minimal and there are no applicable risks to the public. The proposed rule was published July 5, 2011 (76 FR 39043). The comment period ended on September 6, 2011. DoD anticipates publishing a final rule in the second quarter of FY 2012.

- Final rule on TRICARE: TRICARE Young Adult. The purpose of this interim final rule is to establish the TRICARE Young Adult program implementing section 702 of the Ike Skelton NDAA for FY 2011 (Pub. L. 111-383) to provide medical coverage to unmarried children under the age of 26 who no longer meet the age requirements for TRICARE eligibility (age 21, or 23 if enrolled in a full-time course of study at an institution of higher learning approved by the Secretary of Defense) and who are not eligible for medical coverage from an eligible employer-sponsored plan (as defined in section 5000A(f)(2) of the Internal Revenue Code of 1986). If qualified, they can purchase TRICARE Standard/Extra or TRICARE Prime benefits coverage. The particular TRICARE plan available depends on the military sponsor's eligibility and the availability of the TRICARE plan in the dependent's geographic location. It is projected that implementation of this rule will result in an estimated initial start-up cost of $3,000,000. Premiums are designed to cover the anticipated health care costs, as well as ongoing administrative costs. The interim final rule was published April 27, 2011 (76 FR 23479), with an immediate effective date. The comment period ended June 27, 2011. DoD anticipates publishing a final rule in the first quarter of FY 2012.

6. Personnel and Readiness, Department of Defense

The Department of Defense will publish a rule regarding Service Academies:

- Final Rule: Service Academies. This rule establishes policy, assigns responsibilities, and prescribes procedures for Department of Defense oversight of the Service Academies. Administrative costs are negligible and benefits are clear, concise rules that enable the Secretary of Defense to insure that the Service Academies are efficiently operated and meet the needs of the armed forces. The proposed rule was published October 18, 2007 (72 FR 59053), and included policy that has since changed. The final rule, particularly the explanation of separation policy, will reflect recent changes in
the Don’t Ask, Don’t Tell policy. DoD anticipates publishing the final rule in the second quarter of FY 2012.

BILLING CODE 5001–06–S

Statement of Regulatory Priorities

I. Introduction

The U.S. Department of Education (Department) supports States, local communities, institutions of higher education, and others in improving education nationwide and in helping to ensure that all Americans receive a quality education. We provide leadership and financial assistance pertaining to education at all levels to a wide range of stakeholders and individuals, including State educational agencies, local school districts, providers of early learning programs, elementary and secondary schools, institutions of higher education, career and technical schools, nonprofit organizations, postsecondary students, members of the public, families, and many others. These efforts are helping to ensure that all children and students from pre-kindergarten through grade 12 will be ready for, and succeed in, postsecondary education and that students attending postsecondary institutions are prepared for a profession or career.

We also vigorously monitor and enforce the implementation of Federal civil rights laws in educational programs and activities that receive Federal financial assistance, and support innovative programs, research and evaluation activities, technical assistance, and the dissemination of research and evaluation findings to improve the quality of education.

Overall, the laws, regulations, and programs we administer will affect nearly every American during his or her life. Indeed, in the 2011 to 2012 school year, about 55 million students will attend an estimated 99,000 elementary and secondary schools in approximately 13,800 public school districts, and about 21 million students will enroll in degree-granting postsecondary schools. All of these students may benefit from some degree of financial assistance or support from the Department.

In developing and implementing regulations, guidance, technical assistance, and monitoring related to our programs, we are committed to working closely with affected persons and groups. Specifically, we work with a broad range of interested parties and the general public including families, students, and educators; State, local, and tribal governments; and neighborhood groups, community-based early
learning programs, elementary and secondary schools, colleges, rehabilitation service providers, adult education providers, professional associations, advocacy organizations, businesses, and labor organizations.

We also continue to seek greater and more useful public participation in our rulemaking activities through the use of transparent and interactive rulemaking procedures and new technologies. If we determine that it is necessary to develop regulations, we seek public participation at the key stages in the rulemaking process. We invite the public to submit comments on all proposed regulations through the Internet or by regular mail.

To facilitate the public's involvement, we participate in the Federal Docketing Management System (FDMS), an electronic single Governmentwide access point (www.regulations.gov) that enables the public to submit comments on different types of Federal regulatory documents and read and respond to comments submitted by other members of the public during the public comment period. This system provides the public with the opportunity to submit comments electronically on any notice of proposed rulemaking or interim final regulations open for comment, as well as read and print any supporting regulatory documents.

We are continuing to streamline information collections, reduce the burden on information providers involved in our programs, and make information easily accessible to the public.

II. Regulatory Priorities

A. American Recovery and Reinvestment Act of 2009

On February 17, 2009, President Obama signed into law the American Recovery and Reinvestment Act of 2009 (ARRA), historic legislation designed, in part, to invest in critical sectors, including education. ARRA laid the foundation for education reform by supporting investments in innovative strategies that are most likely to lead to improved results for students, long-term gains in school and school system capacity, and increased productivity and effectiveness. ARRA provided funding for several key discretionary grant programs, including the Race to the Top Fund and the Investing in Innovation Fund (i3) programs.

The Race to the Top Fund program, the largest competitive education grant program in U.S. history, is designed to provide incentives to States to implement system-changing reforms that result in improved student achievement, narrowed achievement gaps, and increased high school graduation and college
enrollment rates. Congress authorized and provided $4.35 billion for ARRA in 2010, and the Department awarded approximately $4 billion in Race to the Top State grant funds in two phases. The Department awarded $600 million to Delaware and Tennessee under the Race to the Top Phase 1 competition and approximately $3.4 billion to the winners of the Phase 2 competition: The District of Columbia, Florida, Georgia, Hawaii, Maryland, Massachusetts, New York, North Carolina, Ohio, and Rhode Island.

In announcing the winners of the Race to the Top Phase 2 competition, the Secretary noted that “[w]e had many more competitive applications than money to fund them in this round” and expressed the hope that any Race to the Top funding included in the Department’s FY 2011 appropriations would be available for Race to the Top Phase 3 awards. In particular, there were nine finalists in the Phase 2 competition that did not receive funding despite submitting bold and ambitious plans for comprehensive reforms and innovations in their systems of elementary and secondary education. These nine finalists were: Arizona, California, Colorado, Illinois, Kentucky, Louisiana, New Jersey, Pennsylvania, and South Carolina.

On April 15, 2011, President Obama signed into law Public Law 112-10, the Department of Defense and Full-Year Continuing Appropriations Act, 2011 (FY 2011 Appropriations Act), which made $698.6 million available for the Race to the Top Fund, authorized the Secretary to make awards on “the basis of previously submitted applications,” and amended ARRA to permit the Secretary to make grants for improving early childhood care and learning under the program.

Race to the Top--Early Learning Challenge (RTT-ELC). On May 25, 2011, Secretary Duncan and the Secretary of Health and Human Services, Kathleen Sebelius, announced the RTT-ELC, a new $500 million State-level grant competition to be held in 2011 and authorized under ARRA and the FY 2011 Appropriations Act. The Departments of Education and Health and Human Services are administering this competition jointly. At its core is a strong commitment by the Administration to stimulate a national effort to make sure all children enter kindergarten ready to succeed. Through the RTT-ELC, the Administration seeks to help close the achievement gap between children with high needs and their peers by supporting State efforts to build strong systems of early learning and development that provide increased access to high-quality programs for the children who need it most. This competition represents an unprecedented opportunity for States to focus deeply on their early learning and development systems
for children from birth through age five. It is an opportunity to build a more unified approach to supporting young children and their families—an approach that increases access to high-quality early learning and development programs and services, and helps ensure that children enter kindergarten with the skills, knowledge, and dispositions toward learning that they need to be successful.

The Departments of Education and Health and Human Services have published requirements for the FY 2011 competition and will complete the competition and make awards by the end of 2011.

Race to the Top Phase 3. On May 25, 2011, the Department also announced that approximately $200 million of the FY 2011 Race to the Top funds would be made available to some or all of the nine unfunded finalists from the 2010 Race to the Top Phase 2 competition. The Department recognizes that $200 million is not sufficient to support full implementation of the plans submitted during the Phase 2 competition, and therefore believes that making these funds available to the remaining nine finalists is the best way to create incentives for these States to carry out the bold reforms proposed in their applications. We have issued final eligibility requirements for the nine unfunded finalists to apply for Race to the Top Phase 3 funds.

B. Elementary and Secondary Education Act of 1965, as Amended

In 2010, the Administration released the Blueprint for Reform: The Reauthorization of the Elementary and Secondary Education Act, the President’s plan for revising the Elementary and Secondary Education Act of 1965 (ESEA) and replacing the No Child Left Behind Act of 2001 (NCLB).

The blueprint can be found at the following Web site:

We look forward to congressional reauthorization of the ESEA that will build on many of the reforms States and LEAs will be implementing under the ARRA grant programs. In the interim, we may propose amendments to our current regulations implementing the ESEA.

Additionally, as we continue to work with Congress on reauthorization of the ESEA, we are currently implementing a plan to provide flexibility on certain provisions of current law for States and school districts that are willing to embrace reform. The mechanisms we are implementing will ensure continued accountability and commitment to quality education for all students while at the same time
providing States and school districts with increased flexibility to implement State and local reforms to improve student achievement.

C. Higher Education Act of 1965, as Amended

Changes to the FFEL and Direct Loan Programs. On March 30, 2010, the President signed into law the Health Care and Education Reconciliation Act of 2010, Public Law 111-152, title II of which is the SAFRA Act. SAFRA made a number of changes to the Federal student financial aid programs under title IV of the Higher Education Act of 1965, as amended (HEA). One of the most significant changes made by SAFRA is that it ended new loans under the Federal Family Education Loan (FFEL) Program authorized by title IV, part B, of the HEA as of July 1, 2010.

On May 5, 2011, ED announced through a notice in the Federal Register that it was beginning a negotiated rulemaking process to streamline the loan program regulations by repealing unnecessary FFEL Program regulations and incorporating and modifying necessary requirements within the Direct Loan Program regulations, as appropriate. ED held four public hearings in May 2011 to obtain public feedback on proposed amendments, as well as on possible amendments to other ED regulations, including those governing income-based and income-contingent loan repayment plans and loan discharges based on the total and permanent disability of the borrower. Based on the feedback received from these hearings, ED will soon form a negotiated rulemaking committee to consider proposed amendments and intends to conduct these negotiations in 2012.

Approval of New Gainful Employment Programs. Over the last 2 years, the Department has conducted two significant rulemakings to enhance its program integrity regulations related to the title IV, student aid programs. As part of this effort, on October 29, 2010, the Department issued regulations that included requirements for an institution to notify the Department before offering a new educational program that provides training leading to gainful employment in a recognized occupation (Gainful Employment--New Programs). The Department established the notification requirement out of concern that some institutions might attempt to circumvent proposed regulations regarding gainful employment standards by adding new programs before those standards could take effect. The Department explained that the notification process requirements were intended to
remain in effect until the final regulations that established eligibility measures for gainful employment programs would take effect.

We published the final regulations establishing the gainful employment eligibility measures on June 13, 2011 (Gainful Employment--Debt Measures). In those regulations, the Department established measures for gainful employment programs that are intended to identify the worst performing programs. We believe that when these new regulations go into effect on July 1, 2013, the notification process for all new gainful employment programs established in the Gainful Employment--New Programs final regulations will no longer be needed. Accordingly, the Department has issued a new NPRM, which among other changes, proposes to reduce burden for institutions by amending the Gainful Employment--New Programs final regulations to establish a smaller group of gainful employment programs for which an institution must obtain approval from the Department.

Title II of the HEA. The Secretary intends to develop regulations under title II of the HEA to streamline the program, institutional, and State report cards; prescribe data quality standards to ensure reliability, validity, and accuracy of the data submitted; and establish standards for identifying low-performing teacher preparation programs.

**D. Individuals with Disabilities Education Act**

We have issued final regulations that revise the regulations implementing the Early Intervention Program for Infants and Toddlers with Disabilities authorized under part C of the Individuals with Disabilities Education Act (IDEA) to make changes needed for the appropriate implementation of the early intervention program. The final part C regulations incorporate provisions from the 2004 amendments to part C of the IDEA. Additionally, the final regulations provide States with flexibility in some areas, while ensuring State accountability to improve results, and needed services for infants and toddlers with disabilities and their families.

The Department has also issued a notice of proposed rulemaking to revise the regulations implementing the Assistance to States for the Education of Children with Disabilities program authorized under part B of the IDEA and intends to issue final regulations in the coming year.

Specifically, over the last 6 months, we engaged in a review of one particular provision of the part B regulations, relating to the use of public benefits or insurance to pay for services provided to children
under part B. IDEA and the part B regulations allow public agencies to use public benefits or insurance (e.g., Medicaid) to provide or pay for services required under part B with the consent of the parent of a child who is enrolled in a public benefits or insurance program. Public insurance is an important source of financial support for services required under part B. With respect to the use of public insurance, our current regulations specifically provide that a public agency must obtain parental consent each time access to public benefits or insurance is sought.

We are now proposing to amend the regulations to provide that, instead of having to obtain parental consent each time access to public benefits or insurance is sought, the public agency responsible for providing special education and related services to a child would be required, before accessing a child’s or parent’s public benefits or insurance, to provide written notification to the child’s parents. The notification would inform parents of their rights under the part B regulations regarding the use of public benefits or insurance to pay for part B services, including information about the limitations on a public agency’s billing of public benefits or insurance programs, as well as parents’ rights under the Family Educational Rights and Privacy Act and IDEA to consent prior to the disclosure of personally identifiable information.

We are proposing these amendments to reduce unnecessary burden on a public agency’s ability to access public benefits or insurance in appropriate circumstances but still maintain critical parent protections, and we do this for several reasons. Specifically, we are mindful of the importance of ensuring that parents have sufficient information to make decisions about a public agency’s use of their public benefits or insurance and the disclosure of their child’s educational records for that purpose. At the same time, these proposed amendments are designed to address the concern expressed to the Department by many State personnel and other interested parties that, since the publication of the part B regulations in 2006, the inability to obtain parental consent has contributed to public agencies’ failure to claim all of the Federal financial assistance available for part B services covered under Medicaid. In addition, public agencies have expressed concern over using limited resources and the significant administrative burden of obtaining parental consent for the use of Medicaid and other public benefits or insurance each time that access to public benefits or insurance is sought. Consequently, many of these parties have requested that the Department remove the parental consent requirement.
E. *Family Educational Rights and Privacy Act*

Given the President's emphasis on improving the collection and use of data as a key element of educational reform, we intend to issue final regulations in the coming year to amend our current regulations for the Family Educational Rights and Privacy Act of 1974 (FERPA) to ensure that States are able to effectively establish and expand robust statewide longitudinal data systems while protecting student privacy.

F. *Other Potential Regulatory Activities*

Congress may reauthorize the Adult Education and Family Literacy Act (AEFLA) (title II of the Workforce Investment Act of 1998) and the Rehabilitation Act of 1973 (title IV of the Workforce Investment Act of 1998). The Administration is working with Congress to ensure that any changes to these laws (1) improve the State grant and other programs providing assistance for adult education under the AEFLA and for vocational rehabilitation and independent living services for persons with disabilities under the Rehabilitation Act of 1973; and (2) provide greater accountability in the administration of programs under both statutes. Changes to our regulations may be necessary as a result of the reauthorization of these two statutes.

III. *Retrospective Review of Existing Regulations*

Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review" (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of the entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final agency plans can be found at: http://www2.ed.gov/about/open.html.

<table>
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<tr>
<th>RIN</th>
<th>Title of Rulemaking</th>
<th>Do we expect this rulemaking to significantly reduce burden on small businesses?</th>
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IV. Principles for Regulating

Over the next year, other regulations may be needed because of new legislation or programmatic changes. In developing and promulgating regulations we follow our Principles for Regulating, which determine when and how we will regulate. Through consistent application of the following principles, we have eliminated unnecessary regulations and identified situations in which major programs could be implemented without regulations or with limited regulatory action.

In deciding when to regulate, we consider the following:
• Whether regulations are essential to promote quality and equality of opportunity in education.
• Whether a demonstrated problem cannot be resolved without regulation.
• Whether regulations are necessary to provide a legally binding interpretation to resolve ambiguity.
• Whether entities or situations subject to regulation are similar enough that a uniform approach through regulation would be meaningful and do more good than harm.
• Whether regulations are needed to protect the Federal interest; that is, to ensure that Federal funds are used for their intended purpose and to eliminate fraud, waste, and abuse.

In deciding how to regulate, we are mindful of the following principles:

• Regulate no more than necessary.
• Minimize burden, to the extent possible, and promote multiple approaches to meeting statutory requirements if possible.
• Encourage coordination of federally funded activities with State and local reform activities.
• Ensure that the benefits justify the costs of regulating.
• To the extent possible, establish performance objectives rather than specify compliance behavior.
• Encourage flexibility, to the extent possible, and as needed to enable institutional forces to achieve desired results.
Abstract:
The Secretary proposes to amend the title IV, HEA student assistance regulations to (1) reflect that, as of July 1, 2010, under title II of the Health Care and Education Reconciliation Act of 2010 (the SAFRA Act), no new Federal Family Education Loan Program loans will be made and (2) to reflect other changes to improve the effectiveness and efficiency of the student loan programs, particularly with regard to the discharge of loans for persons with total and permanent disabilities.

Statement of Need:
These regulations are needed to reflect the provisions of the SAFRA Act (title II of the Health Care and Education Reconciliation Act of 2010) and to reflect other amendments to the HEA resulting from the SAFRA Act.

Summary of Legal Basis:
Health Care and Education Reconciliation Act of 2010, Public Law 111-152.

Alternatives:
The Department is still developing these proposed regulations; our discussion of alternatives will be included in the notice of proposed rulemaking.

Anticipated Cost and Benefits:
Estimates of the costs and benefits are currently under development and will be included in the notice of proposed rulemaking.

Risks:
None.

Timetable:

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<th>Action</th>
<th>Date</th>
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<td>03/00/12</td>
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Regulatory Flexibility Analysis Required:
Undetermined

Government Levels Affected:
None

URL For Public Comments:
Fall 2011 Statement of Regulatory and Deregulatory Priorities

The Department of Energy (Department or DOE) makes vital contributions to the Nation’s welfare through its activities focused on improving national security, energy supply, energy efficiency, environmental remediation, and energy research. The Department’s mission is to:

- Promote dependable, affordable, and environmentally sound production and distribution of energy;
- Advance energy efficiency and conservation;
- Provide responsible stewardship of the Nation’s nuclear weapons;
- Provide a responsible resolution to the environmental legacy of nuclear weapons production;
- Strengthen U.S. scientific discovery, economic competitiveness, and improving quality of life through innovations in science and technology.
The Department’s regulatory activities are essential to achieving its critical mission and to implementing major initiatives of the President’s National Energy Policy. Among other things, the Regulatory Plan and the Unified Agenda contain the rulemakings the Department will be engaged in during the coming year to fulfill the Department’s commitment to meeting deadlines for issuance of energy conservation standards and related test procedures. The Regulatory Plan and Unified Agenda also reflect the Department’s continuing commitment to cut costs, reduce regulatory burden, and increase responsiveness to the public.

Energy Efficiency Program for Consumer Products and Commercial Equipment

The Energy Policy and Conservation Act (EPCA) requires DOE to set appliance efficiency standards at levels that achieve the maximum improvement in energy efficiency that is technologically feasible and economically justified. The standards already published in 2011 have an estimated net benefit to the Nation of up to $16.6 billion over 30 years. By 2045, these standards are expected to save enough energy to operate all U.S. homes for more than 7 months.

The Department continues to follow its schedule for setting new appliance efficiency standards. These rulemakings are expected to save American consumers billions of dollars in energy costs. The schedule outlines how DOE will address the various appliance standards rulemakings necessary to meet statutory requirements established in EPCA, the Energy Policy Act of 2005 (EPACT 2005), and the Energy Independence and Security Act of 2007 (EISA 2007).

The overall plan for implementing the schedule is contained in the Report to Congress under section 141 of EPACT 2005 that was released on January 31, 2006. This plan was last updated in the August 2011 report to Congress and now includes the requirements of the Energy Independence and Security Act of 2007 (EISA 2007). The reports to Congress are posted at:
The August 2011 report identifies all products for which DOE has missed the deadlines established in EPCA (42 U.S.C. section 6291 et seq.). It also describes the reasons for such delays and the Department’s plan for expeditiously prescribing new or amended standards. Information and timetables concerning these actions can also be found in the Department’s regulatory agenda, which is posted online at: www.reginfo.gov.

**Estimate of Combined Aggregate Costs and Benefits**

The regulatory actions included in this regulatory plan are expected to provide significant benefits to the Nation for product categories including: fluorescent lamp ballasts, manufactured housing, battery chargers and external power supplies, walk-in coolers and freezers, and incandescent reflector lamps. DOE believes that the benefits to the Nation of the proposed energy standards for fluorescent lamp ballasts (energy savings, consumer average lifecycle cost savings, national net present value increase, and emission reductions) outweigh the costs (loss of industry net present value and life-cycle cost increases for some consumers). DOE estimates that these regulations will produce an energy savings between 3.7 and 6.3 quads over 30 years. The benefit to the Nation will be between $8.1 billion (7% discount rate) and $24.7 billion (3% discount rate). DOE believes that the proposed energy standards for manufactured housing, battery chargers and external power supplies, walk-in coolers and freezers, and incandescent reflector lamps will also be beneficial to the Nation. However, because DOE has not yet proposed candidate standard levels for this equipment, DOE cannot provide an estimate of combined aggregate costs and benefits for these actions. DOE will, however, in compliance with all applicable law, issue standards that provide the maximum energy savings that are technologically feasible and economically justified. Estimates of energy savings will be provided when DOE issues the notices of proposed rulemaking for this equipment.
27. ENERGY EFFICIENCY STANDARDS FOR BATTERY CHARGERS AND EXTERNAL POWER SUPPLIES

Priority:
Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:
Undetermined

Legal Authority:
42 USC 6295(u)

CFR Citation:
10 CFR 430

Legal Deadline:
Final, Statutory, July 1, 2011.

Abstract:
In addition to the existing general definition of “external power supply,” the Energy Independence and Security Act of 2007 (EISA) defines a “Class A external power supply” and sets efficiency standards for those products. EISA directs DOE to publish a final rule to determine whether the standards set for Class A external power supplies should be amended. EISA also requires DOE to issue a final rule prescribing energy conservation standards for battery chargers, if technologically feasible and economically justified.

Statement of Need:
The Energy Policy and Conservation Act (EPCA) requires minimum energy standards for appliances, which has the effect of eliminating inefficient appliances and equipment from the market.

Summary of Legal Basis:
Title III of EPCA sets forth a variety of provisions designed to improve energy efficiency. Part A of title III (42 U.S.C. 6291 to 6309) provides for the Energy Conservation Program for Consumer Products other than Automobiles. EPCA directs DOE to conduct a rulemaking to establish energy conservation standards for battery chargers or determine that no energy conservation standard is technically feasible and economically justified (42 U.S.C. 6295 (u)(1)(E)(i)and (ii)).
In addition to the existing general definition of “external power supply,” EPCA defines a “Class A external power supply” (42 U.S.C. 6291(36)(C)) and sets efficiency standards for those products (42 U.S.C. 6295(u)(3)). EPCA directs DOE to publish a final rule to determine whether amended standards should be set for Class A external power supplies, or new standards set for other classes of external power supplies. If such determination is positive, DOE must include any amended or new standards as part of that final rule.

DOE is bundling the two requirements to establish energy conservation standards for battery chargers and to consider amended or new standards for external power supplies into a single rulemaking.

**Alternatives:**

The statute requires the Department to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of the alternative standard levels, including the existing standard, based on the criteria specified by the statute.

**Anticipated Cost and Benefits:**

Because DOE has not yet proposed candidate standard levels for this equipment, DOE cannot provide an estimate of combined aggregate costs and benefits for these actions. DOE will, however, in compliance with all applicable law, issue standards that provide the maximum energy savings that are technologically feasible and economically justified. Estimates of energy savings will be provided when DOE issues the notices of proposed rulemaking for this equipment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Yes

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
Local, State

**Federalism:**
Undetermined

**URL For More Information:**
www1.eere.energy.gov/buildings/appliance_standards/residential/battery_external.html

**Agency Contact:**
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Office of Building Technologies Program, EE–2J
Department of Energy
Energy Efficiency and Renewable Energy
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Washington, DC 20585
Phone: 202 586–4549
Email: victor.petrolati@ee.doe.gov

**Related RIN:** Related to 1904–AB75

**RIN:** 1904–AB57
28. ENERGY CONSERVATION STANDARDS FOR WALK–IN COOLERS AND WALK–IN FREEZERS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
42 USC 6313(f)(4)

CFR Citation:
10 CFR 431

Legal Deadline:
Final, Statutory, January 1, 2012.

Abstract:

Statement of Need:
The Energy Policy and Conservation Act requires minimum energy efficiency standards for appliances, which has the effect of eliminating inefficient appliances and equipment from the market.

Summary of Legal Basis:
Section 312 of the Energy Independence and Security Act of 2007 (EISA) establishes definitions and standards for walk-in coolers and walk-in freezers. EISA directs DOE to establish performance-based standards not later than January 1, 2012 (42 U.S.C. 6313 (f)(4)).

Alternatives:
The statute requires the Department to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is
technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of the alternative standard levels, including the existing standard, based on the criteria specified by the statute.

**Anticipated Cost and Benefits:**

Because DOE has not yet proposed candidate standard levels for this equipment, DOE cannot provide an estimate of combined aggregate costs and benefits for these actions. DOE will, however, in compliance with all applicable law, issue standards that provide the maximum energy savings that are technologically feasible and economically justified. Estimates of energy savings will be provided when DOE issues the notice of proposed rulemaking for this equipment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Local, State

**Federalism:**

Undetermined

**Additional Information:**
Comments pertaining to this rule may be submitted electronically to WICF-2008-STD-0015@ee.doe.gov.

**URL For More Information:**

www.eere.energy.gov/buildings/appliance_standards/commercial/wicf.html

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Charles Llenza

Office of Building Technologies Program, EE–2J

Department of Energy

Energy Efficiency and Renewable Energy

1000 Independence Avenue SW.

Washington, DC 20585

Phone: 202 586–2192

Email: charles.llenza@ee.doe.gov

**Related RIN:** Related to 1904–AB85

**RIN:** 1904–AB86

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**DOE—EE**

29. ENERGY EFFICIENCY STANDARDS FOR MANUFACTURED HOUSING

**Priority:**

Economically Significant. Major under 5 USC 801.

**Unfunded Mandates:**

Undetermined

**Legal Authority:**

42 USC 17071

**CFR Citation:**

10 CFR 460
Legal Deadline:
Final, Statutory, December 19, 2011.

Abstract:
The rule would establish energy efficiency standards for manufactured housing and a system to ensure compliance with, and enforcement of, the standards.

Statement of Need:
The Energy Independence and Security Act requires increased energy efficiency standards for manufactured housing.

Summary of Legal Basis:

Alternatives:
The statute requires DOE to conduct a rulemaking to establish standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, DOE conducts a thorough analysis of the alternative standard levels, including the existing standard, based on the criteria specified by the statute.

Anticipated Cost and Benefits:
Because DOE has not yet proposed candidate standard levels, DOE cannot provide an estimate of combined aggregate costs and benefits for these actions. DOE will, however, in compliance with all applicable law, issue standards that provide the increased energy savings that are technologically feasible and economically justified. Estimates of energy savings will be provided when DOE issues the notice of proposed rulemaking.

Timetable:

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Regulatory Flexibility Analysis Required:
Undetermined

Government Levels Affected:
None

URL For More Information:
www.energycodes.gov/status/mfg_housing.stm

URL For Public Comments:
www.regulations.gov

Agency Contact:
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Program Manager, Office of Building Technologies Program, EE–2J
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Energy Efficiency and Renewable Energy
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Washington, DC 20585
Phone: 202 586–7935
Email: ajett.majette@hq.doe.gov

RIN: 1904–AC11

30. ENERGY CONSERVATION STANDARDS FOR ER, BR, AND SMALL DIAMETER INCANDESCENT REFLECTOR LAMPS

Priority:
Other Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined
Legal Authority:
42 USC 6291(30)(C)(ii) and (F); 42 USC 6295(i)

CFR Citation:
10 CFR 430

Legal Deadline:
None

Abstract:
Amendments to Energy Policy and Conservation Act (EPCA) in the Energy Independence and Security Act of 2007 (EISA) amended the energy conservation standards to extend coverage to certain classes of IRL that had previously been outside the statutory definition of “incandescent reflector lamp” although these lamps were excluded from the statutory standard levels. However, EISA 2007 authorized DOE to amend these standards if such amendments were warranted. Specifically, as amended, EPCA exempted certain small diameter, ellipsoidal reflector (ER) and bulged reflector (BR) lamps from standards. In June 2009, DOE published a final rule amending existing standards for IRL. In earlier stages of the June 2009 rulemaking, DOE had interpreted its authority with regard to IRL as limited to amending congressionally established standard levels only, and not to the exemptions set by Congress for certain explicitly identified small diameter, ER and BR lamps, commonly used in track lighting and recessed cans. On further review, DOE has concluded that DOE has authority to establish efficiency standards for these currently exempt small diameter ER and BR lamps. However, as a practical matter, DOE could not consider these lamps as part of the previous rulemaking because it had not conducted the requisite analyses to set appropriate standard levels. Pursuant to EPCA, DOE is now conducting a rulemaking as to energy conservation standards for certain incandescent reflector lamps (IRL) that have ER or BR bulb shapes, and for certain IRL with diameters less than 2.25 inches.

Statement of Need:
The Energy Policy and Conservation Act requires minimum energy efficiency standards for appliances, which has the effect of eliminating inefficient appliances and equipment from the market.

Summary of Legal Basis:
Section 322 of the Energy Independence and Security Act of 2007 (EISA) establishes definitions and standards for ER, BR, and BPAR incandescent reflector lamps. (42 U.S.C. 6291(54) to 6291(56), 42 U.S.C. 6295 (i)) Furthermore, section 305 of EISA directs DOE to, not later than 6 years after issuance of any final rule establishing or amending a standard, publish either a notice of determination that standards do not need to be amended or a notice of proposed rulemaking including new proposed standards. (42 U.S.C. 6295 (m))

**Alternatives:**

The statute requires the Department to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, the Department conducts a thorough analysis of the alternative standard levels, including the existing standard, based on the criteria specified by the statute.

**Anticipated Cost and Benefits:**

Because DOE has not yet proposed candidate standard levels for this equipment, DOE cannot provide an estimate of combined aggregate costs and benefits for these actions. DOE will, however, in compliance with all applicable law, issue standards that provide the maximum energy savings that are technologically feasible and economically justified. Estimates of energy savings will be provided when DOE issues the notice of proposed rulemaking for this equipment.

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**Regulatory Flexibility Analysis Required:**

Yes
Small Entities Affected:
Businesses

Government Levels Affected:
Undetermined

Federalism:
Undetermined

URL For More Information:
www1.eere.energy.gov/buildings/appliance_standards/residential/incandescent_lamps.html

URL For Public Comments:
www.regulations.gov

Agency Contact:
Lucy Debutts
Office of Buildings Technologies Program, EE–2J
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Energy Efficiency and Renewable Energy
1000 Independence Avenue SW.
Washington, DC 20585
Phone: 202 287–1604
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Related RIN: Related to 1904–AA92
RIN: 1904–AC15

<table>
<thead>
<tr>
<th>DOE—EE</th>
<th>FINAL RULE STAGE</th>
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<tr>
<td>31. ENERGY EFFICIENCY STANDARDS FOR FLUORESCENT LAMP BALLASTS</td>
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Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:

42 USC 6295(g)

CFR Citation:

10 CFR 430

Legal Deadline:

Final, Judicial, October 28, 2011.

Abstract:

DOE is reviewing and updating energy efficiency standards, as required by the Energy Policy and Conservation Act, to reflect technological advances. All amended energy efficiency standards must be technologically feasible and economically justified. This is the second review of the statutory standards for fluorescent lamp ballasts.

Statement of Need:

The Energy Policy and Conservation Act requires minimum energy efficiency standards for appliances, which has the effect of eliminating inefficient appliances and equipment from the market.

Summary of Legal Basis:

The Energy Policy and Conservation Act (EPCA) of 1975 (42 U.S.C. 6291 to 6309) established an energy conservation program for major household appliances. Amendments to EPCA in the National Appliance Energy Conservation Amendments of 1988 (NAECA 1988) established energy conservation standards for fluorescent lamp ballasts. These amendments also required that DOE (1) conduct two rulemaking cycles to determine whether these standards should be amended, and (2) for each rulemaking cycle, determine whether the standards in effect for fluorescent lamp ballasts should be amended to apply to additional fluorescent lamp ballasts. (42 U.S.C. 6295(g)(7)(A) and (B)). On September 19, 2000, DOE published a final rule in the Federal Register, which completed the first rulemaking cycle to amend energy conservation standards for fluorescent lamp ballasts. 65 FR 56740. This rulemaking encompasses DOE's second cycle of review to determine whether the standards in effect for fluorescent lamp ballasts should be amended and whether the standards should be applicable to additional fluorescent lamp ballasts.

Alternatives:
The statute requires DOE to conduct rulemakings to review standards and to revise standards to achieve the maximum improvement in energy efficiency that the Secretary determines is technologically feasible and economically justified. In making this determination, DOE conducts a thorough analysis of the alternative standard levels, including the existing standard, based on the criteria specified by the statute.

**Anticipated Cost and Benefits:**

DOE believes that the benefits to the Nation from energy standards for fluorescent lamp ballasts (energy savings, consumer average lifecycle cost (LCC) savings, national net present value (NPV) increase, and emission reductions) outweigh the burdens (loss of NPV and LCC increases of some small electric motor users). DOE estimates that energy savings from electricity will be between 3.7 and 6.3 quads over 30 years and the benefits to the Nation will be between $8.1 and $24.7 billion.

**Timetable:**

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<td>73 FR 3653</td>
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<td>Notice: Public Meetings, Data Availability</td>
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<tr>
<td>Notice of Data Availability (NODA); Request for</td>
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<td>76 FR 52892</td>
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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses
Government Levels Affected:
Local, State

Federalism:
This action may have federalism implications as defined in EO 13132.

URL For More Information:
www1.eere.energy.gov/buildings/appliance_standards/residential/fluorescent_lamp_ballasts.html

URL For Public Comments:
www.regulations.gov

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Related RIN: Related to 1904–AB77, Related to 1904–AA99

RIN: 1904–AB50

BILLING CODE 6450–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Statement of Regulatory Priorities for FY 2012

The Department of Health and Human Services is the Federal Government's principal agency charged with protecting the health of all Americans and providing essential human services, especially for those least able to help themselves. The Department operates more than 300 programs covering a wide spectrum of activities, manages almost a quarter of all Federal outlays, and administers more grant dollars than all other Federal agencies combined. The Department's major program responsibilities
include: Medicare and Medicaid; control and prevention of communicable and chronic disease; support for public health preparedness and emergency response; biomedical research; substance abuse and mental health treatment and prevention; assuring safe and effective drugs, devices, and other medical products; protecting the food supply; assistance to low-income families; the Head Start program; and improving access to health care services to the uninsured, isolated, or medically vulnerable. Currently, the Department is the principal agency charged with implementing one of the President's signature achievements—transformative health care reform through the Affordable Care Act of 2010.

To implement this vast program portfolio, the Department develops an active regulatory agenda each year, driven largely by statutory mandates and interactions with stakeholders. The President also called upon Federal agencies to reform the regulatory process in his January 18, 2011, Executive Order 13563 “Improving Regulation and Regulatory Review.” A key directive in that Executive order was to require agencies to conduct an inventory of existing regulations to determine whether such regulations should be modified, streamlined, expanded, or repealed to make an agency's regulatory scheme more effective or less burdensome in achieving its programmatic objectives.

With these regulatory drivers in mind, Secretary Kathleen Sebelius has worked with HHS agencies to craft a regulatory agenda that reflects her commitments to implementing meaningful health care reform, access to health care coverage, and high value health care services that are safe and effective for all Americans. The agenda also reflects her other strategic initiatives, which include securing and maintaining health care coverage for all Americans; improving quality and patient safety; more rapidly responding to adverse events; implementing a 21st century food safety system; helping Americans achieve and maintain healthy living habits; advancing scientific research; and streamlining regulations to reduce the regulatory burden on industry and States. Within this agenda, the Secretary has also been mindful of the need to reform the ongoing regulatory process through retrospective review of existing regulations, and this agenda reflects her commitment to that review by incorporating some of the most significant burden reduction reforms across all Federal agencies. In fact, of the $10 billion in savings from retrospective regulatory review across all Federal agencies announced by the Administrator of the Office
of Information and Regulatory Affairs, $5 billion was attributable to regulations contained within this
Department’s current regulatory agenda.

What follows is an overview of the Department’s regulatory priorities for FY 2012 and some of the
regulations on the agenda that best exemplify these priorities.

Making Health Insurance Coverage More Secure for Those Who Have Insurance and Extending
Coverage to the Uninsured

As a result of the Affordable Care Act, the Department is making affordable health care coverage more
stable and secure through insurance market reforms designed to protect consumers against
unreasonable insurance premium increases, provide them with more comprehensive and understandable
information with which to make decisions, and enable eligible consumers to receive financial support for
health insurance easily and seamlessly. In 2014, all people who suffer from chronic conditions will no
longer be excluded from insurance coverage or charged higher premiums because of a pre-existing
condition or medical history.

Already, insurers are prohibited from putting lifetime dollar limits and restrictive annual caps on what
they will pay for health care services needed by the people they insure, ensuring that those people have
access to medical care throughout their lives, especially when it is most needed. HHS is working with
States to help identify and put a stop to unreasonable health insurance premium rate increases and will
require new health plans to implement a comprehensive appeals process for those beneficiaries who
have been denied coverage or payment by the insurance plan. New health insurers will also be required
to spend the majority of health insurance premiums on medical care and health care quality improvement,
not on administration and overhead. As well, the Affordable Care Act is providing reimbursement to
employers that offer health benefits to early retirees, providing insurance coverage through the Pre-
exising Condition Insurance Plan to people who would otherwise be locked out of the insurance market
because of their pre-existing health conditions, and requiring plans that offer dependent coverage to make that coverage available to young adults up to age 26.

Moving forward this year, the Department will continue to implement the Affordable Care Act to promote consumer protections, improve quality and safety, provide incentives for more efficient care delivery, and slow the growth of health care costs. The Centers for Medicare & Medicaid Services (CMS) will finalize three rules that will expand access to health insurance and provide consumers with better options and information about insurance:

- CMS will issue standards for the establishment of the Affordable Insurance Exchanges (Exchanges) to provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price and quality. These Exchanges will help enhance competition in the health insurance market, improve choice of affordable health insurance, and give small businesses the same purchasing clout as large businesses.

- Another rule helps to make coverage more secure by offsetting market uncertainty and risk selection to maintain the viability of Exchanges. Under risk adjustment, HHS, in consultation with the States, will establish criteria and methods to be used by States in determining the actuarial risk of plans within a State to minimize the negative effects of adverse selection. Under reinsurance, all health insurance issuers, and third-party administrators on behalf of self-insured group health plans, will contribute to a nonprofit reinsurance entity to support reinsurance payments to individual market issuers that cover high risk individuals.

- To extend health insurance to greater numbers of low-income people, Medicaid eligibility in 2014 will expand to cover adults under the age of 65 earning up to 133 percent of the Federal poverty level, and those who earn above that level may be eligible for tax credits through the Exchanges to help pay their premiums. New, simplified procedures for determining Medicaid, CHIP, and tax credit eligibility will be forthcoming in 2012. CMS will simplify eligibility rules to make it easier for eligible
individuals and families to obtain premium tax credits and Medicaid coverage, including ensuring that Medicaid uses the same eligibility standards as other insurance affordability programs available through the Exchange, as directed by law. The rule further outlines how Medicaid and CHIP will coordinate closely with the Exchange, including sharing data to ensure that individuals are determined eligible for the appropriate insurance affordability program regardless of where an applicant submits the application.

*Improving Health Care Quality and Patient Safety*

Across America and for all Americans, the Department is working to improve patient outcomes, ensure patient safety, promote efficiency and accountability, encourage shared responsibility, and reduce health care costs. Through improved administrative processes, reforms, innovations, and additional information to support consumer decisionmaking, HHS is supporting high-value, safe, and effective care across health care settings and in the community.

In 2011, the Department published a key regulation to advance this priority—the final rule for Accountable Care Organizations. This rule establishes a system of shared savings for qualified organizations that deliver primary care services to a given patient population. The objective is to promote accountability and shared responsibility for the delivery of care, especially to those with co-morbidities of chronic health problems in order to prevent unnecessary and costly in-patient hospital care, reduce health care acquired conditions, and improve the quality of life for those individuals. This rule serves as a companion to additional demonstration programs designed to explore alternative services delivery and payment systems that are being sponsored by the new Center for Medicare and Medicaid Innovation. Several more key regulations are on the agenda to move forward in meeting these quality and patient safety goals:

- CMS is implementing value-based purchasing programs throughout its payment structure in order to reward hospitals and other health care providers for delivering high-quality care, rather than just a
high volume of services. The payment rules scheduled for publication this year will reflect a mix of standards, processes, outcomes, and patient experience of care measures, including measures of care transition and changes in patient functional status.

• The Department continues to encourage health care providers to become meaningful users of health information technology (IT) by accelerating health IT adoption and promoting electronic health records to help improve the quality of health care, reduce costs, and ultimately, improve health outcomes. Electronic health records and health information exchange can help clinicians provide higher quality and safer care for their patients. By adopting electronic health records in a meaningful way, clinicians will know more about their patients to better coordinate and improve the quality of patient care, and they can make better decisions about treatments and conditions.

Improving Response to Adverse Events

In a related activity, the FDA will be proposing a new rule to establish a unique identification system for medical devices in order to track a device from pre-market application through distribution and use. This system will allow FDA and other public health entities to track individual devices so that when an adverse event occurs, epidemiologists can quickly track down and identify other users of the device to provide guidance and recommendations on what steps to take to prevent additional adverse actions.

Implementing a 21st Century Food Safety System

The Food Safety Modernization Act of 2010, signed into law by the President in January 2011, directs the Food and Drug Administration (FDA), working with a wide range of public and private partners, to build a new system of food safety oversight—one focused on applying the best available science and good common sense to prevent the problems that can make people sick. In implementing that Act, the
Department’s goal is to shift emphasis from removing unsafe products from the market place to keeping unsafe food from entering commerce in the first place.

FDA will propose several new rules to establish a robust, enhanced food safety program.

- FDA will propose regulations establishing preventive controls in the manufacture and distribution of human foods and of animal feeds. These regulations will constitute the heart of the food safety program by instituting, for the first time, good manufacturing practices for the manufacture and distribution of food products to ensure that those products are safe for consumption and will not cause or spread disease.

- Perhaps most anticipated in light of food borne illnesses occurring in 2011, FDA will introduce a rule addressing produce safety to ensure that produce sold in the marketplace meets rigorous safety standards. The regulation will set enforceable, science-based standards for the safe production and harvesting of fresh produce at the farm and the packing house to minimize the risk of serious adverse health consequences.

- In another proposed rule, FDA will require food importers to have a foreign supplier verification program that will be adequate to provide assurances that each foreign supplier produces food in a manner that provides the same level of protection as required for domestic production under the Food Drug and Cosmetic Act.

- FDA will establish a program to accredit third-party auditors to conduct food safety audits of foreign entities. Such a program will relieve importers of having to establish such programs themselves and, instead, allow them to contract with an accredited auditor to meet the audit requirements.

_Empowering Americans to Make Healthy Choices in the Marketplace_
Roughly two-thirds of adults and one-third of children in the United States are overweight or obese, increasing their risk for chronic diseases, including heart disease, type 2 diabetes, certain cancers, stroke, and arthritis. Almost 10 percent of all medical spending is used to treat obesity-related conditions. In order to reverse the obesity epidemic, HHS is employing a comprehensive approach that includes both clinical and public health strategies and touches people where they live, work, learn, and play.

To help advance this agenda, FDA will finalize two rules aimed at empowering consumers to make healthy eating choices. The rules require nutrition labeling on standard menu items in restaurants and similar retail food establishments, as well as on food sold in vending machines. One rule will require restaurants and similar retail food establishments with 20 or more locations to list calorie content information for standard menu items on restaurant menus and menu boards, including drive-through menu boards. Other nutrient information—total calories, fat, saturated fat, cholesterol, sodium, total carbohydrates, sugars, fiber and total protein—would have to be made available in writing upon request. The other rule will require vending machine operators who own or operate 20 or more vending machines to disclose calorie content for some items. The Department anticipates that such information will ensure that patrons of chain restaurants and vending machines have nutritional information about the food they are consuming.

Two additional rules will also improve dietary information available to consumers. One is a revision to the nutrition and supplement facts labels. Much of the information found on the Nutrition Facts label has not been updated since 1993 when mandatory nutrition labeling of food was first required. The aim of the proposed revision is to provide updated and easier to read nutrition information on the label to help consumers maintain healthy dietary practices. The other proposed rule will focus on the serving sizes of foods that can reasonably consumed in one serving. This rule would amend the labeling regulations to provide updated reference amounts for certain food categories with new consumption data derived from the current National Health and Nutrition Survey.
Advancing Scientific Research

To effectively address the challenges the Department faces in crafting the best, evidence-based approaches to advance health services delivery, protect the public health, ensure essential human services, promote biomedical research, and ensure the availability of safe medical and food products, the Department must rely on research. The lynchpin of this research is found in the ethical rules governing research on human subjects.

In a major undertaking, the Department is in the process of reviewing and revising those ethical rules, commonly referred to as the Common Rule. The Common Rule serves to guide researchers and investigators in the Department, but also throughout the Federal Government, in the conduct and protocols for doing research on human subjects. The proposed revisions will be designed to better protect human subjects who are involved in research, while facilitating research and reducing burden, delay, and ambiguity for investigators.

Streamlining Regulations to Reduce Regulatory Burdens

Consistent with the President’s Executive Order 13563, the Department continues its commitment to reducing the regulatory burden on the health care industry through the use of modern technology. As part of this effort, FDA will advance several rules designed to reduce the reporting and data submission requirements from manufacturers of drugs and medical devices.

In one such rule, FDA will permit manufacturers, importers, and users of medical devices to submit reports of adverse events to the FDA electronically. This proposed change will not only reduce the paper reporting burden on industry, but also allow FDA to more quickly review safety reports and identify emerging public health issues. Under another proposed rule, FDA would revise existing regulations to allow clinical study data and bioequivalence data for new drug applications and biological license applications to be provided electronically. Again, this rule will reduce the reporting burden on industry and also permit FDA to more readily process and review applications.

CMS is also engaged in regulatory reduction and streamlining activities. Of particular note are several rules on conditions of participation for hospitals and other providers. The most comprehensive of these rules is the one reducing regulatory burdens on hospitals, which is expected to save as much as $940
million annually over the next 5 years. This rule will implement changes to hospital conditions of participation to reflect substantial advances in health care delivery and patient safety knowledge and practices.

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<th>HHS—Office of the Secretary (OS)</th>
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32. • HEALTH INFORMATION TECHNOLOGY: NEW AND REVISED STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA FOR ELECTRONIC HEALTH RECORD TECHNOLOGY

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
42 USC 300jj–14

CFR Citation:
45 CFR 170

Legal Deadline:
None

Abstract:
The final rule that established the initial set of standards, implementation specifications, and certification criteria was published in the Federal Register on July 28, 2010. The initial set represented the first round of an incremental approach to adopting future sets of standards, implementation specifications, and certification criteria to enhance electronic health record (EHR) interoperability, functionality, and utility. Under the authority provided by section 3004 of the Public Health Service Act (PHSA), this notice of proposed rulemaking would propose that the Secretary adopt revisions to the initial set as well as new standards, implementation specifications and certification criteria. The proposed new and revised standards, implementation specifications, and certification criteria would establish the technical capabilities that certified EHR technology would need to include to support meaningful use under the CMS Medicare and Medicaid EHR Incentive Programs.

Statement of Need:
The final rule that established the initial set of standards, implementation specifications, and certification criteria was published in the Federal Register on July 28, 2010. The initial set represented the first round of an incremental approach to adopting future sets of standards, implementation specifications, and certification criteria for electronic health record (EHR) technology. In a notice of proposed rulemaking, the Secretary would propose new and revised standards, implementation specifications, and certification criteria that would establish the technical capabilities that certified EHR technology would need to include in order to support meaningful use under the CMS Medicare and Medicaid EHR Incentive Programs.

Summary of Legal Basis:
Under the authority provided by section 3004 of the Public Health Service Act (PHSA), the Secretary would propose to adopt revisions to the initial set of standards, implementation specifications, and certification criteria and propose new standards, implementation specifications and certification criteria.

Alternatives:
No alternatives are available because eligible professionals, eligible hospitals, and critical access hospitals under the CMS Medicare and Medicaid EHR Incentive Programs are required to demonstrate meaningful use of certified EHR technology. This rule ensures that the certification requirements necessary to support the achievement of meaningful use Stage 2 keep pace with the changes to the requirements in the CMS Medicare and Medicaid EHR Incentive Programs.

Anticipated Cost and Benefits:
EHR technology developers seeking certification are expected to incur costs related to EHR technology redesign, reprogramming, and new capability development. Benefits include greater standardization and increased EHR technology interoperability and functionality.

Risks:
Absent a rulemaking, it is unlikely that currently certified EHR technology would include the requisite capacities to support an eligible professional's, eligible hospital's, or critical access hospital's achievement of meaningful use under the CMS Medicare and Medicaid EHR Incentive Programs.

Timetable:

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Regulatory Flexibility Analysis Required:
Undetermined

Government Levels Affected:
None

Agency Contact:
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RIN: 0991–AB82

HHS—Food and Drug Administration (FDA)  PROPOSED RULE STAGE

33. ELECTRONIC SUBMISSION OF DATA FROM STUDIES EVALUATING HUMAN DRUGS AND BIOLOGICS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
21 USC 355; 21 USC 371; 42 USC 262

CFR Citation:
21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96

Legal Deadline:
Abstract:
The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive.

Statement of Need:
Before a drug is approved for marketing, FDA must determine that the drug is safe and effective for its intended use. This determination is based in part on clinical study data and bioequivalence data that are submitted as part of the marketing application. Study data submitted to FDA in electronic format have generally been more efficient to process and review.

FDA's proposed rule would address the submission of study data in a standardized electronic format. Electronic submission of study data would improve patient safety and enhance health care delivery by enabling FDA to process, review, and archive data more efficiently. Standardization would also enhance the ability to share study data and communicate results. Investigators and industry would benefit from the use of standards throughout the lifecycle of a study—in data collection, reporting, and analysis. The proposal would work in concert with ongoing Agency and national initiatives to support increased use of electronic technology as a means to improve patient safety and enhance health care delivery.

Summary of Legal Basis:
Our legal authority to amend our regulations governing the submission and format of clinical study data and bioequivalence data for human drugs and biologics derives from sections 505 and 701 of the Act (21 U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262).

Alternatives:
FDA considered issuing a guidance document outlining the electronic submission and the standardization of study data, but not requiring electronic submission of the data in the standardized format. This
alternative was rejected because the Agency would not fully benefit from standardization until it became
the industry standard, which could take up to 20 years.

We also considered a number of different implementation scenarios, from shorter to longer time-periods.
The 2-year time-period was selected because the Agency believes it would provide ample time for
applicants to comply without too long a delay in the effective date. A longer time-period would delay the
benefit from the increased efficiencies, such as standardization of review tools across applications, and
the incremental cost savings to industry would be small.

**Anticipated Cost and Benefits:**
Standardization of clinical data structure, terminology, and code sets will increase the efficiency of the
Agency review process. FDA estimates that the costs resulting from the proposal would include
substantial one-time costs, additional waves of one-time costs as standards mature, and possibly some
annual recurring costs. One-time costs would include, among other things, the cost of converting data to
standard structures, terminology, and cost sets (i.e., purchase of software to convert data); the cost of
submitting electronic data (i.e., purchase of file transfer programs); and the cost of installing and
validating the software and training personnel. Additional annual recurring costs may result from software
purchases and licensing agreements for use of proprietary terminologies. The proposal could result in
many long-term benefits associated with reduced time for preparing applications, including reduced
preparation costs and faster time to market for beneficial products. In addition, the proposed rule would
improve patient safety through faster, more efficient, comprehensive and accurate data review, as well as
enhanced communication among sponsors and clinicians.

**Risks:**
None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Yes
Small Entities Affected:
Businesses

Government Levels Affected:
None

Agency Contact:
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RIN: 0910–AC52

HHS—FDA

34. CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK–BENEFIT PREVENTIVE CONTROLS FOR FOOD FOR ANIMALS

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
21 USC 342; 21 USC 350e; 21 USC 371; 21 USC 374; 42 USC 264; PL 110–85, sec 1002(a)(2); PL 111–353

CFR Citation:
Legal Deadline:
Final, Statutory, September 27, 2009, FDA is directed to issue proposed and final regulations under FDA Amendments Act by the statutory deadline.

The legal deadline for FDA under the Food Safety and Modernization Act to promulgate regulations is July 2012.

Abstract:
The Food and Drug Administration (FDA) is proposing regulations for preventive controls for animal feed ingredients and mixed animal feed to provide greater assurance that marketed animal feed ingredients and mixed feeds intended for all animals, including pets, are safe. This action is being taken as part of the FDA's Animal Feed Safety System initiative. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007, under section 1002(a), and the Food Safety Modernization Act of 2010 (FSMA), under section 103.

Statement of Need:
Regulatory oversight of the animal food industry has traditionally been limited and focused on a few known safety issues, so there could be potential human and animal health problems that remain unaddressed. The massive pet food recall due to adulteration of pet food with melamine and cyanuric acid in 2007 is a prime example. The actions taken by two protein suppliers in China affected a large number of pet food suppliers in the United States and created a nationwide problem. By the time the cause of the problem was identified, melamine and cyanuric acid contaminated ingredients resulted in the adulteration of millions of individual servings of pet food. Congress passed FSMA which the President signed into law on January 4, 2011 (Pub. L. 111-353). Section 103 of FSMA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 418 (21 U.S.C. 350g) Hazard Analysis and Risk Based Preventive Controls. In enacting FSMA, Congress sought to improve the safety of food in the United States by taking a risk-based approach to food safety, emphasizing prevention. Section 418 of the FD&C Act requires owners, operators, or agents in charge of food facilities to develop and implement a written plan that describes and documents how their facility will implement the hazard analysis and preventive controls required by this section.
Summary of Legal Basis:

FDA's authority for issuing this rule is provided in FSMA (Pub. L. 111-353), which amended the FD&C Act by establishing section 418, which directed FDA to publish implementing regulations. FSMA also amended section 301 of the FD&C Act to add 301(uu) that states the operation of a facility that manufactures, processes, packs, or holds food for sale in the United States if the owner, operator, or agent in charge of such facility is not in compliance with section 418 of the FD&C Act is a prohibited act. Further authority comes from section 1002(a) of title X of the FDAAA of 2007 (21 U.S.C. 2102) requiring the Secretary to update standards for the processing of pet food.

FDA is also issuing this rule under the general requirements of section 402 of the FD&C Act (21 U.S.C. 342) for adulterated food.

In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) authorizes the Agency to issue regulations for the efficient enforcement of the Act.

Alternatives:

The 2011 FSMA limited the Agency's flexibility to exclude many requirements. It described in detail its requirements for subpart C, concerning the hazard analysis and risk-based preventive controls part of the proposed rule. Alternatives include certain requirements listed in subpart B concerning operations and practices.

Anticipated Cost and Benefits:

The benefits of the proposed rule would result from fewer cases of contaminated animal food ingredients or finished animal food products. Discovering contaminated food ingredients before they are used in a finished product would reduce the number of recalls of contaminated animal food products. Benefits would include reduced medical treatment costs for animals and humans, reduced loss of market value of live animals, reduced loss of animal companionship, and reduced loss in value of animal food products. More stringent requirements for animal food manufacturing would maintain public confidence in the safety of animal foods and protect animal and human health. FDA lacks sufficient data to quantify the benefits of the proposed rule.
The compliance costs of the proposed rule would result from the additional labor and capital required to perform the hazard analyses, write and implement the preventive controls, monitor and verify the preventive controls, take corrective actions if preventive controls fail to prevent feeds from becoming contaminated, and implement requirements from the operations and practices section.

**Risks:**

FDA is proposing this rule to provide greater assurance that food intended for animals is safe and will not cause illness or injury to animals or humans. This rule would implement a risk-based, preventive controls food safety system intended to prevent animal food containing hazards, which may cause illness or injury to animals or humans, from entering into the food supply. The rule would apply to domestic and imported animal food (including raw materials and ingredients). Fewer cases of animal food contamination would (1) reduce the risk of serious illness and death to animals, (2) reduce the risk of adverse health effects to humans handling animal food, and (3) reduce the risk of consuming human food from animals that consumed contaminated food.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**International Impacts:**

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Agency Contact:**

Kim Young
HHS—FDA

35. UNIQUE DEVICE IDENTIFICATION

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
Not Yet Determined

CFR Citation:

Legal Deadline:
None

Abstract:
The Food and Drug Administration Amendments Act of 2007 (FDAAA), amended the Federal Food, Drug, and Cosmetic Act by adding section 519(f) (21 U.S.C. 360i(f)). This section requires FDA to promulgate regulations establishing a unique identification system for medical devices requiring the label of medical devices to bear a unique identifier, unless FDA specifies an alternative placement or provides for
exceptions. The unique identifier must adequately identify the device through distribution and use, and may include information on the lot or serial number.

**Statement of Need:**

A unique device identification system will help reduce medical errors; will allow FDA, the healthcare community, and industry to more rapidly review and organize adverse event reports; identify problems relating to a particular device (even down to a particular lot or batch, range of serial numbers, or range of manufacturing or expiration dates); and thereby allow for more rapid, effective, corrective actions that focus sharply on the specific devices that are of concern.

**Summary of Legal Basis:**

Section 519(f) of the FD&C Act (added by sec. 226 of the Food and Drug Administration Amendments Act of 2007) directs the Secretary to promulgate regulations establishing a unique device identification (UDI) system for medical devices, requiring the label of devices to bear a unique identifier that will adequately identify the device through its distribution and use.

**Alternatives:**

FDA considered several alternatives that would allow certain requirements of the proposed rule to vary, such as the required elements of a UDI and the scope of affected devices.

**Anticipated Cost and Benefits:**

FDA estimates that the affected industry would incur one-time and recurring costs, including administrative costs, to change and print labels that include the required elements of a UDI, costs to purchase equipment to print and verify the UDI, and costs to purchase software and integrate and validate the UDI into existing IT systems. FDA anticipates that implementation of a UDI system would help improve the efficiency and accuracy of medical device recalls and medical device adverse event reporting. The proposed rule would also standardize how medical devices are identified and contribute to future potential public health benefits of initiatives aimed at optimizing the use of automated systems in healthcare. Most of these benefits, however, require complementary developments and innovations in the private and public sectors.

**Risks:**
This rule is intended to substantially eliminate existing obstacles to the consistent identification of medical devices used in the United States. By providing the means to rapidly and accurately identify a device and key attributes that affect its safe and effective use, the rule would reduce medical errors that result from misidentification of a device or confusion concerning its appropriate use. The rule will fulfill a statutory directive to establish a unique device identification system.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Federalism:**

Undetermined

**Agency Contact:**

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**RIN:** 0910–AG31
36. PRODUCE SAFETY REGULATION

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
21 USC 342; 21 USC 350h; 21 USC 371; 42 USC 264; PL 111–353 (signed on Jan. 4, 2011)

CFR Citation:
Not Yet Determined

Legal Deadline:
NPRM, Statutory, January 4, 2012, Proposed rule not later than 12 months after the date of enactment of the Food Safety Modernization Act.

Abstract:
The Food Safety Modernization Act requires the Secretary to establish and publish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables, including specific mixes or categories of fruits and vegetables, that are raw agricultural commodities for which the Secretary has determined that such standards minimize the risk of serious adverse health consequences or death. FDA is proposing to promulgate regulations setting enforceable standards for fresh produce safety at the farm and packing house. The purpose of the proposed rule is to reduce the risk of illness associated with contaminated fresh produce. The proposed rule will be based on prevention-oriented public health principles and incorporate what we have learned in the past decade since the Agency issued general good agricultural practice guidelines entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (GAPs Guide). The proposed rule also will reflect comments received on the Agency’s 1998 update of its GAPs guide and its July 2009 draft commodity specific guidances for tomatoes, leafy greens, and melons. Although the proposed rule will be
based on recommendations that are included in the GAPs guide, FDA does not intend to make the entire
guidance mandatory. FDA's proposed rule would, however, set out clear standards for implementation of
modern preventive controls. The proposed rule also would emphasize the importance of environmental
assessments to identify hazards and possible pathways of contamination and provide examples of risk
reduction practices recognizing that operators must tailor their preventive controls to particular hazards
and conditions affecting their operations. The requirements of the proposed rule would be scale
appropriate and commensurate with the relative risks and complexity of individual operations. FDA
intends to issue guidance to assist industry in complying with the requirements of the new regulation.

Statement of Need:
FDA is taking this action to meet the requirements of the FSMA and to address the food safety challenges
associated with fresh produce and thereby protect the public health. Data indicate that between 1973 and
1997, outbreaks of foodborne illness in the U.S. associated with fresh produce increased in absolute
numbers and as a proportion of all reported foodborne illness outbreaks. The Agency issued general
good agricultural practice guidelines for fresh fruits and vegetables over a decade ago. Incorporating
prevention-oriented public health principles and incorporating what we have learned in the past decade
into a regulation is a critical step in establishing standards for the growing, harvesting, packing, and
storing of produce and reducing the foodborne illness attributed to fresh produce.

Summary of Legal Basis:
FDA is relying on the amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act),
provided by section 105 of the Food Safety Modernization Act (codified primarily in sec. 419 of the FD&C
Act (21 U.S.C. 350h)). FDA's legal basis also derives in part from sections 402(a)(4) and 701(a) of the
FD&C Act (21 U.S.C. 342(a)(4) and 371(a)). FDA also intends to rely on section 361 of the Public Health
Service Act (PHS Act) (42 U.S.C. 264), which gives FDA authority to promulgate regulations to control the
spread of communicable disease.

Alternatives:
Section 105 of the Food Safety Modernization Act requires FDA to conduct this rulemaking.

Anticipated Cost and Benefits:
FDA estimates that the costs to more than 300,000 domestic and foreign producers and packers of fresh produce from the proposal would include one-time costs (e.g., new tools and equipment) and recurring costs (e.g., monitoring, training, recordkeeping). FDA anticipates that the benefits would be a reduction in foodborne illness and deaths associated with fresh produce. Monetized estimates of costs and benefits are not available at this time.

**Risks:**

This regulation would directly and materially advance the Federal Government's substantial interest in reducing the risks for illness and death associated with foodborne infections associated with the consumption of fresh produce. Less restrictive and less comprehensive approaches have not been sufficiently effective in reducing the problems addressed by this regulation. FDA anticipates that the regulation would lead to a significant decrease in foodborne illness associated with fresh produce consumed in the U.S.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Federalism:**

Undetermined

**International Impacts:**

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Agency Contact:**

Samir Assar
HHS—FDA

37. HAZARD ANALYSIS AND RISK–BASED PREVENTIVE CONTROLS

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
21 USC 342; 21 USC 371; 42 USC 264; PL 111–353 (signed on Jan. 4, 2011)

CFR Citation:
21 CFR 110

Legal Deadline:
Final, Statutory, July 4, 2012, Final rule must be published no later than 18 months after the date of enactment of the FDA Food Safety Modernization Act.

Not later than 9 months after the date of enactment of the FDA Food Safety Modernization Act.

Abstract:
The Food and Drug Administration (FDA) Food Safety Modernization Act (the FSMA) requires the Secretary of Health and Human Services to promulgate regulations to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and
documenting the implementation of the preventive controls; and to define the terms “small business” and “very small business.” The FSMA also requires the Secretary to promulgate regulations with respect to activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on a farm or another farm under the same ownership and activities that constitute on farm manufacturing or processing of food that is not grown, raised, or consumed on a farm or another farm under the same ownership.

FDA is proposing to amend its current good manufacturing practice (CGMP) regulations (21 CFR part 110) for manufacturing, packing, or holding human food to require food facilities to develop and implement a written food safety plan. This proposed rule would require a food facility to have and implement preventive controls to significantly minimize or prevent the occurrence of hazards that could affect food manufactured, processed, packed, or held by the facility and to provide assurances that such food will not be adulterated under section 402 or misbranded under section 403(w).

Statement of Need:
FDA is taking this action to meet the requirements of the FSMA and to better address changes that have occurred in the food industry and thereby protect public health.

FDA last updated its food CGMP regulations for the manufacturing, packing, or holding of human food in 1986. Modernizing these food CGMP regulations to address risk-based preventive controls and more explicitly address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces, would be a critical step in raising the standards for food production and distribution. By amending 21 CFR 110 to modernize good manufacturing practices, the agency could focus the attention of food processors on measures that have been proven to significantly reduce the risk of food-borne illness. An amended regulation also would allow the agency to better focus its regulatory efforts on ensuring industry compliance with controls that have a significant food safety impact.

Summary of Legal Basis:
FDA is relying on section 103 of the FSMA. FDA is also relying on sections 402(a)(3), (a)(4) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 342(a)(3), (a)(4), and 371(a)).

Under section 402(a)(3) of the FD&C Act, a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Under section 402(a)(4), a food is adulterated if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. Under section 701(a) of the FD&C Act, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act.

FDA's legal basis also derives from section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), which gives FDA authority to promulgate regulations to control the spread of communicable disease.

Alternatives:
An alternative to this rulemaking is not to update the CGMP regulations, and instead issue separate regulations to implement the FDA Food Safety Modernization Act.

Anticipated Cost and Benefits:
FDA estimates that the costs from the proposal to domestic and foreign producers and packers of processed foods would include new one-time costs (e.g., adoption of written food safety plans, setting up training programs, implementing allergen controls, and purchasing new tools and equipment) and recurring costs (e.g., auditing and monitoring suppliers of sensitive raw materials and ingredients, training employees, and completing and maintaining records used throughout the facility). FDA anticipates that the benefits would be a reduced risk of food-borne illness and death from processed foods and a reduction in the number of safety related recalls.

Risks:
This regulation will directly and materially advance the Federal Government's substantial interest in reducing the risks for illness and death associated with food-borne infections. Less restrictive and less comprehensive approaches have not been effective in reducing the problems addressed by this regulation. The regulation will lead to a significant decrease in foodborne illness in the U.S.

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Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Businesses

Government Levels Affected:
None

Federalism:
Undetermined

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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RIN: 0910–AG36

38. FOREIGN SUPPLIER VERIFICATION PROGRAM
**Priority:**
Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:**
Undetermined

**Legal Authority:**
Title III, sec 301 of FDA Food Safety Modernization Act, PL 111–353, establishing sec 805 of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

**CFR Citation:**
Not Yet Determined

**Legal Deadline:**

**Abstract:**
The proposed rule would establish regulations concerning the content of foreign supplier verification programs. The regulations will require that each importer have a foreign supplier verification program that is adequate to provide assurances that each foreign supplier produces food in compliance with: (1) Processes and procedures that provide the same level of public health protection as those required under section 418 (concerning hazard analysis and risk-based preventative controls) or section 419 (concerning produce safety standards) of the FD&C Act; and (2) sections 402 (concerning adulteration) and 403(w) (concerning major food allergens) of the FD&C Act. In promulgating the foreign supplier verification regulations, we will, as appropriate, take into account differences among importers and types of imported foods, including differences related to the level of risk posed by an imported food. Methods of foreign supplier verification may include monitoring records for shipments, lot-by-lot certifications of compliance, annual on-site inspections, checking the hazard analysis and risk-based preventive control plans of foreign suppliers, and periodically testing and sampling shipments.

**Statement of Need:**
The proposed rule is needed to help improve the safety of food that is imported into the United States. Imported food products have increased dramatically over the last several decades. Data indicate that about 15% of the U.S. food supply is imported. FSMA provides the Agency with additional tools and
authorities to help ensure that imported foods are safe for U.S. consumers. Included among these tools and authorities is a requirement that importers perform risk-based foreign supplier verification activities to verify that the food they import is produced in compliance with U.S. requirements and is not adulterated or misbranded. This proposed rule on the content of foreign supplier verification program (FSVPs) sets forth the proposed steps that food importers would be required to take to fulfill their responsibility to ensure the safety of the food they bring into this country.

**Summary of Legal Basis:**

Section 805(c) of the FD&C Act (21 U.S.C. 384a(c)) directs FDA, not later than 1 year after the date of enactment of FSMA, to issue regulations on the content of FSVPs. Section 805(c)(4) states that verification activities under such programs may include monitoring records for shipments, lot-by-lot certification of compliance, annual onsite inspections, checking the hazard analysis and risk-based preventive control plans of foreign suppliers, and periodically testing and sampling shipments of imported products. Section 301(b) of FSMA amends section 301 of the FD&C Act (21 U.S.C. 331) by adding section 301(zz), which designates as a prohibited act the importation or offering for importation of a food if the importer (as defined in section 805) does not have in place an FSVP in compliance with section 805. In addition, section 301(c) of FSMA amends section 801(a) of the FD&C Act (21 U.S.C. 381(a)) by stating that an article of food being imported or offered for import into the United States shall be refused admission if it appears from an examination of a sample of such an article or otherwise that the importer is in violation of section 805.

**Alternatives:**

We are considering a range of alternative approaches to the requirements for foreign supplier verification activities. These might include: (1) Establishing a general requirement that importers determine and conduct whatever verification activity that would adequately address the risks associated with the foods they import; (2) allowing importers to choose from a list of possible verification mechanisms, such as the activities listed in section 805(c)(4) of the FD&C Act; (3) requiring importers to conduct particular verification activities for certain types of foods or risks (e.g., for high-risk foods) but allowing flexibility in verification activities for other types of foods or risks; and (4) specifying use of a particular verification activity for each particular kind of food or risk. To the extent possible while still ensuring that verification
activities are adequate to ensure that foreign suppliers are producing food in accordance with U.S. requirements, we will seek to give importers the flexibility to choose verification procedures that are appropriate to adequately address the risks associated with the importation of a particular food.

**Anticipated Cost and Benefits:**

We have not yet quantified the cost and benefits for this proposed rule. However, the available information suggests that the costs will be significant. Our preliminary analysis of FY10 OASIS data suggests that this rule will cover about 60,000 importers, 240,000 unique combinations of importers and foreign suppliers, and 540,000 unique combinations of importers, products, and foreign suppliers. These numbers imply that provisions that require activity for each importer, each unique combination of importer and foreign supplier, or each unique combination of importer, product, and foreign supplier will generate significant costs. An example of a provision linked to combinations of importers and foreign suppliers would be a requirement to conduct a verification activity, such as an onsite audit, under certain conditions. The cost of onsite audits will depend in part on whether foreign suppliers can provide the same onsite audit results to different importers or whether every importer will need to take some action with respect to each of their foreign suppliers. The benefits of this proposed rule will consist of the reduction of adverse health events linked to imported food that could result from compliance with the FSVP requirements. We have not yet estimated the benefits of the rule.

**Risks:**

As stated above, about 15 percent of the U.S. food supply is imported, and many of these imported foods are high-risk commodities. According to recent data from the Centers for Disease Control and Prevention, each year, about 48 million Americans get sick, 128,000 are hospitalized, and 3,000 die from foodborne diseases. From July 1, 2007, through June 30, 2008, FDA oversaw 40 recalls of imported foods that were so contaminated that the Agency deemed them to be an imminent threat. We expect that the adoption of FSVPs by food importers will lead to a significant reduction to the threat to public health posed by unsafe imported food, though we are still in the process of trying to quantify the reduction in risk that will occur through importer compliance with the FSVP regulations.

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Regulatory Flexibility Analysis Required:
Undetermined

Small Entities Affected:
Businesses

Government Levels Affected:
None

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:
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RIN: 0910–AG64

39. ACCREDITATION OF THIRD PARTIES TO CONDUCT FOOD SAFETY AUDITS AND FOR OTHER RELATED PURPOSES
Priority:
Other Significant

Legal Authority:
PL 111–353, sec 307, FDA Food Safety Modernization Act; Other sections of FDA Food Safety Modernization Act, as appropriate

CFR Citation:
Not Yet Determined

Legal Deadline:
Final, Statutory, July 2012, Promulgate implementing regulations.

Per Public Law 111-353, section 307(c)(5)(C), promulgate, within 18 months of enactment, implementing regulations for accreditation of third-party auditors to conduct food safety audits.

Abstract:
The Food and Drug Administration (FDA) is proposing regulations relating to the accreditation of third-party auditors to conduct food safety audits of foreign entities, including foreign facilities in the food import supply chain. The proposed regulations will include provisions to protect against conflicts of interest between accredited auditors and audited entities, as described in section 307 of the FDA Food Safety Modernization Act (FSMA), Public Law 111-353. As part of this rulemaking, FDA may propose regulations relating to the accreditation of third parties to perform related activities, such as conducting laboratory analyses of food, authorized by other sections of FSMA.

Statement of Need:
The use of accredited third-party auditors to certify high-risk food imports to assist in ensuring the safety of food from foreign origin entering U.S. commerce. Accredited third-party auditors auditing foreign process facilities may be viewed as increasing FDA’s “coverage” of foreign facilities that FDA may not have adequate resources to inspect in a particular year while using identified standards creating overall uniformity to complete the task. Audits that result in issuance of facility certificates will provide FDA information about the compliance status of the facility. Additionally, auditors will be required to submit audit reports that may be reviewed by FDA for purposes of compliance assessment and work planning.

Summary of Legal Basis:
Not later than 2 years after the date of enactment, establish a system for the recognition of accreditation bodies that accredit third-party auditors, certifying that their eligible entities meet the requirements, directly accredit third-party auditors should none be identified and recognized by the 2-year date of enactment, obtain a list of all accredited third-party auditors and their agents from recognized accreditation bodies, and determine requirements for regulatory audit reports while avoiding unnecessary duplication of efforts and costs.

**Alternatives:**

FSMA described in detail the framework for, and requirements of, the accredited third-party auditor program. Alternatives include certain oversight activities required of recognized accreditation bodies that accredit third-party auditors, as distinguished from third-party auditors directly accredited by FDA. Another alternative relates to the nature of the required standards and the degree to which those standards are prescriptive or flexible.

**Anticipated Cost and Benefits:**

The benefits of the proposed rule would result from fewer cases of unsafe or misbranded food entering U.S. commerce. Additional benefits include the increased flow of credible information to FDA regarding the compliance status of foreign firms and their foods that are ultimately offered for import into the United States, which information in turn would inform FDA's work planning for inspection of foreign food facilities and might result in a signal of possible problems with a particular firm or its products, and with sufficient signals, might raise questions about the rigor of the food safety regulatory system of the country of origin.

The compliance costs of the proposed rule would result from the additional labor and capital required of accreditation bodies seeking FDA recognition and of third-party auditors seeking accreditation to the extent that will involve the assembling of information for an application unique to the FDA third-party program. The compliance costs associated with certification will be accounted for separately under the costs associated with participation in the foreign supplier verification program and the costs associated with mandatory certification for high-risk food imports. The third-party program is funded through revenue neutral user fees, which will be developed by FDA through rulemaking. User fee costs will be accounted for in that rulemaking.
Risks:
FDA is proposing this rule to provide greater assurance the food offered for import into the United States is safe and will not cause injury or illness to animals or humans. The rule would implement a program for accrediting third-party auditors to conduct food safety audits of foreign food entities, including registered foreign food facilities, and based on the findings of the regulatory audit, to issue certifications to foreign food entities found to be in compliance with FDA requirements. The certifications would be used by importers seeking to participate in the Voluntary Qualified Importer Program for expedited review and entry of product and would be a means to provide assurance of compliance as required by FDA based on risk-related considerations. The rule would apply to any foreign or domestic accreditation body seeking FDA recognition, any foreign or domestic third-party auditor seeking accreditation, any registered foreign food facility or other foreign food entity subject to a food safety audit (including a regulatory audit conducted for purposes of certification), and any importer seeking to participate in the Voluntary Qualified Importer Program. Fewer cases of unsafe or misbranded food entering U.S. commerce would reduce the risk of serious illness and death to humans and animals.

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Regulatory Flexibility Analysis Required:
No

Government Levels Affected:
Undetermined

International Impacts:
The regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:
Charlotte A. Christin
Senior Policy Advisor
HHS—FDA

FINAL RULE STAGE

40. INFANT FORMULA: CURRENT GOOD MANUFACTURING PRACTICES; QUALITY CONTROL PROCEDURES; NOTIFICATION REQUIREMENTS; RECORDS AND REPORTS; AND QUALITY FACTORS

Priority:

Other Significant

Legal Authority:

21 USC 321; 21 USC 350a; 21 USC 371

CFR Citation:

21 CFR 106 and 107

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is revising its infant formula regulations in 21 CFR parts 106 and 107 to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification,
and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

Statement of Need:
The Agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, records, and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment was extended on June 27, 2003, and ended on August 26, 2003. The comment period was reopened on August 1, 2006, and ended on September 15, 2006.

Summary of Legal Basis:

In 1986, Congress, as part of the Anti-Drug Abuse Act of 1986 (Pub. L. 99-570) (the 1986 amendments), amended section 412 of the act to address concerns that had been expressed by Congress and consumers about the 1980 Act and its implementation related to the sufficiency of quality control testing, CGMP, recordkeeping, and recall requirements. The 1986 amendments: (1) State that an infant formula is deemed to be adulterated if it fails to provide certain required nutrients, fails to meet quality factor requirements established by the Secretary (and, by delegation, FDA), or if it is not processed in compliance with the CGMP and quality control procedures established by the Secretary; (2) require that the Secretary issue regulations establishing requirements for quality factors and CGMP, including quality
control procedures; (3) require that infant formula manufacturers regularly audit their operations to ensure that those operations comply with CGMP and quality control procedure regulations; (4) expand the circumstances in which firms must make a submission to the Agency to include when there is a major change in an infant formula or a change that may affect whether the formula is adulterated; (5) specify the nutrient quality control testing that must be done on each batch of infant formula; (6) modify the infant formula recall requirements; and (7) give the Secretary authority to establish requirements for retention of records, including records necessary to demonstrate compliance with CGMP and quality control procedures. In 1989, the Agency implemented the provisions on recalls (secs. 412(f) and (g) of the Act) by establishing subpart E in 21 CFR part 107 (54 FR 4006, Jan. 27, 1989). In 1991, the Agency implemented the provisions on record and record retention requirements by revising 21 CFR 106.100 (56 FR 66566, Dec. 24, 1991).

The Agency has already promulgated regulations that respond to a number of the provisions of the 1986 amendments. The final rule would address additional provisions of these amendments.

**Alternatives:**

The 1986 amendments require the Secretary (and, by delegation, FDA) to establish, by regulation, requirements for quality factors and CGMPs, including quality control procedures. Therefore, there are no alternatives to rulemaking.

**Anticipated Cost and Benefits:**

FDA estimates that the costs from the final rule to producers of infant formula would include first year and recurring costs (e.g., administrative costs, implementation of quality controls, records, audit plans, and assurances of quality factors in new infant formulas). FDA anticipates that the primary benefits would be a reduced risk of illness due to Cronobacter sakazakii and Salmonella spp in infant formula. Additional benefits stem from the quality factors requirements that would assure the healthy growth of infants consuming infant formula. Monetized estimates of costs and benefits for this final rule are not available at this time. The analysis for the proposed rule estimated costs of less than $1 million per year. FDA was not able to quantify benefits in the analysis for the proposed rule.

**Risks:**
Special controls for infant formula manufacturing are especially important because infant formula, particularly powdered infant formula, is an ideal medium for bacterial growth and because infants are at high risk of foodborne illness because of their immature immune systems. In addition, quality factors are of critical need to assure that the infant formula supports healthy growth in the first months of life when infant formula may be an infant's sole source of nutrition. The provisions of this rule will address weaknesses in production that may allow contamination of infant formula, including, contamination with C. sakazakii and Salmonella spp which can lead to serious illness with devastating sequelae and/or death.

The provisions would also assure that new infant formulas support healthy growth in infants.

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<td>04/28/03</td>
<td>68 FR 22341</td>
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<td>08/01/06</td>
<td>71 FR 43392</td>
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Regulatory Flexibility Analysis Required:

Yes

Small Entities Affected:

Businesses

Government Levels Affected:

None

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Agency Contact:

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Center for Food Safety and Applied Nutrition (HFS–850)
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Phone: 240 402–1459
Email: benson.silverman@fda.hhs.gov

Related RIN: Split from 0910–AA04

RIN: 0910–AF27

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41. MEDICAL DEVICE REPORTING; ELECTRONIC SUBMISSION REQUIREMENTS

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

21 USC 352, 360, 360i, 360j, 371, 374

CFR Citation:

21 CFR 803

Legal Deadline:

None

Abstract:

The Food and Drug Administration (FDA) is amending its postmarket medical device reporting (MDR) regulations to require that manufacturers, importers, and user facilities submit mandatory reports of
medical device adverse events to the Agency in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the Agency to more quickly review safety reports and identify emerging public health issues.

Statement of Need:
The final rule would require user facilities and medical device manufacturers and importers to submit medical device adverse event reports in electronic format instead of using a paper form. FDA is taking this action to improve its adverse event reporting program by enabling it to more quickly receive and process these reports.

Summary of Legal Basis:
The Agency has legal authority under section 519 of the Federal Food, Drug, and Cosmetic Act to require adverse event reports. The final rule would require manufacturers, importers, and user facilities to change their procedures to send reports of medical device adverse events to FDA in electronic format instead of using a hard copy form.

Alternatives:
There are two alternatives. The first alternative is to allow the voluntary submission of electronic MDRs. If a substantial number of reporters fail to voluntarily submit electronic MDRs, FDA will not obtain the benefits of standardized formats and quicker access to medical device adverse event data. The second alternative is to allow small entities more time to comply. This would significantly postpone the benefits of the rule; moreover, it would only delay, rather than reduce or eliminate, the costs of compliance.

Anticipated Cost and Benefits:
The principal benefit would be to public health, due to the increased speed in the processing and analysis of medical device reports currently submitted annually on paper. In addition, requiring electronic submission would reduce FDA annual operating costs and generate industry savings.

The one-time costs are for modifying standard operating procedures and establishing electronic submission capabilities. Annually recurring costs include maintenance of electronic submission
capabilities, including renewing the electronic certificate, and for some firms, the incremental cost to maintain high-speed Internet access.

**Risks:**

None

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Government Levels Affected:**

None

**Agency Contact:**

Nancy Pirt
Regulatory Counsel
Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Fax: 301 847–8145
Email: nancy.pirt@fda.hhs.gov

**RIN:** 0910–AF86
42. ELECTRONIC REGISTRATION AND LISTING FOR DEVICES

Priority:
Other Significant

Legal Authority:
PL 110–85; PL 107–188, sec 321; PL 107–250, sec 207; 21 USC 360(a) through 360(j); 21 USC 360(p)

CFR Citation:
21 CFR 807

Legal Deadline:
None

Abstract:
This rule would codify the requirements for electronic registration and listing. However, for those companies that do not have access to the Web, FDA will offer an avenue by which they can register, list, and update information with a paper submission. The rule also will amend part 807 to reflect the timeframes for device establishment registration and listing established by sections 222 and 223 of Food and Drug Administration Amendment Act (FDAAA) and to reflect the requirement in section 510(i) of the Act, as amended by section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act (BT Act), that foreign establishments provide FDA with additional pieces of information as part of their registration.

Statement of Need:
FDA is amending the medical device establishment registration and listing requirements under 21 CFR part 807 to reflect the electronic submission requirements in section 510(p) of the Act, which was added by section 207 of MDUFMA and later amended by section 224 of FDAAA. FDA also is amending 21 CFR part 807 to reflect the requirements in section 321 of the BT Act for foreign establishments to furnish additional information as part of their registration. This rule will improve FDA’s device establishment registration and listing system and utilize the latest technology in the collection of this information.

Summary of Legal Basis:
The statutory basis for our authority includes sections 510(a) through (j), 510(p), 701, 801, and 1003 of the Act.

**Alternatives:**
The alternatives to this rulemaking include not updating the registration and listing regulations. Because of the new FDAAA statutory requirements and the advances in data collection and transmission technology, FDA believes this rulemaking is the preferable alternative.

**Anticipated Cost and Benefits:**
The Agency believes that there may be some one-time costs associated with the rulemaking, which involve resource costs of familiarizing users with the electronic system. Recurring costs related to submission of the information by domestic firms would probably remain the same or decrease because a paper submission and postage is not required. There might be some increase in the financial burden on foreign firms since they will have to supply additional registration information as required by section 321 of the BT Act.

**Risks:**
None

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
No

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
None

**Agency Contact:**
Nancy Pirt
43. FOOD LABELING: NUTRITION LABELING FOR FOOD SOLD IN VENDING MACHINES

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
21 USC 321; 21 USC 343; 21 USC 371

CFR Citation:
Not Yet Determined

Legal Deadline:
None

Abstract:
The Food and Drug Administration (FDA) published a proposed rule in the Federal Register of April 6, 2011 (72 FR 19238) to establish requirements for nutrition labeling of certain food items sold in certain vending machines. FDA also proposed the terms and conditions for vending machine operators registering to voluntarily be subject to the requirements. FDA took this action to carry out section 4205 of
the Patient Protection and Affordable Care Act ("Affordable Care Act" or "ACA"), which was signed into law on March 23, 2010.

Statement of Need:

This rulemaking was mandated by section 4205 of the Patient Protection and Affordable Care Act (Affordable Care Act).

Summary of Legal Basis:

On March 23, 2010, the Affordable Care Act (Pub. L. 111-148) was signed into law. Section 4205 amended 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by, among other things, creating new clause (H) to require that vending machine operators, who own or operate 20 or more machines, disclose calories for certain food items. FDA has the authority to issue this rule under sections 403(q)(5)(H) and 701(a) of the FD&C Act (21 U.S.C. 343(q)(5)(H), and 371(a)). Section 701(a) of the FD&C Act vests the Secretary of Health and Human Services, and, by delegation, the Food and Drug Administration (FDA) with the authority to issue regulations for the efficient enforcement of the FD&C Act.

Alternatives:

Section 4205 of the Affordable Care Act requires the Secretary (and by delegation, the FDA) to establish by regulation requirements for calorie labeling of articles of food sold from covered vending machines. Therefore, there are no alternatives to rulemaking. FDA has analyzed alternatives that may reduce the burden of the rulemaking, including analyzing the benefits and costs of: Restricting the flexibility of the format for calorie disclosure, lengthening the compliance time, and extending the coverage of the rule to bulk vending machines without selection buttons.

Anticipated Cost and Benefits:

Any vending machine operator operating fewer than 20 machines may voluntarily choose to be covered by the national standard. It is anticipated that vending machine operators that own or operate 20 or more vending machines will bear costs associated with adding calorie information to vending machines. FDA estimates that the total cost of complying with section 4205 of the Affordable Care Act and this rulemaking will be approximately $25.8 million initially, with a recurring cost of approximately $24 million.
Because comprehensive national data for the effects of vending machine labeling do not exist, FDA has not quantified the benefits associated with section 4205 of the Affordable Care Act and this rulemaking. Some studies have shown that some consumers consume fewer calories when calorie content information is displayed at the point of purchase. Consumers will benefit from having this important nutrition information to assist them in making healthier choices when consuming food away from home.

Given the very high costs associated with obesity and its associated health risks, FDA estimates that if 0.02 percent of the adult obese population reduces energy intake by at least 100 calories per week, then the benefits of Section 4205 of the Affordable Care Act and this rulemaking will be at least as large as the costs.

**Risks:**

Americans now consume an estimated one-third of their total calories from foods prepared outside the home and spend almost half of their food dollars on such foods. This rule will provide consumers with information about the nutritional content of food to enable them to make healthier food choices, and may help mitigate the trend of increasing obesity in America.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses, Governmental Jurisdictions

**Government Levels Affected:**

Federal, Local, State

**Federalism:**

This action may have federalism implications as defined in EO 13132.

**Agency Contact:**
HHS—FDA

44. FOOD LABELING: NUTRITION LABELING OF STANDARD MENU ITEMS IN RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
21 USC 321; 21 USC 343; 21 USC 371

CFR Citation:
Not Yet Determined

Legal Deadline:
None

Abstract:
The Food and Drug Administration (FDA) published a proposed rule in the Federal Register of April 6, 2011 (72 FR 19192), to establish requirements for nutrition labeling of standard menu items in chain restaurants and similar retail food establishments. FDA also proposed the terms and conditions for
restaurants and similar retail food establishments registering to voluntarily be subject to the Federal requirements. FDA took this action to carry out section 4205 of the Patient Protection and Affordable Care Act (“Affordable Care Act” or “ACA”), which was signed into law on March 23, 2010.

**Statement of Need:**

This rulemaking was mandated by section 4205 of the Patient Protection and Affordable Care Act (Affordable Care Act).

**Summary of Legal Basis:**

On March 23, 2010, the Affordable Care Act (Pub. L. 111-148) was signed into law. Section 4205 of the Affordable Care Act amended 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) by, among other things, creating new clause (H) to require that certain chain restaurants and similar retail food establishments with 20 or more locations disclose certain nutrient information for standard menu items. FDA has the authority to issue this rule under sections 403(a)(1), 403(q)(5)(H), and 701(a) of the FD&C Act (21 U.S.C. 343(a)(1), 343(q)(5)(H), and 371(a)). Section 701(a) of the FD&C Act vests the Secretary of Health and Human Services, and, by delegation, the Food and Drug Administration (FDA) with the authority to issue regulations for the efficient enforcement of the FD&C Act.

**Alternatives:**

Section 4205 of the Affordable Care Act requires the Secretary, and by delegation the FDA, to establish by regulation requirements for nutrition labeling of standard menu items for covered restaurants and similar retail food establishments. Therefore, there are no alternatives to rulemaking. FDA has analyzed alternatives that may reduce the burden of this rulemaking, including analyzing the benefits and costs of expanding and contracting the set of establishments automatically covered by this rule and shortening or lengthening the compliance time relative to the rulemaking.

**Anticipated Cost and Benefits:**

Chain restaurants and similar retail food establishments operating in local jurisdictions that impose different nutrition labeling requirements will benefit from having a uniform national standard. Any restaurant or similar retail food establishment with fewer than 20 locations may voluntarily choose to be covered by the national standard. It is anticipated that chain restaurants with 20 or more locations will bear costs for adding nutrition information to menus and menu boards. FDA estimates that the total cost
of section 4205 and this rulemaking will be approximately $80 million, annualized over 10 years, with a low annualized estimate of approximately $33 million and a high annualized estimate of approximately $125 million over 10 years. These costs include an initial cost of approximately $320 million with an annually recurring cost of $45 million.

Because comprehensive national data for the effects of menu labeling do not exist, FDA has not quantified the benefits associated with section 4205 of the Affordable Care Act and this rulemaking. Some studies have shown that some consumers consume fewer calories when menus have information about calorie content displayed. Consumers will benefit from having important nutrition information for the approximately 30 percent of calories consumed away from home. Given the very high costs associated with obesity and its associated health risks, FDA estimates that if 0.6 percent of the adult obese population reduces energy intake by at least 100 calories per week, then the benefits of section 4205 of the Affordable Care Act and this rule will be at least as large as the costs.

Risks:
Americans now consume an estimated one-third of their total calories on foods prepared outside the home and spend almost half of their food dollars on such foods. Unlike packaged foods that are labeled with nutrition information, foods in restaurants, for the most part, do not have nutrition information that is readily available when ordered. Dietary intake data have shown that obese Americans consume over 100 calories per meal more when eating food away from home rather than food at home. This rule will provide consumers information about the nutritional content of food to enable them to make healthier food choices and may help mitigate the trend of increasing obesity in America.

Timetable:

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Regulatory Flexibility Analysis Required: Yes
Small Entities Affected:
Businesses, Governmental Jurisdictions

Government Levels Affected:
Federal, Local, State

Federalism:
This action may have federalism implications as defined in EO 13132.

Agency Contact:
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Supervisor, Product Evaluation and Labeling Team
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Food and Drug Administration
Center for Food Safety and Applied Nutrition
(HFS–820)
5100 Paint Branch Parkway
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Phone: 240 402–1802
Fax: 301 436–2636
Email: geraldine.june@fda.hhs.gov

RIN: 0910–AG57

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<th>HHS—Centers for Medicare &amp; Medicaid Services (CMS)</th>
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<td>45. MEDICARE AND MEDICAID PROGRAMS: REFORM OF HOSPITAL AND CRITICAL ACCESS HOSPITAL CONDITIONS OF PARTICIPATION (CMS–3244–P)</td>
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Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
This proposed rule would revise the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These changes are necessary to reflect substantial advances in health care delivery and in patient safety knowledge and practices. They are also an integral part of our efforts to achieve broad-based improvements in the quality of health care furnished through Federal programs and in patient safety, while at the same time reducing procedural burdens on providers.

CMS is revising many of the hospital CoPs to ensure that they meet the needs of hospital and CAH patients in an effective and efficient manner. CMS is proposing changes to reduce unnecessary, obsolete, or burdensome regulations on U.S. hospitals. This retrospective review of existing regulations meets the President's Executive Order that all Federal agencies identify such rules and make proposals to “modify, streamline, expand, or repeal them.” CMS is also proposing additional quality and safety requirements to protect patients.

The provisions that are included in this proposed rule are necessary to implement the requirements of Executive Order 13563 “Improving Regulations and Regulatory Review.”

To date, nearly 90 specific reforms have been identified and scheduled for action. These reforms impact hospitals, physicians, home health agencies, ambulance providers, clinical labs, skilled nursing facilities, intermediate care facilities, managed care plans, Medicare Advantage organizations, and States. Many of these reforms will be included in proposed rules that relate to particular categories of regulations or types of providers. Other reforms are being implemented without the need for regulations.
This proposed rule includes reforms that do not fit directly in other rules scheduled for publication.

**Anticipated Cost and Benefits:**

This proposed rule would reduce costs to tens of thousands of physicians, ambulatory surgical centers, End Stage Renal Disease facilities, and other small entities. Achieving the full scope of potential savings will depend on future decisions by hospitals, by State regulators, and others. Many other factors will influence long-term results. We believe, however, that likely savings and benefits will reach many billions of dollars. Our primary estimate of the net savings to hospitals from reductions in regulatory requirements that we can quantify at this time, offset by increases in other regulatory costs, are approximately $940 million a year.

**Risks:**

None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Agency Contact:**

CDR Scott Cooper
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Clinical Standards Group
HHS—CMS

46. REGULATORY PROVISIONS TO PROMOTE PROGRAM EFFICIENCY, TRANSPARENCY, AND BURDEN REDUCTION (CMS–9070–P)

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
42 USC 1302 and 1395hh and 44 USC 35

CFR Citation:
42 CFR 400, 405, 416, 418, 423; 42 CFR 424, 440, 442, 486, 494

Legal Deadline:
None

Abstract:
This proposed rule identifies and proposes reforms in Medicare and Medicaid regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and beneficiaries. This proposed rule would increase the ability of health care professionals to devote resources to improving patient care, by eliminating or reducing requirements that impede quality patient care or that divert providing high quality patient care.

Statement of Need:
In January 2011, the President issued an Executive order that requires agencies to identify rules that may be “outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or
repeal them in accordance with what has been learned.” In accordance with the Executive order, we identified obsolete and unnecessarily burdensome rules that could be eliminated or reformed to achieve similar objectives, with a particular focus on freeing up resources that health care providers, health plans, and States could use to improve or enhance patient health and safety. We examined policies and practices not codified in rules that could be changed or streamlined to achieve better outcomes for patients while reducing burden on providers of care. We also sought to increase transparency and become a better business partner.

Summary of Legal Basis:
The provisions that are included in this proposed rule are necessary to implement the requirements of Executive Order 13563 “Improving Regulations and Regulatory Review.”

Alternatives:
To date, nearly 90 specific reforms have been identified and scheduled for action. These reforms impact hospitals, physicians, home health agencies, ambulance providers, clinical labs, skilled nursing facilities, intermediate care facilities, managed care plans, Medicare Advantage organizations, and States. Many of these reforms will be included in proposed rules that relate to particular categories of regulations or types of providers. Other reforms are being implemented without the need for regulations. This proposed rule includes reforms that do not fit directly in other rules scheduled for publication.

Anticipated Cost and Benefits:
We anticipate that the provider industry and health professionals would welcome the proposed changes and reductions in burden. We also expect that health professionals would experience increased efficiencies and resources to appropriately devote to improving patient care, increasing accessibility to care, and reducing associated health care costs.

Risks:
None.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
Businesses, Governmental Jurisdictions, Organizations

Government Levels Affected:
Federal, State

Agency Contact:
Michelle Shortt
Director, Regulations Development Group, OSORA
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Centers for Medicare & Medicaid Services
Mailstop C4–26–05
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RIN: 0938–AQ96

HHS—CMS

47. • PROPOSED CHANGES TO HOSPITAL OPPS AND CY 2013 PAYMENT RATES; ASC PAYMENT SYSTEM AND CY 2013 PAYMENT RATES (CMS–1589–P) (SECTION 610 REVIEW)

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
Sec 1833 of the Social Security Act
Abstract:
This final rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. The proposed rule also describes changes to the amounts and factors used to determine payment rates for services. In addition, the rule proposes changes to the Ambulatory Surgical Center Payment System list of services and rates.

Statement of Need:
Medicare pays over 4,000 hospitals for outpatient department services under the hospital outpatient prospective payment system (OPPS). The OPPS is based on groups of clinically similar services called ambulatory payment classification groups (APCs). CMS annually revises the APC payment amounts based on the most recent claims data, proposes new payment policies, and updates the payments for inflation using the hospital operating market basket. The proposed rule solicits comments on the proposed OPPS payment rates and new policies. Medicare pays roughly 5,000 Ambulatory Surgical Centers (ASCs) under the ASC payment system. CMS annually revises the payment under the ASC payment system, proposes new policies, and updates payments for inflation using the Consumer Price Index for All Urban Consumers (CPI-U). CMS will issue a final rule containing the payment rates for the 2013 OPPS and ASC payment system at least 60 days before January 1, 2013.

Summary of Legal Basis:
Section 1833 of the Social Security Act establishes Medicare payment for hospital outpatient services and ASC services. The final rule revises the Medicare hospital OPPS and ASC payment system to implement applicable statutory requirements. In addition, the proposed and final rules describe changes to the outpatient APC system, relative payment weights, outlier adjustments, and other amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective
payment system, as well as changes to the rates and services paid under the ASC payment system. These changes would be applicable to services furnished on or after January 1, 2013.

**Alternatives:**

None. This is a statutory requirement.

**Anticipated Cost and Benefits:**

Total expenditures will be adjusted for CY 2013.

**Risks:**

If this regulation is not published timely, outpatient hospital and ASC services will not be paid appropriately beginning January 1, 2013.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal

**Federalism:**

Undetermined

**Agency Contact:**

Paula Smith
Health Insurance Specialist
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mail Stop C4–05–13
7500 Security Blvd
Baltimore, MD 21244
48. • REVISIONS TO PAYMENT POLICIES UNDER THE PHYSICIAN FEE SCHEDULE AND PART B FOR CY 2013 (CMS–1590–P) (SECTION 610 REVIEW)

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
Social Security Act, secs 1102, 1871, 1848

CFR Citation:
Not Yet Determined

Legal Deadline:
Final, Statutory, November 1, 2012.

Abstract:
This annual proposed rule would revise payment polices under the physician fee schedule, as well as other policy changes to payment under Part B. These changes would be applicable to services furnished on or after January 1.

Statement of Need:
The statute requires that we establish each year, by regulation, payment amounts for all physicians’ services furnished in all fee schedule areas. This major proposed rule would implement changes affecting Medicare Part B payment to physicians and other Part B suppliers. The final rule has a statutory publication date of November 1, 2012, and an implementation date of January 1, 2013.

Summary of Legal Basis:
Section 1848 of the Social Security Act (the Act) establishes the payment for physician services provided under Medicare. Section 1848 of the Act imposes a deadline of no later than November 1 for publication of the final rule or final physician fee schedule.

**Alternatives:**
None. This implements a statutory requirement.

**Anticipated Cost and Benefits:**
Total expenditures will be adjusted for CY 2013.

**Risks:**
If this regulation is not published timely, physician services will not be paid appropriately, beginning January 1, 2013.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Yes

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
Undetermined

**Federalism:**
Undetermined

**Agency Contact:**
Christina Ritter
Director, Division of Practitioner Services
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Mail Stop C4–03–06
7500 Security Blvd
49. • CHANGES TO THE HOSPITAL INPATIENT AN LONG–TERM CARE PROSPECTIVE PAYMENT SYSTEM FOR FY 2013 (CMS–1588–P) (SECTION 610 REVIEW)

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
Sec 1886(d) of the Social Security Act

CFR Citation:
42 CFR 412

Legal Deadline:
NPRM, Statutory, April 1, 2012.
Final, Statutory, August 1, 2012.

Abstract:
This annual major proposed rule would revise the Medicare hospital inpatient and long-term care hospital prospective payment systems for operating and capital-related costs. This proposed rule would implement changes arising from our continuing experience with these systems.

Statement of Need:
CMS annually revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, we describe the proposed changes to the amounts and factors used to determine
the rates for Medicare hospital inpatient services for operating costs and capital-related costs. Also, CMS annually updates the payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). The proposed rule solicits comments on the proposed IPPS and LTCH payment rates and new policies. CMS will issue a final rule containing the payment rates for the FY 2013 IPPS and LTCHs at least 60 days before October 1, 2012.

**Summary of Legal Basis:**

The Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. The Act requires the Secretary to pay for the capital-related costs of hospital inpatient and Long Term Care stays under a PPS. Under these systems, Medicare payment for hospital inpatient and Long Term Care operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. These changes would be applicable to services furnished on or after October 1, 2012.

**Alternatives:**

None. This implements a statutory requirement.

**Anticipated Cost and Benefits:**

Total expenditures will be adjusted for FY 2013.

**Risks:**

If this regulation is not published timely, inpatient hospital and LTCH services will not be paid appropriately beginning October 1, 2012.

**Timetable:**

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<tbody>
<tr>
<td>NPRM</td>
<td>04/00/12</td>
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</tbody>
</table>

**Regulatory Flexibility Analysis Required:** Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal
Agency Contact:

Ankit Patel
Health Insurance Specialist, Division of Acute Care
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Hospital and Ambulatory Policy Group
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RIN: 0938–AR12

<table>
<thead>
<tr>
<th>HHS—CMS</th>
<th>FINAL RULE STAGE</th>
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<tbody>
<tr>
<td>50. MEDICAID ELIGIBILITY EXPANSION UNDER THE AFFORDABLE CARE ACT OF 2010 (CMS–2349–F)</td>
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</tbody>
</table>

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:

CFR Citation:
42 CFR 431, 435, 457

Legal Deadline:
Final, Statutory, January 1, 2014.

Abstract:
This rule implements provisions of the Affordable Care Act expanding access to health insurance through improvements in Medicaid, the establishment of American Health Benefit Exchanges ("Exchanges"), and
coordination between Medicaid, the Children's Health Insurance Program (CHIP), and Exchanges. This rule also implements sections of the Affordable Care Act related to Medicaid eligibility, enrollment simplification, and coordination.

**Statement of Need:**
This rule expands Medicaid eligibility, simplifies Medicaid eligibility procedures, and streamlines Medicaid enrollment processes. It also coordinates eligibility processes and policies with the processes for premium tax credits for Exchange coverage. Millions of uninsured low-income persons who do not have access to, or could not afford, health insurance will obtain coverage.

**Summary of Legal Basis:**
The provisions that are included in this rule are necessary to implement the requirements of sections 1413, 1414, 2001, 2002, 2101, and 2201 of the Affordable Care Act.

**Alternatives:**
None. This is a statutory requirement.

**Anticipated Cost and Benefits:**
We anticipate that this rule provides significant benefits to low-income individuals by expanding the availability of affordable health coverage. We expect that States may incur short term increases in administrative costs (depending on their current systems and practices) but that these costs will be wholly offset by administrative savings over the longer term.

**Risks:**
None.

**Timetable:**

<table>
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<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<tbody>
<tr>
<td>NPRM</td>
<td>08/17/11</td>
<td>76 FR 51148</td>
</tr>
<tr>
<td>NPRM Comment Period End</td>
<td>10/31/11</td>
<td></td>
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<tr>
<td>Final Action</td>
<td>02/00/12</td>
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</tbody>
</table>

**Regulatory Flexibility Analysis Required:**
Undetermined

**Small Entities Affected:**
Governmental Jurisdictions

**Government Levels Affected:**
Federal, Local, State, Tribal

**Agency Contact:**
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**RIN:** 0938–AQ62

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**HHS—CMS**

51. ESTABLISHMENT OF EXCHANGES AND QUALIFIED HEALTH PLANS PART I (CMS–9989–F)

**Priority:**
Economically Significant. Major under 5 USC 801.

**Legal Authority:**
Affordable Care Act, secs 1301 to 1343, secs 1401 to 1413

**CFR Citation:**
45 CFR 155 to 157

**Legal Deadline:**
Final, Statutory, January 1, 2014.

**Abstract:**
This rule implements the new Affordable Insurance Exchanges (“Exchanges”), consistent with title I of the Affordable Care Act of 2010, referred to collectively as the Affordable Care Act. The Exchanges will provide competitive marketplaces for individuals and small employers to directly compare available private health insurance options on the basis of price, quality, and other factors. The Exchanges, which will become operational by January 1, 2014, will help enhance competition in the health insurance market, improve choice of affordable health insurance, and give small businesses the same purchasing clout as large businesses.

**Statement of Need:**

A central aim of Title I of the Affordable Care Act is to expand access to health insurance coverage through the establishment of Exchanges. The number of uninsured Americans is rising due to the lack of affordable insurance, barriers to insurance for people with pre-existing conditions, and high prices due to limited competition and market failures. Millions of people without health insurance use health care services for which they do not pay, shifting the uncompensated cost of their care to health care providers. Providers pass much of this cost to insurance companies, resulting in higher premiums that make insurance unaffordable to even more people. The Affordable Care Act includes a number of policies to address these problems, including the creating of Affordable Insurance Exchanges.

**Summary of Legal Basis:**

This rule implements the new Affordable Insurance Exchanges consistent with title I of the Affordable Care Act of 2010.

**Alternatives:**

None. This is a statutory requirement.

**Anticipated Cost and Benefits:**

This rule will help enhance competition in the health insurance market, promote the choice of affordable health insurance, and give small businesses the same purchasing clout as large businesses. States seeking to operate an Exchange will incur administrative expenses as a result of implementing and subsequently maintaining Exchanges. There is no Federal requirement that each State establish an Exchange.

**Risks:**
If this regulation is not published, the Exchanges will not become operational by January 1, 2014, thereby violating the statute.

**Timetable:**

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<th>Action</th>
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<tbody>
<tr>
<td>NPRM</td>
<td>07/15/11</td>
<td>76 FR 41866</td>
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<td>NPRM Comment Period End</td>
<td>09/28/11</td>
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<tr>
<td>Final Action</td>
<td>02/00/12</td>
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</tbody>
</table>

**Regulatory Flexibility Analysis Required:**

Undetermined

**Small Entities Affected:**

Businesses, Governmental Jurisdictions

**Government Levels Affected:**

Federal, State, Tribal

**Federalism:**

This action may have federalism implications as defined in EO 13132.

**Agency Contact:**

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Department of Health and Human Services
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**RIN:** 0938–AQ67
52. • STATE REQUIREMENTS FOR EXCHANGE—REINSURANCE AND RISK ADJUSTMENTS

(CMS–9975–F)

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
PL 111–148, secs 1341 and 1342

CFR Citation:
45 CFR 155, 156

Legal Deadline:
Final, Statutory, January 1, 2014.

Abstract:
This rule implements requirements for States related to reinsurance, risk corridors, and a permanent risk adjustment. The goals of these programs are to minimize negative impacts of adverse selection inside the Exchanges.

Statement of Need:
This rule finalizes guidelines for the transitional risk-sharing programs, reinsurance and risk corridors, as well as for the risk adjustment program that will continue beyond the first 3 years of Exchange operation. The purpose of these programs is to protect health insurance issuers from the negative effects of adverse selection and to protect consumers from increases in premiums due to uncertainty for issuers.

Summary of Legal Basis:
This rule implements the new Affordable Insurance Exchanges consistent with title I of the Affordable Care Act of 2010.

Alternatives:
None. This is a statutory requirement.

Anticipated Cost and Benefits:
Payments through reinsurance, risk adjustment, and risk corridors reduce the increased risk of financial loss that health insurance issuers might otherwise expect to incur in 2014 due to market reforms such as guaranteed issue and the elimination of medical underwriting. These payments reduce the risk to the
issuer and the issuer can pass on a reduced risk premium to enrollees. Administrative costs will vary across States and health insurance issuers depending on the sophistication of technical infrastructure and prior experience with data collection and risk adjustment. States and issuers that already have systems in place for data collection and reporting will have reduced administrative costs.

Risks:

If this regulation is not published, the Exchanges will not become operational by January 1, 2014, thereby violating the statute.

Timetable:

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<th>Action</th>
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<tr>
<td>Final Action</td>
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</tbody>
</table>

Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Governmental Jurisdictions

Government Levels Affected:

State

Federalism:

This action may have federalism implications as defined in EO 13132.

Agency Contact:

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Centers for Medicare & Medicaid Services

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Baltimore, MD 21244

Phone: 301 492–4428
DEPARTMENT OF HOMELAND SECURITY (DHS)

Fall 2011 Statement of Regulatory Priorities

The Department of Homeland Security (DHS or Department) was created in 2003 pursuant to the Homeland Security Act of 2002, Public Law 107-296. DHS has a vital mission: To secure the Nation from the many threats we face. This requires the dedication of more than 225,000 employees in jobs that range from aviation and border security to emergency response, from cybersecurity analyst to chemical facility inspector. Our duties are wide-ranging, but our goal is clear—keeping America safe.

Our mission gives us six main areas of responsibility:

1. Prevent Terrorism and Enhance Security,
2. Secure and Manage Our Borders,
3. Enforce and Administer our Immigration Laws,
4. Safeguard and Secure Cyberspace,
5. Ensure Resilience to Disasters, and
6. Mature and Strengthen DHS.

In achieving these goals, we are continually strengthening our partnerships with communities, first responders, law enforcement, and government agencies—at the State, local, tribal, Federal, and international levels. We are accelerating the deployment of science, technology, and innovation in order to make America more secure, and we are becoming leaner, smarter, and more efficient, ensuring that every security resource is used as effectively as possible. For a further discussion of our main areas of responsibility, see the DHS website at http://www.dhs.gov/xabout/responsibilities.shtm.
The regulations we have summarized below in the Department's fall 2011 regulatory plan and in the agenda support the Department’s responsibility areas listed above. These regulations will improve the Department’s ability to accomplish its mission.

The regulations we have identified in this year’s fall regulatory plan continue to address legislative initiatives including, but not limited to, the following acts: The Implementing Recommendations of the 9/11 Commission Act of 2008 (9/11 Act), Public Law 110-53 (Aug. 3, 2007); the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA), Public Law 109-295 (Oct. 4, 2006); the Consolidated Natural Resources Act of 2008 (CNRA), Public Law No. 110-220 (May 7, 2008); the Security and Accountability for Every Port Act of 2006 (SAFE Port Act), Public Law 109-347 (Oct. 13, 2006); and the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009, Public Law 110-329 (Sep. 30, 2008).

DHS strives for organizational excellence and uses a centralized and unified approach in managing its regulatory resources. The Office of the General Counsel manages the Department’s regulatory program, including the agenda and regulatory plan. In addition, DHS senior leadership reviews each significant regulatory project to ensure that the project fosters and supports the Department’s mission.

The Department is committed to ensuring that all of its regulatory initiatives are aligned with its guiding principles to protect civil rights and civil liberties, integrate our actions, build coalitions and partnerships, develop human resources, innovate, and be accountable to the American public.

DHS is also committed to the principles described in Executive Orders 13563 and 12866 (as amended). Both Executive orders direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. Many of the regulations in DHS’
regulatory plan support the Department’s efforts pursuant to the DHS Final Plan for the Retrospective Review of Existing Regulations. DHS issued its final plan on August 22, 2011.

Finally, the Department values public involvement in the development of its regulatory plan, agenda, and regulations, and takes particular concern with the impact its rules have on small businesses. DHS and each of its components continue to emphasize the use of plain language in our notices and rulemaking documents to promote a better understanding of regulations and increased public participation in the Department’s rulemakings.

**Retrospective Review of Existing Regulations**

Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011), DHS identified the following regulatory actions in the Department’s Final Plan for the Retrospective Review of Existing Regulations (“DHS Final Plan”). DHS has identified these regulatory actions as associated with retrospective review and analysis. You can view the DHS Final Plan on www.regulations.gov by searching for docket number DHS-2011-0015. Some of the regulatory actions on the below list may be completed actions, which do not appear in The Regulatory Plan. You can find more information about these completed rulemakings in past publications of the Unified Agenda (search the Completed Actions sections) on www.reginfo.gov. Some of the entries on this list, however, are active rulemakings. You can find entries for these rulemakings on www.regulations.gov.

<table>
<thead>
<tr>
<th>RIN</th>
<th>Rule</th>
<th>Significantly Reduces Burdens on Small Businesses</th>
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</thead>
<tbody>
<tr>
<td>1615-AB71</td>
<td>Registration Requirement for Petitioners Seeking to File H-1B Petitions on Behalf of Aliens Subject to Numerical Limitations</td>
<td>No</td>
</tr>
<tr>
<td>1615-AB76</td>
<td>Commonwealth of the Northern Mariana Islands Transitional Worker Classification</td>
<td>No</td>
</tr>
<tr>
<td>1615-AB83</td>
<td>Immigration Benefits Business Transformation, Increment I</td>
<td>No</td>
</tr>
<tr>
<td>1615-AB95</td>
<td>Immigration Benefits Business Transformation: Nonimmigrants; Student and Exchange Visitor Program</td>
<td>No</td>
</tr>
<tr>
<td>No.</td>
<td>Description</td>
<td>Status</td>
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<tr>
<td>1625-AA16</td>
<td>Implementation of the 1995 Amendments to the International Convention on Standards of Training, Certification, and Watchkeeping (STCW) for Seafarers, 1978</td>
<td>No</td>
</tr>
<tr>
<td>1625-AB38</td>
<td>Updates to Maritime Security</td>
<td>No</td>
</tr>
<tr>
<td>TBD</td>
<td>Elimination of TWIC for Certain Mariner Populations (Implementation of Section 809 of the 2010 Coast Guard Authorization Act)</td>
<td>No</td>
</tr>
<tr>
<td>1651-AA73</td>
<td>Establishment of Global Entry Program</td>
<td>No</td>
</tr>
<tr>
<td>1651-AA93</td>
<td>Closing of the Port of Whitetail, Montana</td>
<td>No</td>
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<tr>
<td>1651-AA94</td>
<td>Internet Publication of Administrative Seizure/Forfeiture Notices</td>
<td>No</td>
</tr>
<tr>
<td>1652-AA01</td>
<td>Aviation Security Infrastructure Fee (ASIF)</td>
<td>No</td>
</tr>
<tr>
<td>1652-AA35</td>
<td>Flight Training for Aliens and Other Designated Individuals; Security Awareness Training for Flight School Employees</td>
<td>No</td>
</tr>
<tr>
<td>1653-AA44</td>
<td>Clarification of Eligibility Criteria for F and M Students and for Schools Certified by the Student and Exchange Visitor Program</td>
<td>No</td>
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</tbody>
</table>

The fall 2011 regulatory plan for DHS includes regulations from DHS components—including U.S. Citizenship and Immigration Services (USCIS), the U.S. Coast Guard (Coast Guard), U.S. Customs and Border Protection (CBP), the Federal Emergency Management Agency (FEMA), the U.S. Immigration and Customs Enforcement (ICE), and the Transportation Security Administration (TSA), which have active regulatory programs. In addition, it includes regulations from the Department’s major offices and directorates such as the National Protection and Programs Directorate (NPPD). Below is a discussion of the fall 2011 regulatory plan for DHS regulatory components, as well as for DHS offices and directorates.

**United States Citizenship and Immigration Services**
U.S. Citizenship and Immigration Services (USCIS) administers immigration benefits and services while protecting and securing our homeland. USCIS has a strong commitment to welcoming individuals who seek entry through the U.S. immigration system, providing clear and useful information regarding the immigration process, promoting the values of citizenship, and assisting those in need of humanitarian protection. Based on a comprehensive review of the planned USCIS regulatory agenda, USCIS will promulgate several rulemakings to directly support these commitments and goals.

**Improvements to the Immigration System.** USCIS is currently engaged in a multi-year transformation effort to create a more efficient, effective, and customer-focused organization by improving our business processes and technology. In the coming years, USCIS will publish rules to facilitate that effort, including rules that will remove references to form numbers, form titles, expired regulatory provisions, and descriptions of internal procedure; will mandate electronic filing in certain circumstances; and will comprehensively reorganize 8 CFR part 214. In addition, to streamline processes and improve efficiency, USCIS plans to revise its regulations governing appeals and motions before the Administrative Appeals Office. USCIS will also finalize a final rule related to the extension of immigration law to the Commonwealth of the Northern Mariana Islands.

**Requirements for Filing Motions and Administrative Appeals.** USCIS will propose to revise the procedural regulations governing appeals and motions to reopen or reconsider before its Administrative Appeals Office, and to require that applicants and petitioners exhaust administrative remedies before seeking judicial review of an unfavorable decision. The changes proposed by the rule will streamline the procedures before the Administrative Appeals Office and improve the efficiency of the adjudication process.

**Regulations Related to the Commonwealth of Northern Mariana Islands.** During 2009, USCIS issued three regulations to implement the extension of U.S. immigration law to the Commonwealth of Northern Mariana Islands (CNMI), as required under title VII of the Consolidated Natural Resources Act of 2008. During fiscal year 2011, USCIS issued two final rules related to the extension of the U.S. immigration law
to the CNMI. In fiscal year 2012, USCIS will issue the following CNMI final rule: The joint
USCIS/Department of Justice (DOJ) regulation "Application of Immigration Regulations to the CNMI."

Regulatory Changes Involving Humanitarian Benefits. USCIS offers protection to individuals who face
persecution by adjudicating applications for refugees and asylees. Other humanitarian benefits are
available to individuals who have been victims of severe forms of trafficking or criminal activity.

Asylum and Withholding Definitions. USCIS plans a regulatory proposal to amend the regulations that
govern asylum eligibility and refugee status determinations. The amendments are expected to focus on
portions of the regulations that deal with determinations of whether suffered or feared persecution is on
account of a protected ground, the requirements for establishing that the government is unable or
unwilling to protect the applicant, and the definition of membership in a particular social group. This effort
should provide greater clarity and consistency in this important area of the law.

Exception to the Persecutor Bar for Asylum, Refugee, or Temporary Protected Status, and
Withholding of Removal. In a joint rulemaking, DHS and DOJ will propose amendments to existing DHS
and DOJ regulations to resolve ambiguity in the statutory language precluding eligibility for asylum,
refugee resettlement, temporary protected status, and withholding or removal of an applicant who
ordered, incited, assisted, or otherwise participated in the persecution of others. The proposed rule would
provide a limited exception for persecutory actions taken by the applicant under duress and would clarify
the required level of the applicant's knowledge of the persecution.

"T" and "U" Nonimmigrants. USCIS plans additional regulatory initiatives related to T nonimmigrants
(victims of trafficking), U nonimmigrants (victims of criminal activity), and Adjustment of Status for T and U
status holders. By promulgating additional regulations related to these victims of specified crimes or
severe forms of human trafficking, USCIS hopes to provide greater consistency for these vulnerable
groups, their advocates, and the community. These rulemakings will contain provisions to adjust
documentary requirements for this vulnerable population and provide greater clarity to the law enforcement community.

*Application of the William Wilberforce Trafficking Victims Protection Act of 2008.* In a joint rulemaking, DHS and DOJ will propose amendments to implement the William Wilberforce Trafficking Victims Protection Act of 2008 (TVPRA). Among other things, this statute specified that USCIS has initial jurisdiction over an asylum application filed by an unaccompanied alien child in removal proceedings before an immigration judge in DOJ. The agencies implemented this legislation with interim procedures that the TVPRA mandated within 90 days after enactment. The proposed rule would amend both agencies’ regulations to finalize the procedures to determine when an alien child is unaccompanied and how jurisdiction is transferred to USCIS for initial adjudication of the child's asylum application. In addition, this rule would address adjustment of status for special immigrant juveniles and voluntary departure for unaccompanied alien children in removal proceedings.

**United States Coast Guard**

The U.S. Coast Guard (Coast Guard) is a military, multi-mission, maritime service of the United States and the only military organization within DHS. It is the principal Federal agency responsible for maritime safety, security, and stewardship, and delivers daily value to the Nation through multi-mission resources, authorities, and capabilities.

Effective governance in the maritime domain hinges upon an integrated approach to safety, security, and stewardship. The Coast Guard's policies and capabilities are integrated and interdependent, delivering results through a network of enduring partnerships. The Coast Guard's ability to field versatile capabilities and highly-trained personnel is one of the U.S. Government's most significant and important strengths in the maritime environment.

America is a maritime nation, and our security, resilience, and economic prosperity are intrinsically linked to the oceans. Safety, efficient waterways, and freedom of transit on the high seas are essential to
our well-being. The Coast Guard is leaning forward, poised to meet the demands of the modern maritime environment. The Coast Guard creates value for the public through solid prevention and response efforts. Activities involving oversight and regulation, enforcement, maritime presence, and public and private partnership foster increased maritime safety, security, and stewardship.

The statutory responsibilities of the Coast Guard include ensuring marine safety and security, preserving maritime mobility, protecting the marine environment, enforcing U.S. laws and international treaties, and performing search and rescue. The Coast Guard supports the Department's overarching goals of mobilizing and organizing our Nation to secure the homeland from terrorist attacks, natural disasters, and other emergencies. The rulemaking projects identified for the Coast Guard in the Unified Agenda, and the rules appearing in the fall 2011 regulatory plan below, contribute to the fulfillment of those responsibilities and reflect our regulatory policies.

Implementation of the 1995 Amendments to the International Convention on Standards of Training, Certification, and Watchkeeping (STCW) for Seafarers, 1978. The Coast Guard proposed to amend its regulations to implement changes to an interim rule published on June 26, 1997. These proposed amendments go beyond changes found in the interim rule and seek to more fully incorporate the requirements of the STCW in the requirements for the credentialing of U.S. merchant mariners. The proposed changes are primarily substantive and: (1) Are necessary to continue to give full and complete effect to the STCW Convention; (2) incorporate lessons learned from implementation of the STCW through the interim rule and through policy letters and Navigation and Vessel Inspection Circulars (NVICs); and (3) attempt to clarify regulations that have generated confusion. The Coast Guard published this proposal as a Supplemental Notice of Proposed Rulemaking (SNPRM) on August 1, 2011. The Coast Guard intends to review and analyze comments received on that SNPRM, and publish a subsequent rule complying with the requirements of the newly amended STCW Convention. DHS included this rulemaking in the DHS Final Plan for the Retrospective Review of Existing Regulations, which DHS released on August 22, 2011.
Vessel Requirements for Notices of Arrival and Departure, and Automatic Identification System. The Coast Guard intends to expand the applicability of notice of arrival and departure (NOAD) and automatic identification system (AIS) requirements to include more commercial vessels. This rule, once final, would expand the applicability of notice of arrival (NOA) requirements to include additional vessels, establish a separate requirement for vessels to submit notices of departure (NOD) when departing for a foreign port or place, set forth a mandatory method for electronic submission of NOA and NOD, and modify related reporting content, timeframes, and procedures. This rule would also extend the applicability of AIS requirements beyond Vessel Traffic Service (VTS) areas to all U.S. navigable waters and require additional commercial vessels install and use AIS. These changes are intended to improve navigation safety, enhance Coast Guard's ability to identify and track vessels, and heighten the Coast Guard's overall maritime domain awareness, thus helping the Coast Guard address threats to maritime transportation safety and security and mitigate the possible harm from such threats.

Nontank Vessel Response Plans and Other Vessel Response Plan Requirements. The Coast Guard intends to promulgate a rule to further protect the Nation from the threat of oil spills in U.S. waters, which supports the strategic goals of protection of natural resources and maritime mobility. The rule, once final, would require owners and operators of nontank vessels to prepare and submit oil spill response plans. The Federal Water Pollution Control Act defines nontank vessels as self-propelled vessels of 400 gross tons or greater that operate on the navigable waters of the United States, carry oil of any kind as fuel for main propulsion, and are not tank vessels. The rule would specify the content of a response plan and would address, among other issues, the requirement that a plan for responding to a worst case discharge and a substantial threat of such a discharge. Additionally, the rule would require vessel owners and operators to submit their vessel response plan control number as part of already required notice of arrival information.

Revision to Transportation Worker Identification Credential (TWIC) Requirements for Mariners. The Coast Guard is developing revisions to its merchant mariner credentialing regulations, to implement changes made by section 809 of the Coast Guard Authorization Act of 2010. Section 809 eliminated the requirement for certain mariner populations to obtain TWIC. The Coast Guard is also considering revising its regulations to
provide an exemption for certain fees associated with merchant mariner credentialing for those mariners not required to hold a TWIC who may still be required to visit a TWIC enrollment center to provide the information necessary to obtain a Merchant Mariner Credential. DHS highlighted this rulemaking in the DHS Final Plan for the Retrospective Review of Existing Regulations, which DHS released on August 22, 2011.

**Offshore Supply Vessels of 6000 or more GT ITC.** The Coast Guard Authorization Act of 2010 (the Act) removed the size limit on offshore supply vessels (OSVs) and directed the Coast Guard to issue, as soon as practicable, regulations to implement section 617 of the Act. As required by the Act, this regulation would provide for the safe carriage of oil, hazardous substances, and individuals in addition to crew on OSVs of at least 6000 gross tonnage as measured under the International Convention on Tonnage Measurement of Ships (6,000 GT ITC). In developing the regulations, the Coast Guard is taking into account the characteristics of offshore supply vessels, their methods of operation, and their service in support of exploration, exploitation, or production of offshore mineral or energy resources.

**United States Customs and Border Protection**

U.S. Customs and Border Protection (CBP) is the Federal agency principally responsible for the security of our Nation’s borders at and between the ports of entry and at official crossings into the United States. CBP must accomplish its border security and enforcement mission while facilitating the flow of legitimate trade and travel. The primary mission of CBP is its homeland security mission; that is, to prevent terrorists and terrorist weapons from entering the United States. An important aspect of this priority mission involves improving security at our borders and ports of entry, but it also means extending our zone of security beyond our physical borders.

CBP is also responsible for administering laws concerning the import and export of goods into and out of the United States, and enforcing the laws concerning the entry of persons into and out of the United States. This includes regulating and facilitating international trade; collecting import duties; enforcing U.S. trade, immigration, and other laws of the United States at our borders; inspecting imports and exports;
overseeing the activities of persons and businesses engaged in importing; enforcing the laws concerning smuggling and trafficking in contraband; apprehending individuals attempting to enter the United States illegally; protecting our agriculture and economic interests from harmful pests and diseases; conducting inspections of all people, vehicles, and cargo entering the United States; enforcing export controls; and protecting U.S. businesses from theft of their intellectual property.

In carrying out its priority mission, CBP’s goal is to facilitate the processing of legitimate trade and people efficiently without compromising security. Consistent with its primary mission of homeland security, CBP intends to finalize several rules during the next fiscal year that are intended to improve security at our borders and ports of entry. We have highlighted some of these rules below.

**Electronic System for Travel Authorization (ESTA).** On June 9, 2008, CBP published an interim final rule amending DHS regulations to implement the Electronic System for Travel Authorization (ESTA) for aliens who wish to enter the United States under the Visa Waiver Program (VWP) at air or sea ports of entry. This rule is intended to fulfill the requirements of section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act). The rule establishes ESTA and delineates the data field DHS has determined will be collected by the system. The rule requires that each alien traveling to the United States under the VWP must obtain electronic travel authorization via the ESTA in advance of such travel. VWP travelers may obtain the required ESTA authorization by electronically submitting to CBP biographic and other information as currently required by the I-94W Nonimmigrant Alien Arrival/Departure Form (I-94W). By Federal Register notice dated November 13, 2008, the Secretary of Homeland Security informed the public that ESTA would become mandatory beginning January 12, 2009. This means that all VWP travelers must either obtain travel authorization in advance of travel under ESTA or obtain a visa prior to traveling to the United States.

By shifting from a paper to an electronic form and requiring the data in advance of travel, CBP will be able to determine before the alien departs for the U.S. the eligibility of nationals from VWP countries to travel to the United States and to determine whether such travel poses a law enforcement or security risk.
By modernizing the VWP, the ESTA is intended to increase national security and provide for greater efficiencies in the screening of international travelers by allowing for vetting of subjects of potential interest well before boarding, thereby reducing traveler delays based on lengthy processes at ports of entry. On August 9, 2010, CBP published an interim final rule amending the ESTA regulations to require ESTA applicants to pay a congressionally mandated fee, which is the sum of two amounts, a $10 travel promotion fee for an approved ESTA and a $4.00 operational fee for the use of ESTA set by the Secretary of Homeland Security to at least ensure the recovery of the full costs of providing and administering the ESTA system. During the next fiscal year, CBP intends to issue a final rule on ESTA and the ESTA fee.

*Importer Security Filing and Additional Carrier Requirements.* The Security and Accountability for Every Port Act of 2006 (SAFE Port Act) calls for CBP to promulgate regulations to require the electronic transmission of additional data elements for improved high-risk targeting. See Public Law No. 109-347, section 203 (October 13, 2006). This includes appropriate security elements of entry data for cargo destined for the United States by vessel prior to loading of such cargo on vessels at foreign seaports. The SAFE Port Act requires that the information collected reasonably improve CBP’s ability to identify high-risk shipments to prevent smuggling and ensure cargo safety and security.

On November 25, 2008, CBP published an interim final rule “Importer Security Filing and Additional Carrier Requirements,” amending CBP Regulations to require carriers and importers to provide to CBP via a CBP-approved electronic data interchange system, information necessary to enable CBP to identify high-risk shipments to prevent smuggling, and ensure cargo safety and security. This rule, which became effective on January 26, 2009, improves CBP risk assessment and targeting capabilities, facilitates the prompt release of legitimate cargo following its arrival in the United States, and assists CBP in increasing the security of the global trading system. The comment period for the interim final rule concluded on June 1, 2009. CBP is analyzing comments and conducting a structured review of certain flexibility provided in the interim final rule. CBP intends to publish a final rule during the next fiscal year.

*Implementation of the Guam-CNMI Visa Waiver Program.* CBP published an interim final rule in
November 2008 amending the DHS regulations to replace the current Guam Visa Waiver Program with a new Guam-CNMI Visa Waiver program. This rule implements portions of the Consolidated National Resources Act of 2008 (CNRA), which extends the immigration laws of the United States to the Commonwealth of the Northern Mariana Islands (CNMI) and, among others things, provides for a visa waiver program for travel to Guam and the CNMI. The amended regulations set forth the requirements for nonimmigrant visitors who seek admission for business or pleasure and solely for entry into and stay on Guam or the CNMI without a visa. The rule also establishes six ports of entry in the CNMI for purposes of administering and enforcing the Guam-CNMI Visa Waiver program. CBP intends to issue a final rule during the next fiscal year.

**Global Entry Program.** In the fall of 2009, pursuant to section 7208(k) of the Intelligence Reform and Terrorism Prevention Act of 2004, as amended, CBP issued a Notice of Proposed Rulemaking (NPRM), proposing to establish an international trusted traveler program, called Global Entry. This voluntary program would allow CBP to expedite clearance of pre-approved, low-risk air travelers into the United States. CBP has been operating the Global Entry program as a pilot at several airports since June 6, 2008. Based on the successful operation of the pilot, CBP proposed to establish Global Entry as a permanent voluntary regulatory program. CBP has evaluated the public comments received in response to the NPRM and intends to issue a final rule during the next fiscal year.

In the above paragraphs, DHS discusses the CBP regulations that foster DHS’s mission. CBP also issues regulations related to the mission of the Department of the Treasury. Under section 403(1) of the Homeland Security Act of 2002, the former U.S. Customs Service, including functions of the Secretary of the Treasury relating thereto, transferred to the Secretary of Homeland Security. As part of the initial organization of DHS, the Customs Service inspection and trade functions were combined with the immigration and agricultural inspection functions and the Border Patrol and transferred into CBP. It is noted that certain regulatory authority of the United States Customs Service relating to customs revenue function was retained by the Department of the Treasury (see the Department of the Treasury regulatory plan). In addition to its plans to continue issuing regulations to enhance border security, CBP, during
fiscal year 2012, expects to continue to issue regulatory documents that will facilitate legitimate trade and implement trade benefit program. CBP regulations regarding the customs revenue function are discussed in the regulatory plan of the Department of the Treasury.

**Federal Emergency Management Agency**

The mission of the Federal Emergency Management Agency (FEMA) is to support our citizens and first responders to ensure that, as a Nation, we work together to build, sustain, and improve our capability to prepare for, protect against, respond to, recover from, and mitigate all hazards. In fiscal year 2012, FEMA will continue to serve that mission and promote the Department of Homeland Security's goals. In furtherance of the Department and Agency's goals, in the upcoming fiscal year, FEMA will work on regulations to implement provisions of the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA) (Pub. L. No. 109-295, Oct. 4, 2006) and to implement lessons learned from past events.

*Public Assistance Program Regulations.* FEMA will work to revise the Public Assistance Program regulations in 44 CFR part 206 to reflect changes made to the Robert T. Stafford Disaster Relief and Emergency Assistance Act by PKEMRA, the Pets Evacuation and Transportation Standards Act of 2006 (PETS Act) (Pub. L. No. 109-308, Oct. 6, 2006), the Local Community Recovery Act of 2006 (Pub. L. No. 109-218, Apr. 20, 2006), and the Security and Accountability for Every Port Act of 2006 (SAFE Port Act) (Pub. L. No. 109-347, Oct. 13, 2006), and to make other substantive and nonsubstantive clarifications and corrections to the Public Assistance regulations. The proposed changes would expand eligibility to include performing arts facilities and community arts centers pursuant to section 688 of PKEMRA; include education in the list of critical services pursuant to section 689(h) of PKEMRA, thus allowing private nonprofit educational facilities to be eligible for restoration funding; add accelerated Federal assistance to available assistance pursuant to section 681 of PKEMRA; include household pets and service animals in essential assistance pursuant to section 689 of PKEMRA and section 4 of the PETS Act; provide for expedited payments of grant assistance for the removal of debris pursuant to section 610 of the SAFE Port Act; and allow for a contract to be set aside for award based on a specific geographic area pursuant to section 2 of the Local Community Recovery Act of 2006. Other changes would include adding or changing requirements to improve and streamline the Public Assistance grant application process.
Federal Law Enforcement Training Center

The Federal Law Enforcement Training Center (FLETC) does not have any significant regulatory actions planned for fiscal year 2012.

United States Immigration and Customs Enforcement

ICE is the principal criminal investigative arm of the Department of Homeland Security and one of the three Department components charged with the civil enforcement of the Nation’s immigration laws. Its primary mission is to protect national security, public safety, and the integrity of our borders through the criminal and civil enforcement of Federal law governing border control, customs, trade, and immigration.

During fiscal year 2012, ICE will pursue rulemaking actions that improve two critical subject areas: The detention of aliens who are subject to final orders of removal and the processes for the Student and Exchange Visitor Program (SEVP).

*Continued Detention of Aliens Subject to Final Orders of Removal.* ICE will improve the post order custody review process in a Final Rule related to the continued detention of aliens subject to final orders of removal in light of the U.S. Supreme Court’s decisions in *Zadvydas v. Davis*, 533 U.S. 678 (2001) and *Clark v. Martinez*, 543 U.S. 371 (2005), as well as changes pursuant to the enactment of the Homeland Security Act of 2002. During fiscal year 2012, ICE will also issue a companion Notice of Proposed Rulemaking (NPRM) that will allow the public an opportunity to comment on new sections of the custody determination process not previously published for comment.

*Processes for the Student and Exchange Visitor Program.* ICE will improve SEVP processes by publishing a final Optional Practical Training (OPT) rule, which will respond to comments on the OPT Interim Final Rule (IFR). The IFR increased the maximum period of OPT from 12 months to 29 months
for nonimmigrant students who have completed a science, technology, engineering, or mathematics degree and who accept employment with employers who participate in USCIS’s E-Verify employment verification program.

**National Protection and Programs Directorate**

The goal of the National Protection and Programs Directorate (NPPD) is to advance the Department's risk-reduction mission. Reducing risk requires an integrated approach that encompasses both physical and virtual threats and their associated human elements.

*Ammonium Nitrate Security Program.* The Secure Handling of Ammonium Nitrate Act, section 563 of the Fiscal Year 2008 Department of Homeland Security Appropriations Act, Public Law No. 110-161, amended the Homeland Security Act of 2002 to provide DHS with the authority to “regulate the sale and transfer of ammonium nitrate by an ammonium nitrate facility . . . to prevent the misappropriation or use of ammonium nitrate in an act of terrorism.”

The Secure Handling of Ammonium Nitrate Act directs DHS to promulgate regulations requiring potential buyers and sellers of ammonium nitrate to register with DHS. As part of the registration process, the statute directs DHS to screen registration applicants against the Federal Government’s Terrorist Screening Database. The statute also requires sellers of ammonium nitrate to verify the identities of those seeking to purchase it; to record certain information about each sale or transfer of ammonium nitrate; and to report thefts and losses of ammonium nitrate to DHS.

The Ammonium Nitrate Security Program Notice of Proposed Rulemaking proposes requirements that would implement the Secure Handling of Ammonium Nitrate Act. The rule would aid the Federal Government in its efforts to prevent the misappropriation of ammonium nitrate for use in acts of terrorism. By preventing such misappropriation, this rule aims to limit terrorists’ abilities to threaten the public and to threaten the Nation’s critical infrastructure and key resources. By securing the Nation’s supply of
ammonium nitrate, it will be more difficult for terrorists to obtain ammonium nitrate materials for use in terrorist acts.

On October 29, 2008, DHS published an Advance Notice of Proposed Rulemaking (ANPRM) for the Secure Handling of Ammonium Nitrate Program, and received a number of public comments on that ANPRM. DHS reviewed those comments and published a Notice of Proposed Rulemaking (NPRM) on August 3, 2011. NPPD will accept public comment on until December 1, 2011, after which NPPD will review the public comments and develop a Final Rule related to the Security Handling of Ammonium Nitrate Program.

Transportation Security Administration

The Transportation Security Administration (TSA) protects the Nation’s transportation systems to ensure freedom of movement for people and commerce. TSA is committed to continuously setting the standard for excellence in transportation security through its people, processes, and technology as we work to meet the immediate and long-term needs of the transportation sector.

In fiscal year 2012, TSA will promote the DHS mission by emphasizing regulatory efforts that allow TSA to better identify, detect, and protect against threats against various modes of the transportation system, while facilitating the efficient movement of the traveling public, transportation workers, and cargo.

General Aviation Security and Other Aircraft Operator Security. TSA plans to issue a Supplemental Notice of Proposed Rulemaking (SNPRM) to propose amendments to current aviation transportation security regulations to enhance the security of general aviation (GA) by expanding the scope of current requirements and by adding new requirements for certain GA aircraft operators. To date, the Government's focus with regard to aviation security generally has been on air carriers and commercial
operators. As vulnerabilities and risks associated with air carriers and commercial operators have been reduced or mitigated, terrorists may perceive that GA aircraft are more vulnerable and may view them as attractive targets. This rule would enhance aviation security by requiring operators of certain GA aircraft to adopt a security program and to undertake other security measures. TSA published a Notice of Proposed Rulemaking on October 30, 2008, and received over 7,000 public comments, generally urging significant changes to the proposal. The SNPRM will respond to the comments and contain proposals on addressing security in the GA sector.

Security Training for Surface Mode Employees. TSA will propose regulations to enhance the security of several non-aviation modes of transportation. In particular, TSA will propose regulations requiring freight railroad carriers, public transportation agencies (including rail mass transit and bus systems), passenger railroad carriers, and over-the-road bus operators to conduct security training for front line employees. This regulation would implement sections 1408 (Public Transportation), 1517 (Freight Railroads), and 1534(a) (Over the Road Buses) of the Implementing Recommendations of the 9/11 Commission Act of 2008 (9/11 Act), Public Law 110-53 (Aug. 3, 2007). In compliance with the definitions of frontline employees in the pertinent provisions of the 9/11 Act, the Notice of Proposed Rulemaking (NPRM) would define which employees are required to undergo training. The NPRM would also propose definitions for transportation security-sensitive materials, as required by section 1501 of the 9/11 Act.

Railroad Carrier Vulnerability Assessment and Security Plans. TSA will also propose regulations requiring high-risk freight and passenger railroads to conduct vulnerability self-assessments, as well as develop and implement comprehensive security plans. TSA would need to approve both the vulnerability assessment and security plan. This regulation, implementing section 1512 of the 9/11 Act, would include proposed provisions to identify which railroads would be considered high-risk and include proposed provisions about the associated vulnerability assessment and security planning requirements.
Aircraft Repair Station Security. TSA will finalize a rule requiring repair stations that are certificated by the Federal Aviation Administration under 14 CFR part 145 to adopt and implement standard security programs and to comply with security directives issued by TSA. TSA issued an Notice of Proposed Rulemaking (NPRM) on November 18, 2009. The final rule will also codify the scope of TSA’s existing inspection program and could require regulated parties to allow DHS officials to enter, inspect, and test property, facilities, and records relevant to repair stations. This rulemaking action will implement section 1616 of the 9/11 Act.

Standardized Vetting, Adjudication, and Redress Process and Fees. TSA is developing a proposed rule to revise and standardize the procedures, adjudication criteria, and fees for most of the security threat assessments (STA) of individuals that TSA conducts. DHS is considering a proposal that would include procedures for conducting STAs for transportation workers from almost all modes of transportation, including those covered under the 9/11 Act. In addition, TSA will propose equitable fees to cover the cost of the STAs and credentials for some personnel. TSA plans to identify new efficiencies in processing STAs and ways to streamline existing regulations by simplifying language and removing redundancies.

As part of this proposed rule, TSA will propose revisions to the Alien Flight Student Program (AFSP) regulations. TSA published an interim final rule for ASFP on September 20, 2004. TSA regulations require aliens seeking to train at Federal Aviation Administration-regulated flight schools to complete an application and undergo an STA prior to beginning flight training. There are four categories under which students currently fall; the nature of the STA depends on the student’s category. TSA is considering changes to the AFSP that would improve equity among fee payers and enable the implementation of new technologies to support vetting.

United States Secret Service
The United States Secret Service does not have any significant regulatory actions planned for fiscal year 2012.

DHS Regulatory Plan for Fiscal Year 2012

A more detailed description of the priority regulations that comprise DHS's fall 2011 regulatory plan follows.

<table>
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<tr>
<th>DHS—Office of the Secretary (OS)</th>
<th>PROPOSED RULE STAGE</th>
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<tbody>
<tr>
<td>53. SECURE HANDLING OF AMMONIUM NITRATE PROGRAM</td>
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</table>

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
2008 Consolidated Appropriations Act, sec 563, subtitle J—Secure Handling of Ammonium Nitrate, PL 110–161

CFR Citation:
6 CFR 31

Legal Deadline:

Abstract:
This rulemaking will implement the December 2007 amendment to the Homeland Security Act entitled “Secure Handling of Ammonium Nitrate.” The amendment requires the Department of Homeland Security to “regulate the sale and transfer of ammonium nitrate by an ammonium nitrate facility…to prevent the misappropriation or use of ammonium nitrate in an act of terrorism.”
Statement of Need:
Pursuant to section 563 of the 2008 Consolidated Appropriations Act, subtitle J—Secure Handling of Ammonium Nitrate, Public Law 110-161, the Department of Homeland Security is required to promulgate a rulemaking to create a registration regime for certain buyers and sellers of ammonium nitrate. The rule, as proposed by this NPRM, would create that regime, and would aid the Federal Government in its efforts to prevent the misappropriation of ammonium nitrate for use in acts of terrorism. By preventing such misappropriation, this rule could limit terrorists’ abilities to threaten the public and to threaten the Nation's critical infrastructure and key resources. By securing the Nation's supply of ammonium nitrate, it should be much more difficult for terrorists to obtain ammonium nitrate materials for use in improvised explosive devices. As a result, there is a direct value in the deterrence of a catastrophic terrorist attack using ammonium nitrate, such as the Oklahoma City attack that killed over 160 and injured 853 people.

Summary of Legal Basis:
Section 563 of the 2008 Consolidated Appropriations Act, subtitle J—Secure Handling of Ammonium Nitrate, Public Law 110-161, authorizes and requires this rulemaking.

Alternatives:
The Department considered several alternatives when developing the Ammonium Nitrate Security Program proposed rule. The alternatives considered were: (a) Register individuals applying for an AN Registered User Number using a paper application (via facsimile or the U.S. mail) rather than through in person application at a local Cooperative Extension office or only through a web-based portal; (b) verify AN Purchasers through both an Internet based verification portal and call center rather than only a verification portal or call center; (c) communicate with applicants for an AN Registered User Number through U.S. Mail rather than only through e-mail or a secure web-based portal; (d) establish a specific capability within the Department to receive, process, and respond to reports of theft or loss rather than leverage a similar capability which already exists with the ATF; (e) require AN Facilities to maintain records electronically in a central database provided by the Department rather than providing flexibility to the AN Facility to maintain their own records either in paper or electronically; (f) require agents to register with the Department prior to the sale or transfer of ammonium nitrate involving an agent rather than allow oral confirmation of the agent with the AN Purchaser on whose behalf the agent is working; and (g)
exempt explosives from this regulation rather than not exempting them. As part of its notice of proposed rulemaking, the Department seeks public comment on the numerous alternative ways in which the final Secure Handling of Ammonium Nitrate Program could carry out the requirements of the Secure Handling of Ammonium Nitrate Act.

**Anticipated Cost and Benefits:**

The Department estimates the number of entities that purchase ammonium nitrate to range from 64,950 to 106,200. These purchasers include farms, fertilizer mixers, farm supply wholesalers and cooperatives (co-ops), golf courses, landscaping services, explosives distributors, mines, retail garden centers, and lab supply wholesalers. The Department estimates the number of entities that sell ammonium nitrate to be between 2,486 and 6,236, many of which are also purchasers. These sellers include ammonium nitrate fertilizer and explosive manufacturers, fertilizer mixers, farm supply wholesalers and co-ops, retail garden centers, explosives distributors, fertilizer applicator services, and lab supply wholesalers. Individuals or firms that provide transportation services within the distribution chain may be categorized as sellers, agents, or facilities depending upon their business relationship with the other parties to the transaction. The total number of potentially regulated farms and other businesses ranges from 64,986 to 106,236 (including overlap between the categories).

The cost of this proposed rule ranges from $300 million to $1,041 million over 10 years at a 7 percent discount rate. The primary estimate is the mean which is $670.6 million. For comparison, at a 3 percent discount rate, the cost of the program ranges from $364 million to $1.3 billion with a primary (mean) estimate of $814 million. The average annualized cost for the program ranges from $43 million to $148 million (with a mean of $96 million), also employing a 7 percent discount rate.

Because the value of the benefits of reducing risk of a terrorist attack is a function of both the probability of an attack and the value of the consequence, it is difficult to identify the particular risk reduction associated with the implementation of this rule. These elements and related qualitative benefits include point of sale identification requirements and requiring individuals to be screened against the Terrorist
Screening Database (TSDB) resulting in known bad actors being denied the ability to purchase ammonium nitrate.

The Department of Homeland Security aims to prevent terrorist attacks within the United States and to reduce the vulnerability of the United States to terrorism. By preventing the misappropriation or use of ammonium nitrate in acts of terrorism, this rulemaking will support the Department's efforts to prevent terrorist attacks and to reduce the Nation's vulnerability to terrorist attacks. This rulemaking is complementary to other Department programs seeking to reduce the risks posed by terrorism, including the Chemical Facility Anti-Terrorism Standards program (which seeks in part to prevent terrorists from gaining access to dangerous chemicals) and the Transportation Worker Identification Credential program (which seeks in part to prevent terrorists from gaining access to certain critical infrastructure), among other programs.

**Risks:**
Explosives containing ammonium nitrate are commonly used in terrorist attacks. Such attacks have been carried out both domestically and internationally. The 1995 Murrah Federal Building attack in Oklahoma City claimed the lives of 167 individuals and demonstrated firsthand to America how ammonium nitrate could be misused by terrorists. In addition to the Murrah Building attack, the Provisional Irish Republican Army used ammonium nitrate as part of its London, England bombing campaign in the early 1980s. More recently, ammonium nitrate was used in the 1998 East African Embassy bombings and in November 2003 bombings in Istanbul, Turkey. Additionally, since the events of 9/11, stores of ammonium nitrate have been confiscated during raids on terrorist sites around the world, including sites in Canada, England, India, and the Philippines.

**Timetable:**

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<th>Action</th>
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<td>10/29/08</td>
<td>73 FR 64280</td>
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<td>Correction</td>
<td>11/05/08</td>
<td>73 FR 65783</td>
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Notice of Public Meetings 10/07/11 76 FR 62311
Notice of Public Meetings 11/14/11 76 FR 70366
NPRM Comment Period End 12/01/11

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<th>Regulatory Flexibility Analysis Required:</th>
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Small Entities Affected:
Businesses

Government Levels Affected:
Federal

Federalism:
This action may have federalism implications as defined in EO 13132.

URL For More Information:
www.regulations.gov

URL For Public Comments:
www.regulations.gov

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RIN: 1601–AA52
This rule proposes to amend Department of Homeland Security regulations that govern asylum eligibility. The amendments focus on portions of the regulations that deal with the definitions of membership in a particular social group, the requirements for failure of State protection, and determinations about whether persecution is inflicted on account of a protected ground. This rule codifies long-standing concepts of the definitions. It clarifies that gender can be a basis for membership in a particular social group. It also clarifies that a person who has suffered or fears domestic violence may under certain circumstances be eligible for asylum on that basis. After the Board of Immigration Appeals published a decision on this issue in 1999, Matter of R-A-, Int. Dec. 3403 (BIA 1999), it became clear that the governing regulatory standards required clarification. The Department of Justice began this regulatory initiative by publishing a proposed rule addressing these issues in 2000.

Statement of Need:
This rule provides guidance on a number of key interpretive issues of the refugee definition used by adjudicators deciding asylum and withholding of removal (withholding) claims. The interpretive issues include whether persecution is inflicted on account of a protected ground, the requirements for
establishing the failure of State protection, and the parameters for defining membership in a particular social group. This rule will aid in the adjudication of claims made by applicants whose claims fall outside of the rubric of the protected grounds of race, religion, nationality, or political opinion. One example of such claims which often fall within the particular social group ground concerns people who have suffered or fear domestic violence. This rule is expected to consolidate issues raised in a proposed rule in 2000 and to address issues that have developed since the publication of the proposed rule. This rule should provide greater stability and clarity in this important area of the law.

Summary of Legal Basis:
The purpose of this rule is to provide guidance on certain issues that have arisen in the context of asylum and withholding adjudications. The 1951 Geneva Convention relating to the Status of Refugees contains the internationally accepted definition of a refugee. United States immigration law incorporates an almost identical definition of a refugee as a person outside his or her country of origin “who is unable or unwilling to return to, and is unable or unwilling to avail himself or herself of the protection of, that country because of persecution or a well-founded fear of persecution on account of race, religion, nationality, membership in a particular social group, or political opinion.” Section 101(a)(42) of the Immigration and Nationality Act.

Alternatives:
A sizable body of interpretive case law has developed around the meaning of the refugee definition. Historically, much of this case law has addressed more traditional asylum and withholding claims based on the protected grounds of race, religion, nationality, or political opinion. In recent years, however, the United States increasingly has encountered asylum and withholding applications with more varied bases, related, for example, to an applicant's gender or sexual orientation. Many of these new types of claims are based on the ground of “membership in a particular social group,” which is the least well-defined of the five protected grounds within the refugee definition.

On December 7, 2000, DOJ published a proposed rule in the Federal Register providing guidance on the definitions of “persecution” and “membership in a particular social group.” Prior to publishing a new proposed rule, the Department will be considering how the nexus between persecution and a protected ground might be further conceptualized; how membership in a particular social group might be defined
and evaluated; and what constitutes a State’s inability or unwillingness to protect the applicant where the persecution arises from a non-State actor. This rule will provide guidance to the following adjudicators: USCIS asylum officers, Department of Justice Executive Office for Immigration Review (EOIR) immigration judges, and members of the EOIR Board of Immigration Appeals. The alternative to publishing this rule would be to allow the standards governing this area of law to continue to develop piecemeal through administrative and judicial precedent. This approach has resulted in inconsistent and confusing standards, and the Department has therefore determined that promulgation of the new proposed rule is necessary.

**Anticipated Cost and Benefits:**
By providing a clear framework for key asylum and withholding issues, we anticipate that adjudicators will have clear guidance, increasing administrative efficiency and consistency in adjudicating these cases. The rule will also promote a more consistent and predictable body of administrative and judicial precedent governing these types of cases. We anticipate that this will enable applicants to better assess their potential eligibility for asylum, and to present their claims more efficiently when they believe that they may qualify, thus reducing the resources spent on adjudicating claims that do not qualify. In addition, a more consistent and predictable body of law on these issues will likely result in fewer appeals, both administrative and judicial, and reduce associated litigation costs. The Department has no way of accurately predicting how this rule will impact the number of asylum applications filed in the United States. Based on anecdotal evidence and on the reported experience of other nations that have adopted standards under which the results are similar to those we anticipate for this rule, we do not believe this rule will cause a change in the number of asylum applications filed.

**Risks:**
The failure to promulgate a final rule in this area presents significant risks of further inconsistency and confusion in the law. The Government’s interests in fair, efficient, and consistent adjudications would be compromised.

**Timetable:**

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<td>NPRM</td>
<td>12/07/00</td>
<td>65 FR 76588</td>
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NPRM Comment Period End 01/22/01

NPRM 05/00/12

Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Additional Information:
CIS No. 2092-00
Transferred from RIN 1115-AF92

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RIN: 1615–AA41

DHS—USCIS
55. NEW CLASSIFICATION FOR VICTIMS OF CRIMINAL ACTIVITY; ELIGIBILITY FOR THE U NONIMMIGRANT STATUS

Priority:
Other Significant

Legal Authority:
5 USC 552; 5 USC 552a; 8 USC 1101; 8 USC 1101 note; 8 USC 1102

CFR Citation:
8 CFR 103; 8 CFR 204; 8 CFR 212; 8 CFR 214; 8 CFR 299

Legal Deadline:
None

Abstract:
This rule sets forth application requirements for a new nonimmigrant status. The U classification is for non-U.S. Citizen/Lawful Permanent Resident victims of certain crimes who cooperate with an investigation or prosecution of those crimes. There is a limit of 10,000 principals per year.

This rule establishes the procedures to be followed in order to petition for the U nonimmigrant classifications. Specifically, the rule addresses the essential elements that must be demonstrated to receive the nonimmigrant classification, procedures that must be followed to make an application, and evidentiary guidance to assist in the petitioning process. Eligible victims will be allowed to remain in the United States. The Trafficking Victims Protection Reauthorization Act of 2008, Public Law 110-457, made amendments to the T nonimmigrant status provisions of the Immigration and Nationality Act. The Department will issue a proposed rule to make the changes required by recent legislation and to provide the opportunity for notice and comment.

Statement of Need:
This rule provides requirements and procedures for aliens seeking U nonimmigrant status. U nonimmigrant classification is available to alien victims of certain criminal activity who assist government officials in the investigation or prosecution of that criminal activity. The purpose of the U nonimmigrant classification is to strengthen the ability of law enforcement agencies to investigate and prosecute such
crimes as domestic violence, sexual assault, and trafficking in persons, while offering protection to alien crime victims in keeping with the humanitarian interests of the United States.

**Summary of Legal Basis:**

Congress created the U nonimmigrant classification in the Battered Immigrant Women Protection Act of 2000 (BIWPA). Congress intended to strengthen the ability of law enforcement agencies to investigate and prosecute cases of domestic violence, sexual assault, trafficking of aliens, and other crimes, while offering protection to victims of such crimes. Congress also sought to encourage law enforcement officials to better serve immigrant crime victims.

**Alternatives:**

USCIS has identified four alternatives, the first being chosen for the rule:

1. USCIS would adjudicate petitions on a first in, first out basis. Petitions received after the limit has been reached would be reviewed to determine whether or not they are approvable, but for the numerical cap. Approvable petitions that are reviewed after the numerical cap has been reached would be placed on a waiting list and written notice sent to the petitioner. Priority on the waiting list would be based upon the date on which the petition is filed. USCIS would provide petitioners on the waiting list with interim relief until the start of the next fiscal year in the form of deferred action, parole, or a stay of removal.

2. USCIS would adjudicate petitions on a first in, first out basis, establishing a waiting list for petitions that are pending or received after the numerical cap has been reached. Priority on the waiting list would be based upon the date on which the petition was filed. USCIS would not provide interim relief to petitioners whose petitions are placed on the waiting list.

3. USCIS would adjudicate petitions on a first in, first out basis. However, new filings would be reviewed to identify particularly compelling cases for adjudication. New filings would be rejected once the numerical cap is reached. No official waiting list would be established; however, interim relief until the start of the next fiscal year would be provided for some compelling cases. If a case was not particularly compelling, the filing would be denied or rejected.
4. USCIS would adjudicate petitions on a first in, first out basis. However, new filings would be rejected once the numerical cap is reached. No waiting list would be established nor would interim relief be granted.

**Anticipated Cost and Benefits:**

USCIS estimates the total annual cost of this interim rule to applicants to be $6.2 million. This cost includes the biometric services fee that petitioners must pay to USCIS, the opportunity cost of time needed to submit the required forms, the opportunity cost of time required for a visit to an Application Support Center, and the cost of traveling to an Application Support Center.

This rule will strengthen the ability of law enforcement agencies to investigate and prosecute such crimes as domestic violence, sexual assault, and trafficking in persons, while offering protection to alien crime victims in keeping with the humanitarian interests of the United States.

**Risks:**

In the case of witness tampering, obstruction of justice, or perjury, the interpretive challenge for USCIS was to determine whom the BIWPA was meant to protect, given that these criminal activities are not targeted against a person. Accordingly it was determined that a victim of witness tampering, obstruction of justice, or perjury is an alien who has been directly and proximately harmed by the perpetrator of one of these three crimes, where there are reasonable grounds to conclude that the perpetrator principally committed the offense as a means: (1) To avoid or frustrate efforts to investigate, arrest, prosecute, or otherwise bring him or her to justice for other criminal activity; or (2) to further his or her abuse or exploitation of, or undue control over, the alien through manipulation of the legal system.

**Timetable:**

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
Federal, Local, State

Additional Information:
Transferred from RIN 1115-AG39

Agency Contact:
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RIN: 1615–AA67

56. EXCEPTION TO THE PERSECUTION BAR FOR ASYLUM, REFUGEE, AND TEMPORARY PROTECTED STATUS, AND WITHHOLDING OF REMOVAL

Priority:
Other Significant
Legal Authority:
8 USC 1101; 8 USC 1103; 8 USC 1158; 8 USC 1226; PL 107–26; PL 110–229

CFR Citation:
8 CFR 1; 8 CFR 208; 8 CFR 244; 8 CFR 1244

Legal Deadline:
None

Abstract:
This joint rule proposes amendments to Department of Homeland Security (DHS) and Department of Justice (DOJ) regulations to describe the circumstances under which an applicant will continue to be eligible for asylum, refugee, or temporary protected status, special rule cancellation of removal under the Nicaraguan Adjustment and Central American Relief Act, and withholding of removal, even if DHS or DOJ has determined that the applicant's actions contributed, in some way, to the persecution of others. The purpose of this rule is to resolve ambiguity in the statutory language precluding eligibility for asylum, refugee, and temporary protected status of an applicant who ordered, incited, assisted, or otherwise participated in the persecution of others. The proposed amendment would provide a limited exception for actions taken by the applicant under duress and clarify the required levels of the applicant's knowledge of the persecution.

Statement of Need:
This rule resolves ambiguity in the statutory language precluding eligibility for asylum, refugee, and temporary protected status of an applicant who ordered, incited, assisted, or otherwise participated in the persecution of others. The proposed amendment would provide a limited exception for actions taken by the applicant under duress and clarify the required levels of the applicant's knowledge of the persecution.

Summary of Legal Basis:
In Negusie v. Holder, 129 S. Ct. 1159 (2009), the Supreme Court addressed whether the persecutor bar should apply where an alien's actions were taken under duress. DHS believes that this is an appropriate subject for rulemaking and proposes to amend the applicable regulations to set out its interpretation of the statute. In developing this regulatory initiative, DHS has carefully considered the purpose and history
behind enactment of the persecutor bar, including its international law origins and the criminal law concepts upon which they are based.

Alternatives:
DHS did consider the alternative of not publishing a rulemaking on these issues. To leave this important area of the law without an administrative interpretation would confuse adjudicators and the public.

Anticipated Cost and Benefits:
The programs affected by this rule exist so that the United States may respond effectively to global humanitarian situations and assist people who are in need. USCIS provides a number of humanitarian programs and protection to assist individuals in need of shelter or aid from disasters, oppression, emergency medical issues, and other urgent circumstances. This rule will advance the humanitarian goals of the asylum/refugee program, and other specialized programs. The main benefits of such goals tend to be intangible and difficult to quantify in economic and monetary terms. These forms of relief have not been available to certain persecutors. This rule will allow an exception to this bar from protection for applicants who can meet the appropriate evidentiary standard. Consequently, this rule may result in a small increase in the number of applicants for humanitarian programs. To the extent a small increase in applicants occurs, there could be additional fee costs incurred by these applicants.

Risks:
If DHS were not to publish a regulation, the public would face a lengthy period of confusion on these issues. There could also be inconsistent interpretations of the statutory language, leading to significant litigation and delay for the affected public.

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

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**RIN:** 1615–AB89

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**DHS—USCIS**

57. • ELECTRONIC FILING OF REQUESTS FOR IMMIGRATION BENEFITS; REQUIRING AN APPLICATION TO CHANGE OR EXTEND NONIMMIGRANT STATUS TO BE FILED ELECTRONICALLY

**Priority:**
Other Significant

**Legal Authority:**
8 USC 1101; 8 USC 1103; 8 USC 1151; 8 USC 1153

**CFR Citation:**
8 CFR 103; 8 CFR 204

**Legal Deadline:**
None

**Abstract:**
The Department of Homeland Security (DHS) is proposing regulations to govern the electronic filing of requests for immigration benefit requests with the U.S. Citizenship and Immigration Services (USCIS). DHS also proposes to mandate electronic applications in the new Integrated Operating Environment that is under development, with limited exceptions, for an Application to Extend/Change Nonimmigrant Status from any individual in the M, J, B-1, and B-2 classifications; change of status requests to the F, M, J, B-1, or B-2 classifications; and reinstatement of status requests in the F or M classification.

**Statement of Need:**
USCIS is in the process of transforming its operations to improve service, operational efficiency, and national security. This rule will allow USCIS to modernize its processes, which will provide applicants and petitioners with better and faster services and enhance the ability of USCIS to process cases with greater accuracy, security, and timeliness.

**Summary of Legal Basis:**

The Government Paperwork Elimination Act provides that, when possible, Federal agencies are directed to make available electronic forms and provide for electronic filing and submissions when conducting agency business with the public. See Public Law 105-277, section 1703 (Oct. 21, 1998), 44 U.S.C. 3504. GPEA also establishes the means for the use and acceptance of electronic signatures.

The INA provides a detailed list of classes of nonimmigrant aliens. See, e.g., INA sections 101(a)(15)(B), (C), (F), and (M); 8 U.S.C. 1101(a)(15) (B), (C), (F), and (M). The Secretary of Homeland Security may authorize a change to any other nonimmigrant classification in the case of any alien who is lawfully admitted to the United States as a nonimmigrant, maintains his or her lawful status, does not fall under certain nonimmigrant visa categories that are listed in the statute, and is not inadmissible or whose
inadmissibility has been waived under the pertinent sections of the immigration and nationality laws of the United States. See INA section 248(a); 8 U.S.C. 1258(a).

This rule is also proposed in compliance with Executive Order 13571 “Streamlining Service Delivery and Improving Customer Service.” See Executive Order No. 13571, 76 FR 24339 (Apr. 27, 2011). Executive Order 13571 tasks each Federal department and agency with establishing an initiative that uses technology to improve the experience of individuals and entities receiving services from that Federal department or agency. See Executive Order No. 13571, section 2(a).

Alternatives:
DHS has examined the alternative of maintaining paper processing for applications to extend/change status (Form I-539) and has determined that the continuation of legacy data systems and current processes do not meet the need for USCIS to modernize operations.

Anticipated Cost and Benefits:
DHS is proposing to mandate the electronic filing of stand-alone Applications to Extend/Change Nonimmigrant Status. Only a limited number of nonimmigrants would be impacted by this change. Specifically, those individuals in the following nonimmigrant classifications would be required to file this application electronically: B-1, B-2, F, M, or J. In transforming its immigration benefit processes into a paperless system, DHS anticipates the following benefits:

• Streamlined operations
• More timely submission and adjudication of the benefit requested
• Reduced requests for additional or missing information
• Enhanced security for the applicant
• Enhanced customer service

For those applicants that do not currently possess or have access to the tools needed to submit immigration benefit requests electronically—namely, computer, Internet service, and a scanner—this rule would result in additional costs to these petitioners or applicants. DHS is in the process of examining the potential monetary costs and benefits of the proposed rule.
Risks:

Populations with no or limited Internet access and individuals with no or limited English proficiency may be affected by this rule. This risk can be mitigated by including a waiver process.

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Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:

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RIN: 1615–AB94

DHS—USCIS

58. • IMMIGRATION BENEFITS BUSINESS TRANSFORMATION: NONIMMIGRANTS; STUDENT AND EXCHANGE VISITOR PROGRAM
Abstract:
The Department of Homeland Security (DHS) is amending its nonimmigrant regulations to enable U.S. Citizenship and Immigration Services (USCIS) to migrate from a paper file-based, non-integrated systems environment to an electronic, customer-focused, centralized case management environment for benefit processing. This rulemaking, the second in a series of business transformation rules, primarily focuses on 8 CFR part 214, reorganizes and streamlines general information relating to nonimmigrant classifications, and relocates other information relating to specific, individual nonimmigrant classifications to a separate subpart for each major nonimmigrant classification. DHS is making these amendments because part 214 contains more than 20 nonimmigrant classifications, and it has become very large and complex to navigate. This regulation will provide the public with simpler, better organized regulatory requirements for each nonimmigrant classification and facilitate future revisions.

Statement of Need:
USCIS is in the process of transforming its operations to improve service, operational efficiency, and national security. This rule will provide the public with clearly written, better organized regulatory requirements for each nonimmigrant classification.

Summary of Legal Basis:
This rule will significantly enhance the ability of USCIS to fully implement the Government Paperwork Elimination Act (GPEA). See Public Law 105-277, tit. XVII, section 1701 to 1710, 112 Stat. 2681 at 2681-749, (Oct. 21, 1998) (codified at 44 U.S.C. 3504 & note). GPEA provides that, when possible, Federal agencies use electronic forms, electronic filing, and electronic submissions to conduct agency business with the public. Id. The USCIS modernization and transformation effort will move its operations away from a paper-based system to an electronic environment wherever possible in an effort to implement the requirements of GPEA.

Alternatives:
The regulations for the more than 20 nonimmigrant classifications are included in 8 CFR 214. As more nonimmigrant classifications have been added to the Act and as the statutory requirements for existing classifications have become more complex, sections within 8 CFR 214 have become increasingly difficult to read, comprehend and cite. DHS will reorganize 8 CFR 214 to address this lack of clarity.

Anticipated Cost and Benefits:
DHS will amend its regulations at 8 CFR part 214 to streamline and reorganize the content into a more reader-friendly and logical format. DHS is not making substantive changes to the content or requirements of existing regulations. There are no additional costs anticipated as a result of this rulemaking.

Risks:
This rule may initially lead to confusion of those who are familiar with the previous organization of 8 CFR 214. USCIS can mitigate this risk by informing the public of these changes.

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Additional Information:

CIS# 2505-11. This rule (RIN 1615-AB95) is adopting the following three rules as final rules: 1615-AA35, 1615-AA56, and 1615-AA53.

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Email: dan.konnerth@dhs.gov

RIN: 1615–AB95

DHS—USCIS

59. • APPLICATION OF THE WILLIAM WILBERFORCE TRAFFICKING VICTIMS PROTECTION REAUTHORIZATION ACT OF 2008 TO UNACCOMPANIED ALIEN CHILDREN SEEKING ASYLUM

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

PL 110–457

CFR Citation:

Not Yet Determined
Legal Deadline:
None

Abstract:
This rule implements the provisions of the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (TVPRA), Public Law 110-457, 122 Stat. 5074 (Dec. 23, 2008) relating to unaccompanied alien children seeking asylum. Specifically, the rule proposes to amend Department of Homeland Security and Department of Justice regulations relating to asylum applications filed by unaccompanied alien children. The rule will amend both Departments’ regulations to reflect that U.S. Citizenship and Immigration Services (USCIS) has initial jurisdiction over any asylum application filed by an unaccompanied alien child. The rule will also add new special procedures for all children in interviews before USCIS officers and for unaccompanied alien children in proceedings before immigration judges in the Executive Office for Immigration Review.

Statement of Need:
The TVPRA mandated promulgation of regulations taking into account the specialized needs of unaccompanied alien children and addressing both procedural and substantive aspects of handling unaccompanied alien children's cases. This rule will codify existing agency guidance on the specialized needs of unaccompanied alien children. The rule will also codify agency guidance implementing the TVPRA. Such guidance has been in effect since March 2009 and, based on experience gained in following the guidance, will be revised in the rule.

Summary of Legal Basis:
The purpose of this rule is to comply with the TVPRA mandate to promulgate regulations taking into account the specialized needs of unaccompanied alien children and addressing both procedural and substantive aspects of handling unaccompanied alien children's cases.

Alternatives:
N/A

Anticipated Cost and Benefits:
Congress has given USCIS initial jurisdiction over the asylum claims of unaccompanied alien children. New costs can accrue when EOIR immigration judges transfer cases involving unaccompanied alien
minors to USCIS for asylum interviews and adjudication if USCIS does not grant the asylum application and the case is returned to EOIR for further adjudication. This additional cost is offset, however, when USCIS grants such an application because the costs of USCIS asylum adjudications are generally much lower than the processing of immigration court applications for that benefit. In addition, USCIS provides a non-adversarial setting for asylum seeker interviews and has recently developed extensive and ongoing training in children's issues. These factors can assist unaccompanied children in expressing their fear of return to their native countries. Unaccompanied alien children also compose a uniquely vulnerable population with often compelling protection issues; therefore, affording unaccompanied alien children every consideration in the asylum process greatly benefits them. Finally, benefits will also accrue because the regulation will improve upon the process initially implemented upon passage of the TVPRA, incorporating lessons learned and optimizing the procedures for USCIS and EOIR.

**Risks:**

N/A

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Federal

**Agency Contact:**

Ted Kim
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Department of Homeland Security
U.S. Citizenship and Immigration Services
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20 Massachusetts Avenue NW.
This proposed rule revises the requirements and procedures for the filing of motions and appeals before the Department's U.S. Citizenship and Immigration Services and its Administrative Appeals Office. The proposed changes are intended to streamline the existing processes for filing motions and appeals and will reduce delays in the review and appellate process. This rule also makes additional changes necessitated by the establishment of the Department of Homeland Security and its components.

**Statement of Need:**

This rule proposes to make numerous changes to streamline the current appeal and motion processes which: (1) Will result in cost savings to the Government, applicants, and petitioners; and (2) will provide
for a more efficient use of USCIS officer and clerical staff time, as well as more uniformity with Board of Immigration Appeals appeal and motion processes.

Summary of Legal Basis:


Alternatives:
The alternative to this rule would be to continue under the current process without change.

Anticipated Cost and Benefits:

As a result of streamlining the appeal and motion process, USCIS anticipates quantitative and qualitative benefits to DHS and the public. We also anticipate cost savings to DHS and applicants as a result of the proposed changes.

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Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

None

Additional Information:

Previously 1615-AB29 (CIS 2311-04), which was withdrawn in 2007. DHS has included this rule in its Final Plan for the Retrospective Review of Existing Regulations, which DHS issued on August 22, 2011.

Agency Contact:
61. NEW CLASSIFICATION FOR VICTIMS OF SEVERE FORMS OF TRAFFICKING IN PERSONS; ELIGIBILITY FOR T NONIMMIGRANT STATUS

Priority:
Other Significant

Legal Authority:
5 USC 552; 5 USC 552a; 8 USC 1101 to 1104; 8 USC 1182; 8 USC 1184; 8 USC 1187; 8 USC 1201; 8 USC 1224 to 1227; 8 USC 1252 to 1252a; 22 USC 7101; 22 USC 7105

CFR Citation:
8 CFR 103; 8 CFR 212; 8 CFR 214; 8 CFR 274a; 8 CFR 299

Legal Deadline:
None

Abstract:
T classification was created by 107(e) of the Victims of Trafficking and Violence Protection Act of 2000 (VTVPA), Public Law 106-386. The T nonimmigrant classification was designed for eligible victims of severe forms of trafficking in persons who aid law enforcement with their investigation or prosecution of
the traffickers, and who can establish that they would suffer extreme hardship involving unusual and severe harm if they were removed from the United States. The rule establishes application procedures and responsibilities for the Department of Homeland Security and provides guidance to the public on how to meet certain requirements to obtain T nonimmigrant status. The Trafficking Victims Protection Reauthorization Act of 2008, Public Law 110-457, made amendments to the T nonimmigrant status provisions of the Immigration and Naturalization Act. The Department will issue another interim final rule to make the changes required by recent legislation and to provide the opportunity for notice and comment.

**Statement of Need:**

T nonimmigrant status is available to eligible victims of severe forms of trafficking in persons who have complied with any reasonable request for assistance in the investigation or prosecution of acts of trafficking in persons, and who can demonstrate that they would suffer extreme hardship involving unusual and severe harm if removed from the United States. This rule addresses the essential elements that must be demonstrated for classification as a T nonimmigrant alien; the procedures to be followed by applicants to apply for T nonimmigrant status; and evidentiary guidance to assist in the application process.

**Summary of Legal Basis:**

Section 107(e) of the Trafficking Victims Protection Act (TVPA), Public Law 106-386, as amended, established the T classification to create a safe haven for certain eligible victims of severe forms of trafficking in persons, who assist law enforcement authorities in investigating and prosecuting the perpetrators of these crimes.

**Alternatives:**

To develop a comprehensive Federal approach to identifying victims of severe forms of trafficking in persons, to provide them with benefits and services, and to enhance the Department of Justice’s ability to prosecute traffickers and prevent trafficking in persons in the first place, a series of meetings with stakeholders were conducted with representatives from key Federal agencies; national, State, and local law enforcement associations; non-profit, community-based victim rights organizations; and other groups. Suggestions from these stakeholders were used in the drafting of this regulation.
Anticipated Cost and Benefits:
There is no cost to applicants associated with this regulation. Applicants for T nonimmigrant status do not pay application or biometric fees.

The anticipated benefits of these expenditures include: Assistance to trafficked victims and their families, prosecution of traffickers in persons, and the elimination of abuses caused by trafficking activities.

Benefits which may be attributed to the implementation of this rule are expected to be:

1. An increase in the number of cases brought forward for investigation and/or prosecution;
2. Heightened awareness by the law enforcement community of trafficking in persons;
3. Enhanced ability to develop and work cases in trafficking in persons cross-organizationally and multi-jurisdictionally, which may begin to influence changes in trafficking patterns.

Risks:
There is a 5,000-person limit to the number of individuals who can be granted T-1 status per fiscal year. Eligible applicants who are not granted T-1 status due solely to the numerical limit will be placed on a waiting list to be maintained by U.S. Citizenship and Immigration Services (USCIS).

To protect T-1 applicants and their families, USCIS will use various means to prevent the removal of T-1 applicants on the waiting list, and their family members who are eligible for derivative T status, including its existing authority to grant deferred action, parole, and stays of removal.

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
Federal, Local, State

Additional Information:
CIS No. 2132-01; AG Order No. 2554-2002
There is a related rulemaking, CIS No. 2170-01, the new U nonimmigrant status (RIN 1615-AA67).
Transferred from RIN 1115-AG19

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Related RIN: Related to 1615–AA67

RIN: 1615–AA59
62. ADJUSTMENT OF STATUS TO LAWFUL PERMANENT RESIDENT FOR ALIENS IN T AND U NONIMMIGRANT STATUS

Priority:
Other Significant

Legal Authority:
5 USC 552; 5 USC 552a; 8 USC 1101 to 1104; 8 USC 1182; 8 USC 1184; 8 USC 1187; 8 USC 1201; 8 USC 1224 to 1227; 8 USC 1252 to 1252a; 8 USC 1255; 22 USC 7101; 22 USC 7105

CFR Citation:
8 CFR 204; 8 CFR 214; 8 CFR 245

Legal Deadline:
None

Abstract:
This rule sets forth measures by which certain victims of severe forms of trafficking who have been granted T nonimmigrant status and victims of certain criminal activity who have been granted U nonimmigrant status may apply for adjustment to permanent resident status in accordance with Public Law 106-386, Victims of Trafficking and Violence Protection Act of 2000; and Public Law 109-162, Violence Against Women and Department of Justice Reauthorization Act of 2005. The Trafficking Victims Protection Reauthorization Act of 2008, Public Law 110-457, made amendments to the T nonimmigrant status provisions of the Immigration and Naturalization Act. The Department will issue another interim final rule to make the changes required by recent legislation and to provide the opportunity for notice and comment.

Statement of Need:
This regulation is necessary to permit aliens in lawful T or U nonimmigrant status to apply for adjustment of status to that of lawful permanent residents. T nonimmigrant status is available to aliens who are victims of a severe form of trafficking in persons and who are assisting law enforcement in the investigation or prosecution of the acts of trafficking. U nonimmigrant status is available to aliens who are victims of certain crimes and are being helpful to the investigation or prosecution of those crimes.
Summary of Legal Basis:
This rule implements the Victims of Trafficking and Violence Protection Act of 2000 (VTVPA), Public Law 106-386, 114 Stat. 1464 (Oct. 28, 2000), as amended, to permit aliens in lawful T or U nonimmigrant status to apply for adjustment of status to that of lawful permanent residents.

Alternatives:
USCIS did not consider alternatives to managing T and U applications for adjustment of status. Ease of administration dictates that adjustment of status applications from T and U nonimmigrants would be best handled on a first in, first out basis, because that is the way applications for T and U status are currently handled.

Anticipated Cost and Benefits:
USCIS uses fees to fund the cost of processing applications and associated support benefits. The fees to be collected resulting from this rule will be approximately $3 million in the first year, $1.9 million in the second year, and an average about $32 million in the third and subsequent years. To estimate the new fee collections to be generated by this rule, USCIS estimated the fees to be collected for new applications for adjustment of status from T and U nonimmigrants and their eligible family members. After that, USCIS estimated fees from associated applications that are required such as biometrics, and others that are likely to occur in direct connection with applications for adjustment, such as employment authorization or travel authorization.

The anticipated benefits of these expenditures include: Continued assistance to trafficked victims and their families, increased investigation and prosecution of traffickers in persons, and the elimination of abuses caused by trafficking activities.

Benefits that may be attributed to the implementation of this rule are expected to be:

1. An increase in the number of cases brought forward for investigation and/or prosecution;
2. Heightened awareness of trafficking-in-persons issues by the law
3. Enhanced ability to develop and work cases in trafficking in persons cross-organizationally and multi-jurisdictionally, which may begin to influence changes in trafficking patterns.

**Risks:**

Congress created the U nonimmigrant status (“U visa”) to provide immigration protection to crime victims who assist in the investigation and prosecution of those crimes. Although there are no specific data on alien crime victims, statistics maintained by the Department of Justice have shown that aliens, especially those aliens without legal status, are often reluctant to help in the investigation or prosecution of crimes. U visas are intended to help overcome this reluctance and aid law enforcement accordingly.

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, Local, State

**Additional Information:**

CIS No. 2134-01

Transferred from RIN 1115-AG21

**Agency Contact:**

Laura M. Dawkins
DHS—USCIS

63. APPLICATION OF IMMIGRATION REGULATIONS TO THE COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS

Priority:
Other Significant

Legal Authority:
PL 110–229

CFR Citation:
8 CFR 208 and 209; 8 CFR 214 and 215; 8 CFR 217; 8 CFR 235; 8 CFR 248; 8 CFR 264; 8 CFR 274a

Legal Deadline:
Final, Statutory, November 28, 2009, Consolidated Natural Resources Act (CNRA) of 2008.

Abstract:
This final rule amends the Department of Homeland Security (DHS) and the Department of Justice (DOJ) regulations to comply with the Consolidated Natural Resources Act of 2008 (CNRA). The CNRA extends the immigration laws of the United States to the Commonwealth of the Northern Mariana Islands (CNMI).
This rule finalizes the interim rule and implements conforming amendments to their respective regulations.

Statement of Need:

This rule finalizes the interim rule to conform existing regulations with the CNRA. Some of the changes implemented under the CNRA affect existing regulations governing both DHS immigration policy and procedures and proceedings before the immigration judges and the Board. Accordingly, it is necessary to make amendments both to the DHS regulations and to the DOJ regulations. The Secretary and the Attorney General are making conforming amendments to their respective regulations in this single rulemaking document.

Summary of Legal Basis:

Congress extended the immigration laws of the United States to the CNMI. The stated purpose of the CNRA is to ensure effective border control procedures, to properly address national security and homeland security concerns by extending U.S. immigration law to the CNMI (phasing-out the CNMI's nonresident contract worker program while minimizing to the greatest extent practicable the potential adverse economic and fiscal effects of that phase-out), to maximize the CNMI's potential for future economic and business growth, and to assure worker protections from the potential for abuse and exploitation.

Anticipated Cost and Benefits:

Costs: The interim rule established basic provisions necessary for the application of the INA to the CNMI and updated definitions and existing DHS and DOJ regulations in areas that were confusing or in conflict with how they are to be applied to implement the INA in the CNMI. As such, that rule made no changes that had identifiable direct or indirect economic impacts that could be quantified.

Benefits: This final rule makes additional regulatory changes in order to lessen the adverse impacts of the CNRA on employers and employees in the CNMI and assist the CNMI in its transition to the INA.

Timetable:

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Interim Final Rule Comment Period End 11/27/09
Correction 12/22/09 74 FR 67969
Final Action 03/00/12

Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Additional Information:
CIS 2460-08.

Agency Contact:
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Branch Chief, Business and Trade Services
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Fax: 202 272–1480
Email: kevin.cummings@dhs.gov

Related RIN: Related to 1615–AB76, Related to 1615–AB75

RIN: 1615–AB77
The International Maritime Organization (IMO) comprehensively amended the International Convention on Standards of Training, Certification, and Watchkeeping (STCW) for Seafarers, 1978, in 1995 and 2010. The 1995 amendments came into force on February 1, 1997. This project implements those amendments by revising current rules to ensure that the United States complies with their requirements on: The training of merchant mariners, the documenting of their qualifications, and watch-standing and other arrangements aboard seagoing merchant ships of the United States. In addition, the Coast Guard has identified the need for additional changes to the interim rule issued in 1997. This project supports the Coast Guard's broad role and responsibility of maritime safety. It also supports the roles and responsibilities of the Coast Guard of reducing deaths and injuries of crew members on domestic merchant vessels and eliminating substandard vessels from the navigable waters of the United States. The Coast Guard published an NPRM on November 17, 2009, and Supplemental NPRM (SNPRM) on March 23, 2010.

At a June 2010 diplomatic conference, the IMO adopted additional amendments to the STCW convention which change the minimum training requirements for seafarers. In response to feedback and to the
adoption of those amendments, the Coast Guard developed a second Supplemental NPRM to incorporate the 2010 Amendments into the 1990 interim rule.

**Statement of Need:**

The Coast Guard proposed to amend its regulations to implement changes to its interim rule published on June 26, 1997. These proposed amendments go beyond changes found in the interim rule and seek to more fully incorporate the requirements of the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended (STCW), in the requirements for the credentialing of United States merchant mariners. The new changes are primarily substantive and: (1) Are necessary to continue to give full and complete effect to the STCW Convention; (2) Incorporate lessons learned from implementation of the STCW through the interim rule and through policy letters and NVICs; and (3) Attempt to clarify regulations that have generated confusion.

**Summary of Legal Basis:**

The authority for the Coast Guard to prescribe, change, revise, or amend these regulations is provided under 46 U.S.C. 2103 and 46 U.S.C. chapters 71 and 73; and Department of Homeland Security Delegation No. 0170.1.

**Alternatives:**

For each proposed change, the Coast Guard has considered various alternatives. We considered using policy statements, but they are not enforceable. We also considered taking no action, but this does not support the Coast Guard's fundamental safety and security mission. Additionally, we considered comments made during our 1997 rulemaking to formulate our alternatives. When we analyzed issues, such as license progression and tonnage equivalency, the alternatives chosen were those that most closely met the requirements of STCW.

**Anticipated Cost and Benefits:**

In the SNPRM, we estimated the annualized cost of this rule over a 10-year period to be $32.8 million per year at a 7 percent discount rate. We estimate the total 10-year cost of this rulemaking to be $230.7 million at a 7 percent discount rate and $274.3 million at a 3 percent discount rate.
The changes in anticipated costs since the publication of 2009 NPRM are due to the 2010 amendments to the STCW Convention: Medical examinations and endorsements, leadership and management skills, engine room management training, tankerman endorsements, safety refresher training and able seafarer deck and engine certification requirements. However, there would be potential savings from the costs of training requirements as the Coast Guard would accept various methods for demonstrating competence, including the on-the-job training and preservation of the “hawsepipe” programs.

We anticipate the primary benefit of this rulemaking is to ensure that the U.S. meets its obligations under the STCW Convention. Another benefit is an increase in vessel safety and a resulting decrease in the risk of shipping casualties.

**Risks:**

No risks.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Yes

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
None

**International Impacts:**
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Additional Information:**
The docket number for this rulemaking is USCG-2004-17914. The docket is located at www.regulations.gov. The old docket number is CGD 95-062.

Include Retrospective Review under E.O. 13563.

**URL For More Information:**
www.regulations.gov

**URL For Public Comments:**
www.regulations.gov

**Agency Contact:**
Mark Gould
Project Manager, CG–5221
Department of Homeland Security
U.S. Coast Guard
2100 Second Street SW., STOP 7126
65. VESSEL REQUIREMENTS FOR NOTICES OF ARRIVAL AND DEPARTURE, AND AUTOMATIC IDENTIFICATION SYSTEM

Priority: Other Significant

Legal Authority:
33 USC 1223; 33 USC 1225; 33 USC 1231; 46 USC 3716; 46 USC 8502 and ch 701; sec 102 of PL 107–295; EO 1223

CFR Citation:
33 CFR 62; 33 CFR 66; 33 CFR 160; 33 CFR 161; 33 CFR 164; 33 CFR 165

Legal Deadline:
None

Abstract:
This rulemaking would expand the applicability for Notice of Arrival and Departure (NOAD) and Automatic Identification System (AIS) requirements. These expanded requirements would better enable the Coast Guard to correlate vessel AIS data with NOAD data, enhance our ability to identify and track vessels, detect anomalies, improve navigation safety, and heighten our overall maritime domain awareness.

The NOAD portion of this rulemaking could expand the applicability of the NOAD regulations by changing the minimum size of vessels covered below the current 300 gross tons, require a notice of departure when a vessel is departing for a foreign port or place, and mandate electronic submission of NOAD notices to the National Vessel Movement Center. The AIS portion of this rulemaking would expand
current AIS carriage requirements for the population identified in the Safety of Life at Sea (SOLAS) Convention and the Marine Transportation Marine Transportation Security Act (MTSA) of 2002.

Statement of Need:
There is no central mechanism in place to capture vessel, crew, passenger, or specific cargo information on vessels less than or equal to 300 gross tons (GT) intending to arrive at or depart from U.S. ports unless they are arriving with certain dangerous cargo (CDC) or at a port in the 7th Coast Guard District; nor is there a requirement for vessels to submit notification of departure information. The lack of NOAD information of this large and diverse population of vessels represents a substantial gap in our maritime domain awareness (MDA). We can minimize this gap and enhance MDA by expanding NOAD applicability to vessels greater than 300 GT, all foreign commercial vessels and all U.S. commercial vessels coming from a foreign port, and further enhance (and corroborate) MDA by tracking those vessels (and others) with AIS. This information is necessary in order to expand our MDA and provide Nation maritime safety and security.

Summary of Legal Basis:
This rulemaking is based on congressional authority provided in the Ports and Waterways Safety Act and the Maritime Transportation Security Act of 2002.

Alternatives:
Our goal is to extend our MDA and to identify anomalies by correlating vessel NOAD data with AIS data. NOAD and AIS information from a greater number of vessels, as proposed in this rulemaking, would expand our MDA. We considered expanding NOAD and AIS to even more vessels, but we determined we needed additional legislative authority to expand AIS beyond what we propose in this rulemaking; and that it was best to combine additional NOAD expansion with future AIS expansion. Although not in conjunction with a proposed rule, the Coast Guard sought comment regarding expansion of AIS carriage to other waters and other vessels not subject to the current requirements (68 FR 39369, Jul. 1, 2003; USCG 2003-14878; see also 68 FR 39355). Those comments were reviewed and considered in drafting this rule and are available in this docket. To fulfill our agency obligations, the Coast Guard needs to receive AIS reports and NOADs from vessels identified in this rulemaking that currently are not required to provide this information. Policy or other non-binding statements by the Coast Guard addressed to the
owners of these vessels would not produce the information required to sufficiently enhance our MDA to produce the information required to fulfill our Agency obligations.

**Anticipated Cost and Benefits:**

This rulemaking will enhance the Coast Guard's regulatory program by making it more effective in achieving the regulatory objectives, which, in this case, is improved MDA. We provide flexibility in the type of AIS system that can be used, allowing for reduced cost burden. This rule is also streamlined to correspond with Customs and Border Protection's APIS requirements, thereby reducing unjustified burdens. We are further developing estimates of cost and benefit that were published in 2008. In the 2008 NPRM, we estimated that both segments of the proposed rule would affect approximately 42,607 vessels. The total number of domestic vessels affected is approximately 17,323 and the total number of foreign vessels affected is approximately 25,284. We estimated that the 10-year total present discounted value or cost of the proposed rule to U.S. vessel owners is between $132.2 and $163.7 million (7 and 3 percent discount rates, respectively, 2006 dollars) over the period of analysis.

The Coast Guard believes that this rule, through a combination of NOAD and AIS, would strengthen and enhance maritime security. The combination of NOAD and AIS would create a synergistic effect between the two requirements. Ancillary or secondary benefits exist in the form of avoided injuries, fatalities, and barrels of oil not spilled into the marine environment. In the 2008 NPRM, we estimated that the total discounted benefit (injuries and fatalities) derived from 68 marine casualty cases analyzed over an 8-year data period from 1996 to 2003 for the AIS portion of the proposed rule is between $24.7 and $30.6 million using $6.3 million for the value of statistical life (VSL) at seven and three percent discount rates, respectively. Just based on barrels of oil not spilled, we expect the AIS portion of the proposed rule to prevent 22 barrels of oil from being spilled annually.

**Risks:**

Considering the economic utility of U.S. ports, waterways, and coastal approaches, it is clear that a terrorist incident against our U.S. Maritime Transportation System (MTS) would have a direct impact on U.S. users and consumers and could potentially have a disastrous impact on global shipping, international trade, and the world economy. By improving the ability of the Coast Guard both to identify
potential terrorists coming to the United States while the terrorists are far from our shores and to coordinate appropriate responses and intercepts before the vessel reaches a U.S. port, this rulemaking would contribute significantly to the expansion of MDA, and consequently is instrumental in addressing the threat posed by terrorist actions against the MTS.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Additional Information:**

We have indicated in past notices and rulemaking documents, and it remains the case that we have worked to coordinate implementation of AIS MTSA requirements with the development of our ability to take advantage of AIS data (68 FR 39355 and 39370, Jul. 1, 2003).

The docket number for this rulemaking is USCG-2005-21869. The docket can be found at www.regulations.gov.

**URL For More Information:**
66. NONTANK VESSEL RESPONSE PLANS AND OTHER VESSEL RESPONSE PLAN REQUIREMENTS

Priority:
Other Significant

**Unfunded Mandates:**
Undetermined

**Legal Authority:**
3 USC 301 to 303; 33 USC 1223; 33 USC 1231; 33 USC 3121; 33 USC 1903; 33 USC 1908; 46 USC 6101

**CFR Citation:**
33 CFR 151; 33 CFR 155; 33 CFR 160

**Legal Deadline:**

**Abstract:**
This rulemaking would establish regulations requiring owners or operators of nontank vessels to prepare and submit oil spill response plans. The Federal Water Pollution Control Act defines nontank vessels as self-propelled vessels of 400 gross tons or greater that operate on the navigable waters of the United States, carry oil of any kind as fuel for main propulsion, and are not tank vessels. The NPRM proposed to specify the content of a response plan, and among other issues, address the requirement to plan for responding to a worst-case discharge and a substantial threat of such a discharge. Additionally, the NPRM proposed to update International Shipboard Oil Pollution Emergency Plan (SOPEP) requirements that apply to certain nontank vessels and tank vessels. Finally, the NPRM proposed to require vessel owners and operators to submit their vessel response plan control number as part of the notice of arrival information. This project supports the Coast Guard's broad roles and responsibilities of maritime stewardship.

**Statement of Need:**
This rule implements the statutory requirement for an owner or operator of a self-propelled, nontank vessel of 400 gross tons or greater, which operates on the navigable waters of the United States, to prepare and submit an oil spill response plan to the Coast Guard. This rule specifies the content of a vessel response plan (VRP), including the requirement to plan for responding to a worst-case discharge (WCD) and a substantial threat of such a discharge as mandated in statute. The rule also specifies the
procedures for submitting a VRP to the Coast Guard. This rule will improve our Nation’s pollution response planning and preparedness posture, and help limit the environmental damage resulting from nontank vessel marine casualties.

**Summary of Legal Basis:**

Section 311(j)(5) of the Federal Water Pollution Control Act (FWPCA) (33 U.S.C. 1321(j)(5)), as amended by section 4202 of the Oil Pollution Act of 1990 (OPA 90) (Pub. L. 101-380, 104 Stat 484); the Coast Guard and Maritime Transportation Act of 2004 (Pub. L. 108-293, 118 Stat. 102); and the Coast Guard and Maritime Transportation Act of 2006 (Pub. L. 109-241, 120 Stat. 516) sets out the statutory mandate requiring tank and nontank vessel owners or operators to prepare and submit oil or hazardous substance discharge response plans for certain vessels operating on the navigable waters of the United States.

**Alternatives:**

In the development of these regulations, the Coast Guard considered four alternatives: Three regulatory alternatives and one non-regulatory alternative. The alternatives are—(1) Establish regulations for the submission of NTVRPs to the USCG; (2) amend the tank vessel response plan (TVRP) regulations to incorporate NTVRPs; (3) acceptance of flag-approved SOPEPs; and (4) provide interpretive guidance through a USCG's Navigation and Vessel Inspection Circular (NVIC).

**Anticipated Cost and Benefits:**

We are developing the cost and benefit estimates associated with this step of the rulemaking. The cost elements associated with this rule include: (1) Nontank vessel plan development, maintenance, and submission; (2) the service of an Oil Spill Response Organization (OSRO); (3) the contract with a Qualified Individual (QI) along with a Spill Management Team; and (4) training and exercises. We expect this proposed rule to provide quantifiable benefits in the form of barrels of oil not spilled into the water in addition to qualitative benefits, which include improved preparedness and reaction to an incident, including a worst-case discharge and improved effectiveness of onboard and shore-side response activities.

In the 2009 NPRM, we estimated that the rulemaking would affect about 2,951 U.S. flag vessels and 1,228 associated planholders. We estimated the total 10-year present value cost of the proposed rule to
U.S. flag nontank vessel owners and operators to be about $111.4 million at a 7 percent discount rate and $134.8 million at a 3 percent discount rate. We found the training and exercise requirements to be the most costly element or over 90 percent of the total discounted cost of the proposed rule for vessel owners. We estimated the total U.S. annualized cost of the proposed rule over the 10-year period of analysis to be about $15.8 million at both 7 and 3 percent discount rates.

**Risks:**

Response plans are required by statute. A response plan will not prevent a discharge of oil, but it may help minimize the discharge and resulting damage to the environment. We estimate the proposed rule would prevent between 2,014 and 2,446 barrels of oil from being spilled into the water during the 10-year period of analysis.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Additional Information:**

The docket number for this rulemaking is USCG-2008-1070. The docket can be found at www.regulations.gov.

**URL For More Information:**

www.regulations.gov

**URL For Public Comments:**
DHS—USCG

67. OFFSHORE SUPPLY VESSELS OF AT LEAST 6000 GT ITC

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
PL 111–281, sec 617

CFR Citation:
Not Yet Determined

Legal Deadline:

Abstract:
The Coast Guard Authorization Act of 2010 removed the size limit on offshore supply vessels (OSVs). The Act also directed the Coast Guard to issue, as soon as is practicable, a regulation to implement section 617 of the Act and to ensure the safe carriage of oil, hazardous substances, and individuals in
addition to the crew on vessels of at least 6,000 gross tonnage as measured under the International Convention on Tonnage Measurement of Ships (6,000 GT ITC). Accordingly, the Coast Guard's rule will address design, manning, carriage of personnel, and related topics for OSVs of at least 6,000 GT ITC. This rulemaking will meet the requirements of the Act and will support the Coast Guard's mission of marine safety, security, and stewardship.

Statement of Need:
In section 617 of Public Law 111-281, Congress removed OSV tonnage limits and instructed the Coast Guard to promulgate regulations to implement the amendments and authorities of section 617. Additionally, Congress directed the Coast Guard to ensure the safe carriage of oil, hazardous substances, and individuals in addition to the crew on OSVs of at least 6,000 GT ITC.

Summary of Legal Basis:
The statutory authority to promulgate these regulations is found in section 617(f) of Public Law 111-281.

Alternatives:
The Coast Guard Authorization Act removed OSV tonnage limits and the Coast Guard will examine alternatives during the development of the regulatory analysis.

Anticipated Cost and Benefits:
The Coast Guard is currently developing a regulatory impact analysis of regulations that ensure the safe carriage of oil, hazardous substances, and individuals in addition to the crew on OSVs of at least 6,000 GT ITC. A potential benefit of this rulemaking is the ability of industry to expand and take advantage of new commercial opportunities in the building of larger OSVs.

Risks:
No risks.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Government Levels Affected:
DHS—USCG

68. • REVISION TO TRANSPORTATION WORKER IDENTIFICATION CREDENTIAL (TWIC) REQUIREMENTS FOR MARINERS

Priority:
Other Significant

Legal Authority:
sec 809 of the Coast Guard Authorization Act of 2010, PL 111–281, codified at 46 USC 70105(b)(2); 46 USC 2110(g)

CFR Citation:
46 CFR 10; 46 CFR 11; 46 CFR 12; 46 CFR 15

Legal Deadline:
Abstract:

This Policy Letter describes both short-term and long-term steps that the Coast Guard is taking to implement the requirements of section 809 of Coast Guard Authorization Act of 2010, Public Law 111-281. Section 809 excludes certain mariners from the statutory requirement to obtain and hold a Transportation Worker Identification Credential (TWIC) in order to receive a Merchant Mariner Credential (MMC).

In the short-term, while working to promulgate implementing regulations, the Coast Guard is relaxing its enforcement posture for mariners without a valid TWIC who operate on board vessels that do not have a security plan. The Coast Guard is also altering its policies to allow these mariners to obtain a MMC without holding a valid TWIC. Specifically, mariners already hold or held a TWIC, and who no longer require a TWIC, may skip the TWIC enrollment process and apply for a renewal MMC directly with a Regional Examination Center (REC), in accordance with title 46 CFR, section 10.209. However, mariners that are being issued an initial MMC, or who never held a TWIC, will need to enroll for a TWIC at a TWIC enrollment center. They will also have to pay all applicable fees associated with getting a TWIC. This is required because the TWIC enrollment center is the only place where the Coast Guard can obtain biometric information (fingerprints) from the applicant.

In the long-term, as part of a rulemaking to promulgate implementing regulations, the Coast Guard is considering waiving a portion of the fees for a MMC in order to compensate the mariner for the cost of enrolling for a TWIC. However, it is emphasized that such action is contingent on the promulgation of a regulation to adjust the fee structure.

Statement of Need:

The Coast Guard is revising its merchant mariner credentialing regulations to implement changes made by section 809 of the Coast Guard Authorization Act of 2010, codified at 46 U.S.C. 70105(b)(2), which reduces the population of mariners who are required to obtain and hold a valid Transportation Worker Identification Credential (TWIC). Prior to section 809, 46 U.S.C. 70105(b)(2) required each mariner
required to hold an MMC issued by the Coast Guard to also obtain and hold a valid TWIC issued by the Transportation Security Administration (TSA). Section 809 removes this requirement, and now a TWIC is statutorily required if the mariner is “allowed unescorted access to a secure area designated in a vessel security plan approved under section 70103 of title 46 [U.S.C.]”

The Coast Guard is revising the applicability of the TWIC requirements in Coast Guard merchant mariner credentialing regulations as well as revising some of its merchant mariner credentialing processes contained in Coast Guard regulations. Current Coast Guard regulations in 46 CFR parts 10, 11, 12, and 15 contain the processes for issuing an MMC that are intertwined with TSA processes for issuing a TWIC. The Coast Guard utilizes the TWIC enrollment process to capture information necessary to issue an MMC. Although the Coast Guard is changing some of its processes for obtaining an MMC, some mariners no longer required to hold a TWIC may still have to complete the TWIC enrollment process in order to provide information necessary to obtain an MMC. For any such mariner that must still go through the TWIC enrollment process, including paying the full TWIC enrollment fee, the Coast Guard is revising its regulations to exempt these mariners from paying a portion of the MMC fees in order to offset the TWIC fee and to minimize the burden on those mariners of paying for a TWIC when the mariner is no longer statutorily required to hold one.

**Summary of Legal Basis:**

The Coast Guard's statutory authority to promulgate regulations addressing TWIC requirements for mariners is found in 46 U.S.C. 70105(a) and (b). The Coast Guard's statutory authority to promulgate regulations addressing fee exemptions is found in 46 U.S.C. 2110(g).

**Alternatives:**

This rulemaking implements section 809 of the 2010 Coast Guard Authorization Act. The Coast Guard is currently evaluating the alternatives as we complete the Regulatory Impact Analysis.

**Anticipated Cost and Benefits:**

This rulemaking would provide certain mariner populations a fee exemption when applying or renewing an MMC. These mariner populations would also benefit from cost savings associated with reduced travels to TWIC enrollment centers.
Risks:
No risks.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
Federal

Additional Information:
DHS has included this rule in its Final Plan for the Retrospective Review of Existing Regulations, which DHS issued on August 22, 2011.

Agency Contact:
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U.S. Coast Guard
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RIN: 1625–AB80
69. IMPORTER SECURITY FILING AND ADDITIONAL CARRIER REQUIREMENTS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
PL 109–347, sec 203; 5 USC 301; 19 USC 66; 19 USC 1431; 19 USC 1433 to 1434; 19 USC 1624; 19 USC 2071 note; 46 USC 60105

CFR Citation:
19 CFR 4; 19 CFR 12.3; 19 CFR 18.5; 19 CFR 103.31a; 19 CFR 113; 19 CFR 123.92; 19 CFR 141.113;
19 CFR 146.32; 19 CFR 149; 19 CFR 192.14

Legal Deadline:
None

Abstract:
This interim final rule implements the provisions of section 203 of the Security and Accountability for Every Port Act of 2006. It amended CBP Regulations to require carriers and importers to provide to CBP, via a CBP-approved electronic data interchange system, information necessary to enable CBP to identify high-risk shipments to prevent smuggling and insure cargo safety and security. Under the rule, importers and carriers must submit specified information to CBP before the cargo is brought into the United States by vessel. This advance information will improve CBP’s risk assessment and targeting capabilities, assist CBP in increasing the security of the global trading system, and facilitate the prompt release of legitimate cargo following its arrival in the United States. The interim final rule requested comments on those required data elements for which CBP provided certain flexibilities for compliance and on the revised costs and benefits and Regulatory Flexibility Analysis. CBP plans to issue a final rule after CBP completes a structured review of the flexibilities and analyzes the comments.

Statement of Need:
Vessel carriers are currently required to transmit certain manifest information by way of the CBP Vessel Automated Manifest System (AMS) 24 hours prior to lading of containerized and non-exempt break bulk cargo at a foreign port. For the most part, this is the ocean carrier's or non-vessel operating common carrier's (NVOCC) cargo declaration. CBP analyzes this information to generate its risk assessment for targeting purposes.

Internal and external government reviews have concluded that more complete advance shipment data would produce even more effective and vigorous cargo risk assessments. In addition, pursuant to section 203 of the Security and Accountability for Every Port Act of 2006 (Pub. L. 109-347, 6 U.S.C. 943) (SAFE Port Act), the Secretary of Homeland Security, acting through the Commissioner of CBP, must promulgate regulations to require the electronic transmission of additional data elements for improved high-risk targeting, including appropriate security elements of entry data for cargo destined to the United States by vessel prior to loading of such cargo on vessels at foreign seaports.

Based upon its analysis, as well as the requirements under the SAFE Port Act, CBP is requiring the electronic transmission of additional data for improved high-risk targeting. Some of these data elements are being required from carriers (Container Status Messages and Vessel Stow Plan) and others are being required from “importers,” as that term is defined for purposes of the regulations.

This rule intends to improve CBP's risk assessment and targeting capabilities and enables the agency to facilitate the prompt release of legitimate cargo following its arrival in the United States. The information will assist CBP in increasing the security of the global trading system and, thereby, reducing the threat to the United States and world economy.

**Summary of Legal Basis:**

Pursuant to section 203 of the Security and Accountability for Every Port Act of 2006 (Pub. L. 109-347, 6 U.S.C. 943) (SAFE Port Act), the Secretary of Homeland Security, acting through the Commissioner of CBP, must promulgate regulations to require the electronic transmission of additional data elements for
improved high-risk targeting, including appropriate security elements of entry data for cargo destined to the United States by vessel prior to loading of such cargo on vessels at foreign seaports.

**Alternatives:**

CBP considered and evaluated the following four alternatives:

Alternative 1 (the chosen alternative): Importer Security Filings and Additional Carrier Requirements are required. Bulk cargo is exempt from the Importer Security Filing requirements;

Alternative 2: Importer Security Filings and Additional Carrier Requirements are required. Bulk cargo is not exempt from the Importer Security Filing requirements;

Alternative 3: Only Importer Security Filings are required. Bulk cargo is exempt from the Importer Security Filing requirements; and

Alternative 4: Only the Additional Carrier Requirements are required.

**Anticipated Cost and Benefits:**

When the NPRM was published, CBP estimated that approximately 11 million import shipments conveyed by 1,000 different carrier companies operating 37,000 unique voyages or vessel-trips to the United States will be subject to the rule. Annualized costs range from $890 million to $7.0 billion (7 percent discount rate over 10 years).

The annualized cost range estimate resulted from varying assumptions about the importers' estimated security filing transaction costs or fees charged to the importers by the filing parties, the potential for supply chain delays, and the estimated costs to carriers for transmitting additional data to CBP.

The regulation may increase the time shipments are in transit, particularly for shipments consolidated in containers. For such shipments, the supply chain is generally more complex and the importer has less control of the flow of goods and associated security filing information. Foreign cargo consolidators may be
consolidating multiple shipments from one or more shippers in a container destined for one or more buyers or consignees. In order to ensure that the security filing data is provided by the shippers to the importers (or their designated agents) and is then transmitted to and accepted by CBP in advance of the 24-hour deadline, consolidators may advance their cut-off times for receipt of shipments and associated security filing data.

These advanced cut-off times would help prevent a consolidator or carrier from having to unpack or unload a container in the event the security filing for one of the shipments contained in the container is inadequate or not accepted by CBP. For example, consolidators may require shippers to submit, transmit, or obtain CBP approval of their security filing data before their shipments are stuffed in the container, before the container is sealed, or before the container is delivered to the port for lading. In such cases, importers would likely have to increase the times they hold their goods as inventory, and thus incur additional inventory carrying costs to sufficiently meet these advanced cut-off times imposed by their foreign consolidators. The high end of the cost ranges presented assumes an initial supply chain delay of 2 days for the first year of implementation (2008) and a delay of 1 day for years 2 through 10 (2009 to 2017).

Ideally, the quantification and monetization of the benefits of this regulation would involve estimating the current level of risk of a successful terrorist attack, absent this regulation, and the incremental reduction in risk resulting from implementation of the regulation. CBP would then multiply the change by an estimate of the value individuals place on such a risk reduction to produce a monetary estimate of direct benefits. However, existing data limitations and a lack of complete understanding of the true risks posed by terrorists prevent us from establishing the incremental risk reduction attributable to this rule. As a result, CBP has undertaken a “break-even” analysis to inform decisionmakers of the necessary incremental change in the probability of such an event occurring that would result in direct benefits equal to the costs of the proposed rule. CBP's analysis finds that the incremental costs of this regulation are relatively small compared to the median value of a shipment of goods, despite the rather large absolute estimate of present value cost.
The benefit of this rule is the improvement of CBP's risk assessment and targeting capabilities, while at the same time, enabling CBP to facilitate the prompt release of legitimate cargo following its arrival in the United States. The information will assist CBP in increasing the security of the global trading system, and thereby reducing the threat to the United States and the world economy.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**International Impacts:**

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
DHS—USCBP

70. CHANGES TO THE VISA WAIVER PROGRAM TO IMPLEMENT THE ELECTRONIC SYSTEM FOR TRAVEL AUTHORIZATION (ESTA) PROGRAM

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
8 USC 1103; 8 USC 1187

CFR Citation:
8 CFR 217.5

Legal Deadline:
None

Abstract:
This interim final rule implements the Electronic System for Travel Authorization (ESTA) for aliens who travel to the United States under the Visa Waiver Program (VWP) at air or sea ports of entry. Under the rule, VWP travelers are required to provide certain biographical information to CBP electronically before departing for the United States. This allows CBP to determine before their departure whether these travelers are eligible to travel to the United States under the VWP and whether such travel poses a security risk. The rule is intended to fulfill the requirements of section 711 of the Implementing recommendations of the 9/11 Commission Act of 2007 (9/11 Act). In addition to fulfilling a statutory mandate, the rule serves the twin goals of promoting border security and legitimate travel to the United States. By modernizing the VWP, the ESTA is intended to increase national security and to provide for greater efficiencies in the screening of international travelers by allowing for vetting of subjects of potential interest well before boarding, thereby reducing traveler delays at the ports of entry. CBP requested comments on all aspects of the interim final rule and plans to issue a final rule after completion of the comment analysis.

**Statement of Need:**

Section 711 of the 9/11 Act requires the Secretary of Homeland Security, in consultation with the Secretary of State, to develop and implement a fully automated electronic travel authorization system that will collect biographical and other information in advance of travel to determine the eligibility of the alien to travel to the United States, and to determine whether such travel poses a law enforcement or security risk. ESTA is intended to fulfill these statutory requirements.

Under this rule, VWP travelers provide certain information to CBP electronically before departing for the United States. VWP travelers who receive travel authorization under ESTA are not required to complete the paper Form I-94W when arriving on a carrier that is capable of receiving and validating messages pertaining to the traveler's ESTA status as part of the traveler's boarding status. By automating the I-94W process and establishing a system to provide VWP traveler data in advance of travel, CBP is able to determine the eligibility of citizens and eligible nationals from VWP countries to travel to the United States and to determine whether such travel poses a law enforcement or security risk, before such individuals begin travel to the United States. ESTA provides for greater efficiencies in the screening of international
travelers by allowing CBP to identify subjects of potential interest before they depart for the United States, thereby increasing security and reducing traveler delays upon arrival at U.S. ports of entry.

**Summary of Legal Basis:**

The ESTA program is based on congressional authority provided under section 711 of the Implementing Recommendations of the 9/11 Commission Act of 2007 and section 217 of the Immigration and Nationality Act (INA).

**Alternatives:**

CBP considered three alternatives to this rule:

1. The ESTA requirements in the rule, but with a $1.50 fee per each travel authorization (more costly)

2. The ESTA requirements in the rule, but with only the name of the passenger and the admissibility questions on the I-94W form (less burdensome)

3. The ESTA requirements in the rule, but only for the countries entering the VWP after 2009 (no new requirements for VWP, reduced burden for newly entering countries).

CBP determined that the rule provides the greatest level of enhanced security and efficiency at an acceptable cost to traveling public and potentially affected air carriers.

**Anticipated Cost and Benefits:**

The purpose of ESTA is to allow DHS and CBP to establish the eligibility of certain foreign travelers to travel to the United States under the VWP, and whether the alien's proposed travel to the United States poses a law enforcement or security risk. Upon review of such information, DHS will determine whether the alien is eligible to travel to the United States under the VWP.

Costs to Air & Sea Carriers
CBP estimated that eight U.S.-based air carriers and eleven sea carriers will be affected by the rule. An additional 35 foreign-based air carriers and five sea carriers will be affected. CBP concluded that costs to air and sea carriers to support the requirements of the ESTA program could cost $137 million to $1.1 billion over the next 10 years depending on the level of effort required to integrate their systems with ESTA, how many passengers they need to assist in applying for travel authorizations, and the discount rate applied to annual costs.

Costs to Travelers

ESTA will present new costs and burdens to travelers in VWP countries who were not previously required to submit any information to the U.S. Government in advance of travel to the United States. Travelers from Roadmap countries who become VWP countries will also incur costs and burdens, though these are much less than obtaining a nonimmigrant visa (category B1/B2), which is currently required for short-term pleasure or business to travel to the United States. CBP estimated that the total quantified costs to travelers will range from $1.1 billion to $3.5 billion depending on the number of travelers, the value of time, and the discount rate. Annualized costs are estimated to range from $133 million to $366 million.

Benefits

As set forth in section 711 of the 9/11 Act, it was the intent of Congress to modernize and strengthen the security of the Visa Waiver Program under section 217 of the Immigration and Nationality Act (INA, 8 U.S.C. 1187) by simultaneously enhancing program security requirements and extending visa-free travel privileges to citizens and eligible nationals of eligible foreign countries that are partners in the war on terrorism.

By requiring passenger data in advance of travel, CBP may be able to determine, before the alien departs for the United States, the eligibility of citizens and eligible nationals from VWP countries to travel to the United States under the VWP, and whether such travel poses a law enforcement or security risk. In addition to fulfilling a statutory mandate, the rule serves the twin goals of promoting border security and
legitimate travel to the United States. By modernizing the VWP, ESTA is intended to both increase national security and provide for greater efficiencies in the screening of international travelers by allowing for the screening of subjects of potential interest well before boarding, thereby reducing traveler delays based on potentially lengthy processes at U.S. ports of entry.

CBP concluded that the total benefits to travelers could total $1.1 billion to $3.3 billion over the period of analysis. Annualized benefits could range from $134 million to $345 million.

In addition to these benefits to travelers, CBP and the carriers should also experience the benefit of not having to administer the I-94W except in limited situations. While CBP has not conducted an analysis of the potential savings, it should accrue benefits from not having to produce, ship, and store blank forms. CBP should also be able to accrue savings related to data entry and archiving. Carriers should realize some savings as well, though carriers will still have to administer the I-94 for those passengers not traveling under the VWP and the Customs Declaration forms for all passengers aboard the aircraft and vessel.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Government Levels Affected:**

None
International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Additional Information:
http://www.cbp.gov/xp/cgov/travel/id_visa/esta/

URL For More Information:
www.regulations.gov

URL For Public Comments:
www.regulations.gov

Agency Contact:
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Related RIN: Related to 1651–AA83

RIN: 1651–AA72
Abstract:

CBP already operates several regulatory and non-regulatory international registered traveler programs, also known as trusted traveler programs. In order to comply with the Intelligence Reform Terrorism Prevention Act of 2004 (IRTPA), CBP is proposing to amend its regulations to establish another international registered traveler program called Global Entry. The Global Entry program would expedite the movement of low-risk, frequent international air travelers by providing an expedited inspection process for pre-approved, pre-screened travelers. These travelers would proceed directly to automated Global Entry kiosks upon their arrival in the United States. This Global Entry Program, along with the other programs that have already been established, are consistent with CBP’s strategic goal of facilitating legitimate trade and travel while securing the homeland. A pilot of Global Entry has been operating since June 6, 2008.

Statement of Need:

CBP has been operating the Global Entry program as a pilot at several airports since June 6, 2008, and the pilot has been very successful. As a result, there is a desire on the part of the public that CBP establish the program as a permanent program, and expanded the program to additional airports and to citizens from other countries if possible. By establishing this program, CBP will make great strides toward facilitating the movement of people in a more efficient manner, thereby accomplishing our strategic goal of balancing legitimate travel with security. Through the use of biometric and recordkeeping technologies, the risk of terrorists entering the United States would be reduced. Improving security and facilitating travel at the border, both of which are accomplished by Global Entry, are primary concerns within CBP jurisdiction.

Summary of Legal Basis:

The Global Entry program is based on section 7208(k) of the Intelligence Reform and Terrorism Prevention Act of 2004 (IRTPA), as amended by section 565 of the Consolidated Appropriations Act,
which requires the Secretary of Homeland Security to create a program to expedite the screening and processing of pre-approved low risk air travelers into the United States.

**Anticipated Cost and Benefits:**

Global Entry is a voluntary program that provides a benefit to the public by speeding the CBP processing time for participating travelers. Travelers who are otherwise admissible to the United States will be able to enter or exit the country regardless of whether they participate in Global Entry. CBP estimates that over a 5-year period, 250,000 enrollees will be processed (an annual average of 50,000 individuals). CBP estimates that each application will require 40 minutes (0.67 hours) of the enrollee's time to search existing data resources, gather the data needed, and complete and review the application form. Additionally, an enrollee will experience an “opportunity cost of time” to travel to an Enrollment Center upon acceptance of the initial application. We assume that 1 hour will be required for this time spent at the Enrollment Center and travel to and from the Center, though we note that during the pilot program, many applicants coordinated their trip to an Enrollment Center with their travel at the airport. CBP has used 1 hour of travel time so as not to underestimate potential opportunity costs for enrolling in the program. CBP used a value of $28.60 for the opportunity cost for this time, which is taken from the Federal Aviation Administration's “Economic Values for FAA Investment and Regulatory Decisions, A Guide.” (Jul. 3, 2007) This value is the weighted average for U.S. business and leisure travelers. For this evaluation, CBP assumed that all enrollees will be U.S. citizens, U.S. nationals, or Lawful Permanent Residents.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No
Government Levels Affected:
None

Additional Information:
Includes Retrospective Review under E.O. 13563.

URL For More Information:
www.globalentry.gov

Agency Contact:
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Email: john.p.wagner@cbp.dhs.gov
RIN: 1651–AA73

72. IMPLEMENTATION OF THE GUAM–CNMI VISA WAIVER PROGRAM

Priority:
Other Significant. Major under 5 USC 801.

Legal Authority:
PL 110–229, sec 702

CFR Citation:
8 CFR 100.4; 8 CFR 212.1; 8 CFR 233.5; 8 CFR 235.5; 19 CFR 4.7b; 19 CFR 122.49a

Legal Deadline:
Abstract:
This rule amends Department of Homeland Security (DHS) regulations to implement section 702 of the Consolidated Natural Resources Act of 2008 (CNRA). This law extends the immigration laws of the United States to the Commonwealth of the Northern Mariana Islands (CNMI) and provides for a joint visa waiver program for travel to Guam and the CNMI. This rule implements section 702 of the CNRA by amending the regulations to replace the current Guam Visa Waiver Program with a new Guam-CNMI Visa Waiver Program. The amended regulations set forth the requirements for nonimmigrant visitors who seek admission for business or pleasure and solely for entry into and stay on Guam or the CNMI without a visa. This rule also establishes six ports of entry in the CNMI for purposes of administering and enforcing the Guam-CNMI Visa Waiver Program.

Statement of Need:
Currently, aliens who are citizens of eligible countries may apply for admission to Guam at a Guam port of entry as nonimmigrant visitors for a period of fifteen (15) days or less, for business or pleasure, without first obtaining a nonimmigrant visa, provided that they are otherwise eligible for admission. Section 702(b) of the Consolidated Natural Resources Act of 2008 (CNRA), supersedes the Guam visa waiver program by providing for a visa waiver program for Guam and the Commonwealth of the Northern Mariana Islands (Guam-CNMI Visa Waiver Program). Section 702(b) requires DHS to promulgate regulations within 180 days of enactment of the CNRA to allow nonimmigrant visitors from eligible countries to apply for admission into Guam and the CNMI, for business or pleasure, without a visa, for a period of authorized stay of no longer than 45 days.

Summary of Legal Basis:
The Guam-CNMI Visa Waiver Program is based on congressional authority provided under 702(b) of the Consolidated Natural Resources Act of 2008 (CNRA).

Alternatives:
None

Anticipated Cost and Benefits:
The most significant change for admission to the CNMI as a result of the rule will be for visitors from those countries who are not included in either the existing U.S. Visa Waiver Program or the Guam-CNMI Visa Waiver Program established by the rule. These visitors must apply for U.S. visas, which require in-person interviews at U.S. embassies or consulates and higher fees than the CNMI currently assesses for its visitor entry permits. CBP anticipates that the annual cost to the CNMI will be $6 million. These are losses associated with the reduced visits from foreign travelers who may no longer visit the CNMI upon implementation of this rule. In addition, we estimate Government implementation costs of between $87 and 91 million over the 5-year period of analysis.

The anticipated benefits of the rule are enhanced security that will result from the federalization of the immigration functions in the CNMI.

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Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

International Impacts:

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Agency Contact:
Erin Martin
Program Manager, Office of Field Operations
Department of Homeland Security
U.S. Customs and Border Protection
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Phone: 202 344–2728
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Related RIN: Related to 1651–AA81
RIN: 1651–AA77

DHS—Transportation Security Administration
(TSA) PROPOSED RULE STAGE

73. GENERAL AVIATION SECURITY AND OTHER AIRCRAFT OPERATOR SECURITY

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
6 USC 469; 18 USC 842; 18 USC 845; 46 USC 70102 to 70106; 46 USC 70117; 49 USC 114; 49 USC 114(f)(3); 49 USC 5103; 49 USC 5103a; 49 USC 40113; 49 USC 44901 to 44907; 49 USC 44913 to 44914; 49 USC 44916 to 44918; 49 USC 44932; 49 USC 44935 to 44936; 49 USC 44942; 49 USC 46105

CFR Citation:

Legal Deadline:
None
Abstract:

On October 30, 2008, the Transportation Security Administration (TSA) issued a Notice of Proposed Rulemaking (NPRM), proposing to amend current aviation transportation security regulations to enhance the security of general aviation by expanding the scope of current requirements, and by adding new requirements for certain large aircraft operators and airports serving those aircraft. TSA also proposed that all aircraft operations, including corporate and private charter operations, with aircraft having a maximum certificated takeoff weight (MTOW) above 12,500 pounds (large aircraft) be required to adopt a large aircraft security program. TSA also proposed to require certain airports that serve large aircraft to adopt security programs. TSA is preparing a supplemental NPRM (SNPRM), which will include a comment period for public comments.

After considering comments received on the NPRM and meeting with stakeholders, TSA decided to revise the original proposal to tailor security requirements to the general aviation industry. TSA is considering alternatives to the following proposed provisions in the SNPRM: (1) The type of aircraft subject to TSA regulation; (2) compliance oversight; (3) watch list matching of passengers; (4) prohibited items; (5) scope of the background check requirements and the procedures used to implement the requirement; and (6) other issues. Additionally, in the SNPRM, TSA plans to propose security measures for foreign aircraft operators. U.S. and foreign operators would implement commensurate measures under the proposed rule.

Statement of Need:

This rule would enhance current security measures and might apply security measures currently in place for operators of certain types of aircraft to operators of other aircraft, including general aviation operators. While the focus of TSA's existing aviation security programs has been on air carriers and commercial operators, TSA is aware that general aviation aircraft of sufficient size and weight may inflict significant damage and loss of lives if they are hijacked and used as missiles. TSA has current regulations that apply to large aircraft operated by air carriers and commercial operators, including the twelve-five program, the partial program, and the private charter program. However, the current regulations in 49 CFR part 1544 do not cover all general aviation operations, such as those operated by corporations and individuals, and
such operations do not have the features that are necessary to enhance security. Therefore, TSA is preparing a SNPRM which proposes to establish new security measures for operators, including general aviation operators, that are not covered under TSA's current regulations.

**Summary of Legal Basis:**
49 U.S.C. 114, 40113, 44903.

**Alternatives:**
DHS considered continuing to use voluntary guidance to secure general aviation, but determined that to ensure that each aircraft operator maintains an appropriate level of security, these security measures would need to be mandatory requirements.

**Anticipated Cost and Benefits:**
TSA has not quantified benefits. Unquantified benefits of this rule include those in the areas of security and quality governance. The rule would enhance security by expanding the mandatory use of security measures to certain operators of large aircraft that are not currently required to have a security plan. These measures would deter malicious individuals from perpetrating acts that might compromise transportation or national security by using large aircraft for these purposes.

As stated above, TSA is revising this proposed rule and preparing a SNPRM. Aircraft operators, passengers, and TSA would incur costs to comply with the requirements of the proposed rule. TSA is currently evaluating the costs of the revised rule which will be published in the SNPRM.

TSA uses a break-even analysis to assess the trade-off between the beneficial effects of the SNPRM and the costs of implementing the rulemaking. This break-even analysis uses scenarios extracted from the TSA Transportation Sector Security Risk Assessment (TSSRA) to determine the degree to which the SNPRM must reduce the overall risk of a terrorist attack in order for the expected benefits of the SNPRM to justify the estimated costs. For its analyses, TSA uses scenarios with varying levels of risk, but only details the consequence estimates. To maintain consistency, TSA developed the analyses with a method similar to that used for the break-even analyses conducted in earlier DHS rules. After estimating the total consequences of each scenario by monetizing lives lost, injuries incurred, capital replacement, and clean-
up, TSA will use this figure and the annualized cost of the SNPRM to calculate the frequency of attacks averted in order for the SNPRM to break even.

Risks:
This rulemaking addresses the national security risk of general aviation aircraft being used as a weapon or as a means to transport persons or weapons that could pose a threat to the United States.

Timetable:

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<td>73 FR 77045</td>
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Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Businesses

Government Levels Affected:
Local

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Additional Information:

**URL For More Information:**
www.regulations.gov

**URL For Public Comments:**
www.regulations.gov

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**Related RIN:** Related to 1652–AA03, Related to 1652–AA04

**RIN:** 1652–AA53
74. FREIGHT RAILROADS, PUBLIC TRANSPORTATION AND PASSENGER RAILROADS, AND
OVER–THE–ROAD BUSES—SECURITY TRAINING OF EMPLOYEES

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:

49 USC 114; PL 110–53, secs 1408, 1517, and 1534

CFR Citation:

49 CFR 1520; 49 CFR 1570; 49 CFR 1580; 49 CFR 1582 (New); 49 CFR 1584 (New)

Legal Deadline:

Final, Statutory, November 1, 2007, Interim Rule for public transportation agencies is due 90 days after
date of enactment.

Final, Statutory, February 3, 2008, Rule for railroads and over–the–road buses are due 6 months after
date of enactment.

Final, Statutory, August 3, 2008, Rule for public transportation agencies is due 1 year after date of
enactment.

According to section 1408 of Public Law 110-53, Implementing Recommendations of the 9/11
Commission Act of 2007 (Aug. 3, 2007; 121 Stat. 266), interim final regulations for public transportation
agencies are due 90 days after the date of enactment (Nov. 1, 2007), and final regulations are due 1 year
after the date of enactment of this Act.

Abstract:

The Transportation Security Administration (TSA) will propose a new regulation to improve the security of
freight railroads, public transportation and passenger railroads, and over-the-road buses in accordance
with the Implementing Recommendations of the 9/11 Commission Act of 2007. This rulemaking will
propose general requirements for the owner/operators of a freight railroad, a public transportation system
or passenger railroad, and over-the-road bus operation determined by TSA to be high-risk to develop and
implement a security training program to prepare security-sensitive employees, including frontline
employees identified in sections 1402 and 1501 of the Act, for potential security threats and conditions.
The rulemaking will also propose extending the security coordinator and reporting security incident
requirements applicable to rail operators under current 49 CFR part 1580 to the non-rail transportation components of covered public transportation agencies. In addition, the rulemaking will also propose requiring the affected over-the-road bus owner/operators to identify security coordinators and report security incidents, similar to the requirements for rail in current 49 CFR 1580. The regulation will take into consideration any current security training requirements or best practices.

**Statement of Need:**
A security training program for freight railroads, public transportation agencies and passenger railroads, and over-the-road bus operations is proposed to prepare freight railroad security-sensitive employees, public transportation and passenger railroad security-sensitive employees, and over-the-road bus security sensitive employees for potential security threats and conditions.

**Summary of Legal Basis:**

**Alternatives:**
TSA is required by statute to publish regulations requiring security training programs for these owner/operators. As part of its notice of proposed rulemaking, TSA will seek public comment on the alternative ways in which the final rule could carry out the requirements of the statute.

**Anticipated Cost and Benefits:**
TSA will estimate the costs that the freight railroad systems, public transportation agencies and passenger railroads, and over-the-road bus (OTRB) entities covered by this proposed rule would incur following its implementation. These costs will include estimates for the following elements: (1) Creating or modifying a security training program and submitting it to TSA; (2) Training (initial and recurrent) all security-sensitive employees; (3) Maintaining records of employee training; (4) Being available for inspections; (5) As applicable, providing information on security coordinators and alternates; and (6) As applicable, reporting security concerns. TSA will also estimate the costs TSA itself would expect to incur with the implementation of this rule.
TSA has not quantified benefits. However, the primary benefit of the Security Training NPRM will be to enhance United States surface transportation security by reducing the vulnerability of freight railroad systems, public transportation agencies, and passenger railroads to terrorist activity through the training of security-sensitive employees. TSA uses a break-even analysis to assess the trade-off between the beneficial effects of the Security Training NPRM and the costs of implementing the rulemaking. This break-even analysis uses scenarios extracted from the TSA Transportation Sector Security Risk Assessment (TSSRA) to determine the degree to which the Security Training NPRM must reduce the overall risk of a terrorist attack in order for the expected benefits of the NPRM to justify the estimated costs. For its analyses, TSA uses scenarios with varying levels of risk, but only details the consequence estimates. To maintain consistency, TSA developed the analyses with a method similar to that used for the break-even analyses conducted in earlier DHS rules.

After estimating the total consequence of each scenario by monetizing lives lost, injuries incurred, and capital replacement and clean-up, TSA will use this figure and the annualized cost of the NPRM for freight rail, public transportation and passenger rail, and OTRB operators to calculate a breakeven annual likelihood of attack.

**Risks:**

The Department of Homeland Security aims to prevent terrorist attacks within the United States and to reduce the vulnerability of the United States to terrorism. By providing for security training for personnel, TSA intends in this rulemaking to reduce the risk of a terrorist attack on this transportation sector.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Local

**URL For More Information:**
URL For Public Comments:
www.regulations.gov

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Steve Sprague
75. FREIGHT RAILROADS AND PASSENGER RAILROADS—VULNERABILITY ASSESSMENT AND SECURITY PLAN

Priority:

Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:

Undetermined

Legal Authority:

49 USC 114; PL 110–53, sec 1512

CFR Citation:

49 CFR 1520; 49 CFR 1570; 49 CFR 1580; 49 CFR 1582 (New)

Legal Deadline:

Final, Statutory, August 3, 2008, Rule for freight railroads and passenger railroads is due no later than 12 months after date of enactment.

Abstract:
The Transportation Security Administration (TSA) will propose a new regulation to improve the security of freight railroads and passenger railroads in accordance with the Implementing Recommendations of the 9/11 Commission Act of 2007. This rulemaking will propose thresholds for which a risk determination can be made to determine whether a freight railroad and passenger railroad should be considered “high risk.” The rulemaking will also propose requirements for vulnerability assessments and security plans for owner/operators of those railroads. The proposed requirements include procedures for TSA's review and approval of these assessments and plans, and recordkeeping requirements. The regulation will take into consideration any current security assessment and planning requirements or best practices.

Statement of Need:
The rulemaking will propose requirements for owner/operators of high-risk freight railroads and high-risk passenger railroads to conduct vulnerability assessments and carry-out security plans to address the railroad carrier's preparedness and response for potential security threats and conditions.

Summary of Legal Basis:

Alternatives:
TSA is required by statute to publish regulations requiring vulnerability assessments and security plans for owner/operators of high-risk freight railroads and high-risk passenger railroads. As part of its notice of proposed rulemaking, TSA will seek public comment on the alternative ways in which the final rule could carry out the requirements of the statute.

Anticipated Cost and Benefits:
TSA will estimate the costs that the freight rail systems and passenger railroad carriers covered by this proposed rule would incur following its implementation. These costs will include estimates for the following elements: (1) Completing, modifying, or updating a vulnerability assessment and submitting it to
TSA; (2) Developing, modifying, or updating a security plan and submitting it to TSA; (3) Implementing a security plan; (4) Maintaining records, including master copies of the vulnerability assessment and security plan and all plans or documents referenced in the security plan; and (5) Being available for inspection.

The expected primary benefit of the Vulnerability Assessment and Security Plan NPRM will be to enhance U.S. surface transportation security by reducing vulnerability to terrorist attacks in two different ways. First, vulnerability assessments, as required in this proposed rule, would identify assets and infrastructure that are critical to owner/operators and provide an assessment of security risks that need to be mitigated at these locations. Second, in an effort to mitigate security risks, security plans would help target resources and mitigation strategies toward security gaps in an owner/operator's specific freight or passenger railroad operation to address the risks identified by the vulnerability assessments.

TSA has not quantified benefits. For the purposes of this rulemaking, TSA employs a break even analysis to compare the cost of the risk reduction resulting from the proposed rule with the dollar value of the type of terrorist attacks that could potentially be averted due to the requirements in the proposed rule. This provides a framework for evaluating the tradeoff between program costs and benefits. For purposes of this analysis, TSA evaluates three scenarios in the freight rail mode of surface transportation and three scenarios in the passenger railroad mode of surface transportation covered by the proposed rule. For each scenario, TSA calculates a total monetary consequence from an estimated statistical value of the human casualties and capital replacement resulting from the attack. TSA compared an expected value of the monetary cost of an attack to the each rail mode and TSA's annualized cost of conducting vulnerability assessments and implementing security plans, discounted at 7 percent, to estimate how often an attack of that nature would need to be averted for the expected benefits to equal estimated costs. For a given level of pre-existing or baseline risk of an attack, the calculation of the break-even point—the reduction in baseline risk for which the estimated costs and expected benefits are equal—and a detailed description of each scenario is presented in the regulatory evaluation for this NPRM.

**Risks:**
The Department of Homeland Security aims to prevent terrorist attacks within the United States and to reduce the vulnerability of the United States to terrorism. By providing for owner/operators of high-risk freight railroads and owner/operators of high-risk passenger railroads to conduct vulnerability assessments and adopt and carry out security plans, TSA intends in this rulemaking to reduce the risk of a terrorist attack on the passenger rail transportation sector.

Timetable:

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Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Local

Federalism:

Undetermined

URL For More Information:

www.regulations.gov

URL For Public Comments:

www.regulations.gov

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**Related RIN:** Related to 1652–AA58, Related to 1652–AA60

**RIN:** 1652–AA56
76. STANDARDIZED VETTING, ADJUDICATION, AND REDRESS SERVICES

Priority:
Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:
Undetermined

Legal Authority:
49 USC 114; PL 110–53, secs 1411, 1414, 1520, 1522, 1602; 6 USC 469

CFR Citation:
Not Yet Determined

Legal Deadline:
None

Abstract:
The Transportation Security Administration (TSA) will propose new regulations to revise and standardize the procedures, adjudication criteria, and fees for most of the security threat assessments (STA) of individuals for which TSA is responsible. In accordance with the Implementing Recommendations of the 9/11 Commission Act of 2007 (9/11 Act), the scope of the rulemaking will include transportation workers from all modes of transportation who are required to undergo an STA in other regulatory programs, including certain aviation workers and frontline employees for public transportation agencies and railroads.

In addition, TSA will propose fees to cover the cost of the STAs, and credentials for some personnel. TSA plans to improve efficiencies in processing STAs and streamline existing regulations by simplifying language and removing redundancies.

As part of this proposed rule, TSA will propose revisions to the Alien Flight Student Program (AFSP) regulations. TSA published an interim final rule for ASFP on September 20, 2004. TSA regulations
require aliens seeking to train at Federal Aviation Administration-regulated flight schools to complete an
application and undergo an STA prior to beginning flight training. There are four categories under which
students currently fall; the nature of the STA depends on the student's category. TSA is considering
changes to the AFSP that would improve the equity among fee payers and enable the implementation of
new technologies to support vetting.

Statement of Need:
Through this rulemaking, TSA proposes to carry out statutory mandates to perform security threat
assessments (STA) of certain transportation workers pursuant to the 9/11 Act. Also, TSA proposes to fully
satisfy 6 U.S.C. 469, which requires TSA to fund security threat assessment and credentialing activities
through user fees. The proposed rulemaking would increase transportation security by enhancing
identification and immigration verification standards, providing for more thorough vetting, improving the
reliability and consistency of the vetting process, and increasing fairness to vetted individuals by providing
more robust redress and reducing redundant STA requirements.

Summary of Legal Basis:
49 U.S.C. 114(f): Under the Aviation and Transportation Security Act (ATSA) (Pub. L. 170-71, Nov. 19,
2001, 115 Stat. 597), TSA assumed responsibility to oversee the vetting of certain aviation workers. See

Under the Maritime Transportation Security Act (MTSA), (Pub. L. 107-295, sec. 102, Nov. 25, 2002, 116
Stat. 2064), codified at 46 U.S.C. 70105, TSA vets certain merchant mariners and individuals who require
unescorted access to secure areas of vessels and maritime facilities.

Under the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and
individuals seeking hazardous materials endorsements (HME) to commercial driver's licenses (CDL)
issued by the States.

In 6 U.S.C. 469, Congress directed TSA to fund vetting and credentialing programs through user fees.

**Alternatives:**

TSA considered a number of viable alternatives to lessen the impact of the proposed on entities deemed “small” by the Small Business Administration (SBA) standards. This included: (1) Extending phone pre-enrollment to populations eligible to enroll via the web; and (2) changing the current delivery and activation process and instituting centralized activation of biometric credentials that allow applicants to receive their credentials through the mail rather than returning to the enrollment center to pick up the credential. These alternatives are discussed in detail in the rule and regulatory evaluation.

**Anticipated Cost and Benefits:**

TSA conducted a regulatory evaluation to estimate the costs regulated entities, individuals, and TSA would incur to comply with the requirements of the NPRM. The NPRM would impose new requirements for some individuals, codify existing requirements not included in the Code of Federal Regulations (CFR), and modify current STA requirements for many transportation workers. The primary benefit of the NPRM would be that it will improve TSA’s vetting product, process, and structure by improving STAs, increasing equity, decreasing reliance on appropriated funds, and improving reusability of STAs and mitigating redundant STAs.

TSA has not quantified benefits. TSA uses a break-even analysis to assess the trade-off between the beneficial effects of the NPRM and the costs of implementing the rulemaking. This break-even analysis uses scenarios from the TSA Transportation Sector Security Risk Assessment (TSSRA) to determine the degree to which the NPRM must reduce the overall risk of a terrorist attack in order for the expected benefits of the NPRM to justify the estimated costs. For its analyses, TSA uses scenarios with varying levels of risk, but only details the consequence estimates. To maintain consistency, TSA developed the analyses with a method similar to that used for the break-even analyses conducted in earlier DHS rules.
After estimating the total consequences of each scenario by monetizing lives lost, injuries incurred, capital replacement, and clean-up, TSA will use this figure and the annualized cost of the NPRM to calculate the frequency of attacks averted in order for the NPRM to break even.

TSA estimates that the total savings to the alien flight students, over a 5-year period, will be $18,107 at a 7 percent discount rate.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:**

Undetermined

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Related RIN: Related to 1652–AA35

RIN: 1652–AA61

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<td>77. AIRCRAFT REPAIR STATION SECURITY</td>
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Priority:

Other Significant. Major under 5 USC 801.
Legal Authority:
49 USC 114; 49 USC 44924

CFR Citation:
49 CFR 1554

Legal Deadline:
Final, Statutory, August 8, 2004, Rule within 240 days of the date of enactment of Vision 100.
Final, Statutory, August 3, 2008, Rule within 1 year after the date of enactment of 9/11 Commission Act.


Abstract:
The Transportation Security Administration (TSA) proposed to add a new regulation to improve the security of domestic and foreign aircraft repair stations, as required by the section 611 of Vision 100—Century of Aviation Reauthorization Act and section 1616 of the 9/11 Commission Act of 2007. The regulation proposed general requirements for security programs to be adopted and implemented by repair stations certificated by the Federal Aviation Administration (FAA). A notice of proposed rulemaking (NPRM) was published in the Federal Register on November 18, 2009, requesting public comments to be submitted by January 19, 2010. The comment period was extended to February 19, 2010, on request of the stakeholders to allow the aviation industry and other interested entities and individuals additional time to complete their comments.

TSA has coordinated its efforts with the FAA throughout the rulemaking process to ensure that the final rule does not interfere with FAA’s ability or authority to regulate part 145 repair station safety matters.

Statement of Need:
The Transportation Security Administration (TSA) is proposing regulations to improve the security of domestic and foreign aircraft repair stations. The NPRM proposed to require repair stations that are
certificated by the Federal Aviation Administration to adopt and carry out a security program. The proposal will codify the scope of TSA’s existing inspection program. The proposal also provides procedures for repair stations to seek review of any TSA determination that security measures are deficient.

Summary of Legal Basis:

Section 611(b)(1) of Vision 100-Century of Aviation Reauthorization Act (Pub. L. 108-176; Dec. 12, 2003; 117 Stat. 2490), codified at 49 U.S.C. 44924, requires TSA to issue “final regulations to ensure the security of foreign and domestic aircraft repair stations” within 240 days from date of enactment of Vision 100. Section 1616 of Public Law 110-53, Implementing Recommendations of the 9/11 Commission Act of 2007 (Aug. 3, 2007; 121 Stat. 266) requires that the FAA may not certify any foreign repair stations if the regulations are not issued within 1 year after the date of enactment of the 9/11 Commission Act unless the repair station was previously certificated or is in the process of certification.

Alternatives:

TSA is required by statute to publish regulations requiring security programs for aircraft repair stations. As part of its notice of proposed rulemaking, TSA sought public comment on the numerous alternative ways in which the final rule could carry out the requirements of the statute.

Anticipated Cost and Benefits:

TSA anticipates costs to aircraft repair stations mainly related to the establishment of security programs, which may include adding such measures as access controls, a personnel identification system, security awareness training, the designation of a security coordinator, employee background verification, and contingency plan.

The NPRM estimated the total 10-year undiscounted cost of the program at $344 million. The cost of the program, annualized and discounted at 7 percent, is $241 million. Security coordinator and training costs represent the largest portions of the program.

TSA has not quantified benefits. However, a major line of defense against an aviation-related terrorist act is the prevention of explosives, weapons, and/or incendiary devices from getting on board a plane. To
date, efforts have been primarily related to inspection of baggage, passengers, and cargo, and security measures at airports that serve air carriers. With this rule, attention is given to aircraft that are located at repair stations, and to aircraft parts that are at repair stations, themselves to reduce the likelihood of an attack against aviation and the country. Since repair station personnel have direct access to all parts of an aircraft, the potential exists for a terrorist to seek to commandeer or compromise an aircraft when the aircraft is at one of these facilities. Moreover, as TSA tightens security in other areas of aviation, repair stations increasingly may become attractive targets for terrorist organizations attempting to evade aviation security protections currently in place.

TSA uses a break-even analysis to assess the trade-off between the beneficial effects of the final rule and the costs of implementing the rulemaking. This break-even analysis uses three attack scenarios to determine the degree to which the final rule must reduce the overall risk of a terrorist attack in order for the expected benefits of the final rule to justify the estimated costs. For its analyses, TSA uses scenarios with varying levels of risk, but only details the consequence estimates. To maintain consistency, TSA developed the analyses with a method similar to that used for the break-even analyses conducted in earlier DHS rules. After estimating the total consequences of each scenario by monetizing lives lost, injuries incurred, and capital replacement, TSA will use this figure and the annualized cost of the final rule to calculate the frequency of attacks averted in order for the final rule to break even.

**Risks:**
The Department of Homeland Security aims to prevent terrorist attacks within the United States and to reduce the vulnerability of the United States to terrorism. By requiring security programs for aircraft repair stations, TSA will focus on preventing unauthorized access to repair work and to aircraft to prevent sabotage or hijacking.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Yes

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
None

**URL For More Information:**
www.regulations.gov

**URL For Public Comments:**
www.regulations.gov

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**RIN:** 1652–AA38
78. CONTINUED DETENTION OF ALIENS SUBJECT TO FINAL ORDERS OF REMOVAL

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
8 USC 1103; 8 USC 1223; 8 USC 1227; 8 USC 1231; 8 USC 1253

CFR Citation:
8 CFR 241

Legal Deadline:
None

Abstract:
This notice of proposed rulemaking (NPRM) is proposing to amend the Department of Homeland Security (DHS) regulatory provisions for custody determinations for aliens in immigration detention who are subject to an administratively final order of removal. The proposed amendment would add a paragraph to 8 CFR 241.4(g) providing that U.S. Immigration and Customs Enforcement (ICE) shall have a reasonable period of time to effectuate an alien's removal where the alien is not in immigration custody when the order of removal becomes administratively final. The proposed rule would also clarify the removal period time frame afforded to the agency following an alien's compliance with his or her obligations regarding removal subsequent to a period of obstruction or failure to cooperate. The rule proposes to make conforming changes to 241.13(b)(2). Lastly, the rule proposes to add a paragraph to 8 CFR 241.13(b)(3) to make clear that aliens certified by the Secretary under section 236A of the Immigration and Nationality Act, 8 U.S.C. 1226a, are not subject to the provisions of 8 CFR 241.13, in accordance with the separate detention standard provided under the Act.

Statement of Need:
The companion final rule will improve the post order custody review process in the final rule related to the Detention of Aliens Subject to Final Orders of Removal in light of the U.S. Supreme Court's decisions in Zadvydas v. Davis, 533 U.S. 678 (2001), Clark v. Martinez, 543 U.S. 371 (2005) and conforming changes as required by the enactment of the Homeland Security Act of 2002 (HSA). This notice of proposed
rulemaking (NPRM) will propose to amend 8 CFR 241.1(g) to provide for a new 90-day removal period once an alien comes into compliance with his or her obligation to make timely application in good faith for travel or other documents and not conspire or act to prevent removal.

**Anticipated Cost and Benefits:**
This proposed rule will clarify the regulatory provisions concerning the removal of aliens that are subject to an administratively final order of removal. DHS does not anticipate there will be cost impacts to the public as a result of the rule.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Agency Contact:**

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**Related RIN:** Related to 1653–AA13

**RIN:** 1653–AA60
79. CONTINUED DETENTION OF ALIENS SUBJECT TO FINAL ORDERS OF REMOVAL

Priority:
Other Significant

Legal Authority:
8 USC 1103; 8 USC 1223; 8 USC 1227; 8 USC 1231; 8 USC 1253; . . .

CFR Citation:
8 CFR 241

Legal Deadline:
None

Abstract:
The U.S. Department of Homeland Security is finalizing, with amendments, the interim rule that was published on November 14, 2001, by the former Immigration and Naturalization Service (Service). The interim rule included procedures for conducting custody determinations in light of the U.S. Supreme Court's decision in Zadvydas v. Davis, 533 U.S. 678 (2001), which held that the detention period of certain aliens who are subject to a final administrative order of removal is limited under section 241(a)(6) of the Immigration and Nationality Act (Act) to the period reasonably necessary to effect their removal. The interim rule amended section 241.4 of title 8, Code of Federal Regulations (CFR), in addition to creating two new sections: 8 CFR 241.13 (establishing custody review procedures based on the significant likelihood of the alien's removal in the reasonably foreseeable future) and 241.14 (establishing custody review procedures for special circumstances cases). Subsequently, in the case of Clark v. Martinez, 543 U.S. 371 (2005), the Supreme Court clarified a question left open in Zadvydas, and held that section 241(a)(6) of the Act applies equally to all aliens described in that section. This rule amends the interim rule to conform to the requirements of Martinez. Further, the procedures for custody determinations for post-removal period aliens who are subject to an administratively final order of removal, and who have not been released from detention or repatriated, have been revised in response to comments received and experience gained from administration of the interim rule published in 2001.
This final rule also makes conforming changes as required by the enactment of the Homeland Security Act of 2002 (HSA). Additionally, certain portions of the final rule were determined to require public comment and, for this reason, have been developed into a separate/companion notice of proposed rulemaking; RIN 1653-AA60.

**Statement of Need:**

This rule will improve the post order custody review process in the final rule related to the Detention of Aliens Subject to Final Orders of Removal in light of the U.S. Supreme Court's decisions in Zadvydas v. Davis, 533 U.S. 678 (2001), Clark v. Martinez, 543 U.S. 371 (2005) and conforming changes as required by the enactment of the Homeland Security Act of 2002 (HSA). A companion notice of proposed rulemaking (NPRM) will propose to amend 8 CFR 241.1(g) to provide for a new 90-day removal period once an alien comes into compliance with his or her obligation to make timely application in good faith for travel or other documents and not conspire or act to prevent removal.

**Anticipated Cost and Benefits:**

The changes are administrative and procedural in nature, and will not result in cost impacts to the public. The benefits of making these changes to the regulations will allow for expedited review of the post-order custody review process.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None
Additional Information:
INS No. 2156-01
Transferred from RIN 1115-AG29

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RIN: 1653–AA13

DHS—USICE

80. EXTENDING PERIOD FOR OPTIONAL PRACTICAL TRAINING BY 17 MONTHS FOR F–1 NONIMMIGRANT STUDENTS WITH STEM DEGREES AND EXPANDING THE CAP–GAP RELIEF FOR ALL F–1 STUDENTS WITH PENDING H–1B PETITIONS

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
8 USC 1101 to 1103; 8 USC 1182; 8 USC 1184 to 1187; 8 USC 1221; 8 USC 1281 and 1282; 8 USC 1301 to 1305

CFR Citation:
8 CFR 214

Legal Deadline:
None
Abstract:
Currently, foreign students in F-1 nonimmigrant status who have been enrolled on a full-time basis for at least one full academic year in a college, university, conservatory, or seminary certified by U.S. Immigration and Custom Enforcement's (ICE) Student and Exchange Visitor Program (SEVP) are eligible for 12 months of optional practical training (OPT) to work for a U.S. employer in a job directly related to the student's major area of study. The maximum period of OPT is 29 months for F-1 students who have completed a science, technology, engineering, or mathematics (STEM) degree and accept employment with employers enrolled in U.S. Citizenship and Immigration Services' (USCIS') E-Verify employment verification program. Employers of F-1 students with an extension of post-completion OPT authorization must report to the student's designated school official (DSO) within 48 hours after the OPT student has been terminated from, or otherwise leaves, his or her employment with that employer prior to end of the authorized period of OPT.

The final rule will respond to public comments and may make adjustments to the regulations.

Statement of Need:
ICE will improve SEVP processes by publishing the Final Optional Practical Training (OPT) rule, which will respond to comments on the OPT interim final rule (IFR). The IFR increased the maximum period of OPT from 12 months to 29 months for nonimmigrant students who have completed a science, technology, engineering, or mathematics (STEM) degree and who accept employment with employers who participate in the U.S. Citizenship and Immigration Services' (USCIS') E-Verify employment verification program.

Alternatives:
DHS is considering several alternatives to the 17-month extension of OPT and cap-gap extension, ranging from taking no action to further extension for a larger populace. The interim final rule addressed an immediate competitive disadvantage faced by U.S. industries and ameliorated some of the adverse impacts on the U.S. economy. DHS continues to evaluate both quantitative and qualitative alternatives.

Anticipated Cost and Benefits:
Based on an estimated 12,000 students per year that will receive an OPT extension and an estimated 5,300 employers that will need to enroll in E-verify, DHS projects that this rule will cost students approximately $1.49 million per year in additional information collection burdens, $4,080,000 in fees, and cost employers $1,240,000 to enroll in E-Verify and $168,540 per year thereafter to verify the status of new hires. However, this rule will increase the availability of qualified workers in science, technology, engineering, and mathematical fields; reduce delays that place U.S. employers at a disadvantage when recruiting foreign job candidates, thereby improving strategic and resource planning capabilities; increase the quality of life for participating students, and increase the integrity of the student visa program.

**Timetable:**

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<td>73 FR 18944</td>
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**Regulatory Flexibility Analysis Required:**

No

**Government Levels Affected:**

None

**URL For More Information:**

www.dhs.gov/sevis/

**Agency Contact:**

Sharon Snyder

Acting Branch Chief, SEVP Policy, Student and Exchange Visitor Program

Department of Homeland Security

U.S. Immigration and Customs Enforcement

Potomac Center North

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Washington, DC 20024–6121
81. UPDATE OF FEMA'S PUBLIC ASSISTANCE REGULATIONS

Priority:
Other Significant

Legal Authority:
42 USC 5121 to 5207

CFR Citation:
44 CFR 206

Legal Deadline:
None

Abstract:
This proposed rule would revise the Federal Emergency Management Agency's Public Assistance program regulations. Many of these changes reflect amendments made to the Robert T. Stafford Disaster Relief and Emergency Assistance Act by the Post-Katrina Emergency Management Reform Act of 2006 and the Security and Accountability For Every Port Act of 2006. The proposed rule also proposes to reflect lessons learned from recent events, and propose further substantive and non-substantive clarifications and corrections to improve upon the Public Assistance regulations. This proposed rule is intended to improve the efficiency and consistency of the Public Assistance program, as well as implement new statutory authority by expanding Federal assistance, improving the Project Worksheet process, empowering grantees, and improving State Administrative Plans.

Statement of Need:
The proposed changes implement new statutory authorities and incorporate necessary clarifications and corrections to streamline and improve the Public Assistance program. Portions of FEMA's Public
Assistance regulations have become out of date and do not implement all of FEMA’s available statutory authorities. The current regulations inhibit FEMA’s ability to clearly articulate its regulatory requirements, and the Public Assistance applicants' understanding of the program. The proposed changes are intended to improve the efficiency and consistency of the Public Assistance program.

**Summary of Legal Basis:**

**Alternatives:**
One alternative is to revise some of the current regulatory requirements (such as application deadlines) in addition to implementing the amendments made to the Stafford Act by (1) the Post-Katrina Emergency Management Reform Act of 2006 (PKEMRA), Public Law 109-295, 120 Stat. 1394; 2) the Security and Accountability For Every Port Act of 2006 (SAFE Port Act), Public Law 109-347, 120 Stat. 1884; 3) the Local Community Recovery Act of 2006, Public Law 109-218, 120 Stat. 333; and 4) the Pets Evacuation and Transportation Standards Act of 2006 (PETS Act), Public Law 109-308, 120 Stat. 1725. Another alternative is to expand funding by expanding force account labor cost eligibility to Category A Projects (debris removal).

**Anticipated Cost and Benefits:**
The proposed rule is expected to have economic impacts on the public, grantees, subgrantees, and FEMA. The expected benefits are a reduction in property damages, societal losses, and losses to local businesses, as well as improved efficiency and consistency of the Public Assistance program. FEMA estimates the primary economic impact of the proposed rule is the additional transfer of funding from FEMA through the Public Assistance program to grantees and subgrantees that is effectuated by this rulemaking.

**Risks:**
This action does not adversely affect public health, safety, or the environment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Government Levels Affected:**

Federal, Local, State, Tribal

**Federalism:**

This action may have federalism implications as defined in EO 13132.

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**RIN:** 1660–AA51

**BILLING CODE** 9110–9B–S

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**Statement of Regulatory Priorities**

The regulatory plan for the Department of Housing and Urban Development (HUD) for fiscal year (FY) 2012 highlights the most significant regulations and policy initiatives that HUD seeks to complete during the upcoming fiscal year. As the Federal agency that serves as the Nation’s housing agency, HUD’s
mission is to create strong, sustainable, inclusive communities and quality affordable homes for all. HUD strives to meet the challenges of this mission by focusing on people and places through policies and initiatives that address the unique conditions and needs of communities. For example, HUD recognizes that the “American Dream” no longer refers to a singular vision of success, such as owning a home, and, therefore, through programs such as HUD’s Housing Counseling program, HUD assists individuals and families to make decisions about owning or renting that are financially appropriate to the individual or family.\(^1\) HUD also has been placing greater focus on improving locational outcomes for households receiving rental assistance. HUD’s Choice Neighborhood initiative provides funding for plans that link housing to schools, jobs, and affordable transportation in order to transform neighborhoods of concentrated poverty into sustainable mixed-income communities with well-functioning services, public assets, and access to opportunity. HUD’s Neighborhood Stabilization Program helps communities acquire, rehabilitate, and resell foreclosed and abandoned properties in order to more quickly prevent decline in neighborhoods hard-hit by the foreclosure process.

In addition to meeting the challenges of HUD’s mission through revitalized policies and initiatives, President Obama challenged all agencies to identify opportunities to significantly improve near-term performance. These opportunities were incorporated as key outcome measures into HUD’s strategic plan, representing challenging, near-term, high-impact outcomes that reflect HUD’s commitment to addressing some of the most fundamental housing and community challenges facing America. Building on the directions to improve performance, but on a longer-term basis, President Obama issued Executive Order 13563 entitled “Improving Regulation and Regulatory Review.” Executive Order 13563 supplements and reaffirms the rulemaking principles of Executive Order 12866 “Regulatory Planning and Review,” which include identifying regulatory approaches that reduce burden, considering the costs and benefits of rules, and encouraging public participation, but also directs agencies to undertake a retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal such regulations as appropriate. The Executive order recognizes the significant role that regulations play in protecting public health, welfare, safety, and the

\(^1\) This statement is based on language found on page 4, paragraph 2, of the Introduction to HUD’s FY 2010 to 2015 Strategic Plan. (See http://portal.hud.gov/hudportal/documents/huddoc?id=DOC_4436.pdf.)
environment, and in promoting economic growth, innovation, competitiveness, and job creation, but also that regulations cannot remain stagnant. Agencies must frequently review regulations to ensure that they are meeting the challenges of today and not addressing conditions, whether housing, health, business, labor, or environmental, that are no longer reflected in today’s economy. In this regard, Executive Order 13563 directed agencies to undertake periodic retrospective review of their regulations, and to develop, prepare, and post their plans for retrospective review of rules. HUD’s plan and that of all agencies can be found at http://www.whitehouse.gov/21stcenturygov/actions/21st-century-regulatory-system. HUD’s semiannual agenda of regulations includes the rules highlighted in HUD’s retrospective review of rules plans.

The rules highlighted in HUD’s regulatory plan for FY 2011 reflect both HUD’s continuing efforts to fulfill its mission and improve performance, including by addressing regulations that necessitate update and modification. HUD’s FY 2011 regulatory plan reflects HUD’s retrospective review of the regulations governing one of HUD’s major mortgage insurance programs. Another rule highlighted in this regulatory plan revises the regulations of another significant program to address the unique conditions and needs of participants in one of HUD’s major assistance programs. The third rule related to a significant HUD program is designed to implement flexibility provided by a recently enacted statute.

**Priority: Create Financially Sustainable Homeownership Opportunities.**

HUD’s HECM program was established by statute to assist in alleviating economic hardship caused by the increasing costs of health, housing, and other needs at a time in life when one’s income is reduced. The HECM program, administered through HUD’s Federal Housing Administration (FHA), enables older homeowners to withdraw some of the equity in their home in the form of monthly payments for life or a fixed term, or in a lump sum, or through a line of credit. In addition, the HECM mortgage can be used to purchase a primary home when the borrower is 62 years of age or older and is able to use cash in hand, money from the sale of assets, or money from an allowable FHA funding source to pay the difference between the reverse mortgage and the sales price plus closing costs for the property.
To be eligible for a HECM mortgage, current homeowners must be 62 years of age or older, own their home outright, or have a low mortgage balance that can be paid off at closing with proceeds from the reverse mortgage. Homeowners can only have one HECM at any one time and the home must be their principal residence. In addition, the HECM can be used to purchase a primary home if the borrower is able to pay the difference between the HECM and the sales price and closing costs for the property. The borrower remains the owner of the home and may sell it and move at any time, keeping the sales proceeds that exceed the mortgage balance. A borrower cannot be forced to sell the home to pay off the mortgage, even if the mortgage balance grows to exceed the value of the property, unless they fail to perform an obligation of the mortgage.

As the Nation’s population has increased in age, the attraction of the HECM has increased as well. In 1990, there were approximately 157 HECMs. By 2008, there were more than 112,000 HECMs. The situation that HUD has confronted recently with increasing frequency is that HECM homeowners are not paying property taxes, insurance, and other property charges. Payment of these items is the responsibility of the homeowner, and failure to pay places the homeowner in default of its obligations under the mortgage and makes the homeowner vulnerable to loss of his or her home. FHA-approved lenders are responsible for keeping all tax and insurance payments current, in compliance with the HECM regulations. If homeowners stop making payments, lenders are allowed to access any remaining home equity to pay taxes and insurance premiums. Once homeowner funds are exhausted, lenders are legally required to advance their own funds for such payments and seek reimbursement from homeowners.

With the same recognition that homeownership may not be the best choice for every individual or family, a HECM may not be the best choice for every senior homeowner. The security that the HECM program was designed to bring to seniors may be lost if the senior homeowner cannot maintain payment of taxes and insurance payments.

Regulatory Action: Strengthening the Home Equity Conversion Mortgage (HECM) Program To Promote Sustained Homeownership.
To address this growing issue in the HECM program, HUD proposes to require FHA-approved mortgagees that originate HECM mortgages to perform a financial capacity and credit history assessment of prospective HECM mortgagors prior to loan approval and closing. Mortgagees will be required to evaluate whether the HECM mortgagor’s cash flow and credit history support the mortgagor’s ability to comply with the obligations of the HECM and are sufficient to meet recurring living expenses. The proposed rule would also cap the amount of insurance benefits paid in connection with a claim involving amounts advanced by the mortgagee on behalf of a HECM mortgagor who fails to pay such property charges when the HECM proceeds have been exhausted, and establish a new property inspection requirement to insure that homes secured with a HECM mortgage are adequately maintained and meet applicable property standards.

These changes to the HECM program are necessary to ensure that senior homeowners do not enter a program seeking security in their later life only to find themselves without a home. Additionally, without such changes, the HECM program will place the FHA Insurance Fund at significant risk, with the possible result being the unavailability of HECMs in the future.

**Priority: Improve the Quality of Affordable Rental Housing.**

In an era when more than one-third of all American families rent their homes, the current housing market does not create and sustain a sufficient supply of affordable rental homes, especially for low-income households. In many communities, affordable rental housing does not exist without public support. Despite significant improvements in housing quality in recent decades, much of America’s rental housing stock is not energy efficient or even accessible to people with disabilities, and pockets of severely substandard housing remain across the country. Even before the recent recession, the number of households with severe housing cost burdens had increased substantially since 2000, and homelessness among families with children is a growing problem throughout our Nation. When it comes to strong, safe, and healthy communities, lower-cost rental housing is particularly scarce. As the lead Federal housing agency, HUD will work with its Federal, State, local, and private partners to meet
affordable and quality rental housing needs for all.\textsuperscript{2} In this regard, HUD will strengthen the indicators by which HUD measures the performance of public housing agencies in administering its Section 8 rental assistance program, referred to as the Housing Choice Voucher program.

HUD’s Housing Choice Voucher program is the Federal Government’s major program for assisting very low-income families, the elderly, and the disabled to afford decent, safe, and sanitary housing in the private market. Since housing assistance is provided on behalf of the family or individual, participants are able to find their own housing, including single-family homes, townhouses, and apartments. The participant is free to choose any housing that meets the requirements of the program and is not limited to units located in subsidized housing projects. Housing choice vouchers are administered locally by public housing agencies (PHAs). The PHAs receive Federal funds from HUD to administer the voucher program. A family that is issued a housing voucher is responsible for finding a suitable housing unit of the family’s choice where the owner agrees to rent under the program. Rental units must meet minimum standards of health and safety, as determined by the PHA.\textsuperscript{3}

Through HUD’s Section Eight Management Assessment Program (SEMAP), HUD measures the performance of PHAs in their administration of the Housing Choice Voucher program in key areas. The areas of review indicate whether PHAs are helping eligible families to afford decent rental units at a reasonable subsidy cost. SEMAP requires PHAs to undertake an annual Housing Quality Standard (HQS) inspection of units.

\textit{Regulatory Action: Tenant-Based Rental Assistance; Improving Performance Through a Strengthened SEMAP.}

HUD recognizes that SEMAP is more process-oriented than results-oriented. To make SEMAP a more effective assessment tool, HUD is proposing to revise the management indicators used by HUD to measure the performance of PHAs. For example, the proposed rule would revise the indicator that

\textsuperscript{2} This statement is taken from the first column of page 19 of section 2 of HUD’s FY 2010 to 2015 Strategic Plan. (See http://portal.hud.gov/hudportal/documents/huddoc?id=DOC_4436.pdf.)
\textsuperscript{3} The information in this paragraph is taken from HUD’s webpage on Housing Choice Vouchers found at http://portal.hud.gov/hudportal/HUD?src=/program_offices/public_indian_housing/programs/hcv/about/fact_sheet.)
measures Section 8 voucher use to encourage PHAs to maximize the number of Section 8 families served. Under this revised indicator, HUD will not only consider the number of vouchers available to a PHA, but also the funds available to the PHA, including budget authority and a portion of reserves. HUD also proposes to assume responsibility for conducting the inspections used to measure a PHA’s compliance with housing quality standards (HQS). Currently, HUD measures HQS compliance through a reporting requirement for PHA self-conducted inspections. The proposed rule would also establish a new deconcentration indicator that will evaluate the ability of Section 8 families with children to access neighborhoods with below-average poverty rates or neighborhoods with above-average schools.

**Priority: Utilize Housing as a Platform for Improving the Quality of Life.**

Stable housing, made possible with HUD support, provides an ideal platform for delivering a wide variety of health and social services to improve health, education, and economic outcomes. HUD housing serves at least two broad populations: People who are in a position to markedly increase their self-sufficiency and people who will need long-term support (for example, the frail elderly and people with severe disabilities). For those individuals who are able, increasing self-sufficiency requires access to life-skills training, wealth-creation and asset-building opportunities, job training, and career services. For those who need long-term support, HUD housing will provide access to income support and other benefits that can enhance an individual’s quality of life.

HUD’s Supportive Housing for Persons with Disabilities Program (Section 811) is a critical HUD program that allows persons with disabilities to live as independently as possible in the community by increasing the supply of rental housing with the availability of supportive services. HUD increases the supply of rental housing for persons with disabilities by providing interest-free capital advances to nonprofit sponsors to help them finance the development of rental housing such as independent living projects, condominium units, and small group homes with the availability of supportive services for persons with disabilities. The capital advance can finance the construction, rehabilitation, or acquisition with or without rehabilitation of supportive housing. The advance does not have to be repaid as long as the housing remains available for very low-income persons with disabilities for at least 40 years. Over the last several years, the Section 811 program has not been as effective as desired because the
The underlying statutory foundation for the program required substantial reform and improvements to meet the challenges of current market conditions and reflect modern practices with respect to production of housing.

The Frank Melville Supportive Housing Investment Act of 2010 (Pub. L. 111-374) (Melville Act), which was enacted on January 4, 2011, amended section 811 of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 8013), which authorizes the supportive housing program for persons with disabilities (Section 811 program). The Melville Act made significant changes to the Section 811 program, with one of the most significant changes being the establishment of new project rental assistance authority. This new authority allows HUD to make Section 811 program operating assistance available to State housing agencies and similar organizations for the purposes of granting funds to the development of supportive housing for persons with disabilities, and overseeing compliance with the requirements applicable to such housing.

**Regulatory Action: Supportive Housing for Persons With Disabilities: Implementing New Project Rental Assistance Authority.**

While the Melville Act makes many important changes to the Section 811 program, HUD’s first priority is to implement the requirements for the new project rental assistance authority. Project rental assistance has long been part of eligible assistance for the Section 811 program, and the existing Section 811 program regulations provide that project rental assistance is available for operating costs. The new project rental assistance provided by the Melville Act offers another method of financing for supportive housing for persons with disabilities for projects that do not receive capital advances. The new project rental assistance is designed to promote and facilitate the creation of integrated supportive housing units, which is achieved by making funds available to State housing agencies and other appropriate entities. As provided by the Melville Act, projects eligible for the new project rental assistance can be either new or existing multifamily housing projects.

HUD’s proposed rule establishes the requirements and procedures that would govern the eligibility and use of the new project rental assistance authority in HUD’s Section 811 program.
Retrospective Review of Agency Regulations

Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review" (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. HUD’s retrospective review plan can be found at:


<table>
<thead>
<tr>
<th>Regulation Identifier Number (RIN)</th>
<th>Title</th>
<th>Anticipated Reductions in Regulatory Burden</th>
</tr>
</thead>
<tbody>
<tr>
<td>2502-AI92</td>
<td>Federal Housing Administration (FHA): Refinancing an Existing Cooperative Under Section 207 Pursuant to Section 223(f) of the National Housing Act; Final Rule</td>
<td>• Removes a regulatory restriction on FHA refinancing of existing mortgage debt by owners of multifamily cooperative projects, thus expanding the number of individuals eligible to participate in FHA programs.</td>
</tr>
</tbody>
</table>
| 2502-AJ03                         | Streamlining Inspection and Warranty Requirements for Federal Housing Administration (FHA) Single Family Mortgage Insurance: Removal of the FHA Inspector Roster and of the 10-Year Protection Plan Requirements for High Loan-to-Value Ratio Mortgages; Proposed Rule | • Removes the regulations for the FHA Inspector Roster, making it easier for lenders and borrowers to have inspections performed and streamlining the mortgage insurance application process.  
  • Removes the outdated 10-year protection plan requirement for high Loan-to-Value newly constructed single family homes securing FHA-insured mortgages. This eliminates an unnecessary layer of regulatory burden. |
<p>| 2502-AI91                         | Approval of Farm Credit System Lending Institutions in FHA Mortgage Insurance Programs; Proposed Rule | • Enables direct lending institutions of the Farm Credit System to seek approval as FHA mortgagees and lenders, removing a regulatory barrier to participation in FHA programs. |</p>
<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
<th>Key Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>2502-AJ06</td>
<td>Expansion of Eligibility of Nonprofit Organizations To Participate in FHA</td>
<td>• Expands roster eligibility to include nonprofit organizations created by State and local governments that qualify for tax exemption under section 115 of the Internal Revenue Code.</td>
</tr>
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<td></td>
<td>Single Family Mortgage Insurance Programs; Proposed Rule</td>
<td>• Removes requirement that a nonprofit organization have a voluntary board in order to be eligible for roster placement.</td>
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<tr>
<td>2502-AJ02</td>
<td>Federal Housing Administration (FHA) Single Family Mortgage Insurance:</td>
<td>• Brings certainty to and streamlines the announced maximum mortgage amounts for each calendar year by removing a regulation that is no longer relevant.</td>
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<td>Removal of Requests for Alternative Mortgage Amounts; Proposed Rule</td>
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<tr>
<td>2502-AI99</td>
<td>Federal Housing Administration (FHA): Suspension of FHA’s Regulation Placing</td>
<td>• Removes permanent time restrictions on resale of FHA-insured properties, thus lifting burdensome regulatory impediments to receiving FHA mortgage insurance.</td>
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<td>Time Restrictions on Resale of FHA-Insured Property; Proposed Rule</td>
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<tr>
<td>2502-AJ01</td>
<td>Federal Housing Administration (FHA): Suspension of Single Family Mortgage</td>
<td>• Removes regulations for an underutilized program, streamlining the application process for FHA-insured</td>
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<td>Insurance for Military Impacted Areas; Proposed Rule</td>
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<tr>
<td>2502-AJ00</td>
<td>Federal Housing Administration (FHA): Approval of Lending Institutions and</td>
<td>• Removes overly burdensome reporting requirements for small lenders wishing to participate in FHA programs.</td>
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<tr>
<td></td>
<td>Mortgagees—Alternative Reporting Requirements for Small Supervised Lenders</td>
<td>• Eliminates duplicative reporting requirements for lenders who already report to other Federal agencies, thus reducing paperwork and minimizing the burden of the process of becoming an FHA-approved.</td>
</tr>
<tr>
<td>2502-AI98</td>
<td>Section 8 New Construction and Substantial Rehabilitation Programs: Changes</td>
<td>• By reducing regulatory barriers, this change removes a disincentive for nonprofit owners to promote affordable housing.</td>
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<td>to Limitation on Distributions of Project Funds and Adjustment of Initial Equity; Proposed Rule</td>
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<tr>
<td>2502-AI67</td>
<td>Streamlining Requirements Governing the Use of Funding for Supportive Housing for</td>
<td>• Removes restrictions on the portions of developments not funded through capital advances.</td>
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<td>the Elderly and Persons With Disabilities Programs; Proposed Rule</td>
<td>• Removes regulatory barriers on participations by creating new exemptions to the conflict of interest provisions.</td>
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</table>
| 2577-AC68 | Public Housing Assessment System (PHAS); Final Rule | • Provides flexibility regarding amenities that may be provided in projects.  
• Streamlines requirements for release of capital advance funds upon completion. |
| 2577-AC50 | Public Housing Capital Fund Program; Final Rule | • Consolidates assessment regulations in 24 CFR part 902.  
• Removes outdated Public Housing Management Assessment Program (PHMAP) regulations at 24 CFR part 901.  
• Streamlines public housing modernization requirements.  
• Consolidates the modernization requirements for the public housing programs in HUD’s Capital Fund Program regulations at 24 CFR part 905.  
• Removes outdated parts 941, 968, 969, which currently codify the legacy modernization program requirements. |
| 2577-AC88 | Streamlined Application Process in Public/Private Partnerships for Mixed-Finance Development of Public Housing Units; Proposed Rule | • Reduces document submission burdens on Public Housing Agencies (PHAs). |
| 2577-AC89 | Revisions to the Consortia of Public Housing Agencies; Proposed Rule | • Enables PHAs to establish cross-jurisdictional consortia that would be treated as a single PHA, with a single jurisdiction and a single set of reporting and audit requirements, for purposes of administering the Housing Choice Voucher program in a more streamlined and less burdensome fashion. |
| 2577-AC87 | Removal of the Indian HOME Investment Partnerships Program Regulations; Final Rule | • Removes outdated regulations for the legacy Indian HOME program. |
| 2577-AC86 | Public Housing and Section 8 Programs: Housing Choice Voucher—Improving Portability for Voucher Families Proposed Rule | • Removes the administrative burdens involved with processing portability requests. |
| 2577-AC76 | Revision to the Section 8 Management Assessment Program (SEMAP) Lease-Up Indicator; Proposed Rule | • Removes complexity and administrative burden caused by use of both the fiscal year and calendar year systems.  
• Provides a critical synchronization of administration of the voucher program, which will reduce program inefficiencies. |
| 2506-AC26 | Implementation of the Homeless Emergency Assistance and Rapid Transition to Housing Act of 2009 (HEARTH Act) | • Provides for consolidated grant application and administration to ease administrative burden and improve coordination among providers and, consequently, increase the effectiveness of responses to the needs of homeless persons.  
• Provides for increased coordination and planning between programs to better meet the needs of homeless persons.  
• Modernizes the Continuum of Care program and Emergency Shelter Grants program. |
| 2501-AC94 | HOME Investment Partnerships—Improving Performance and Accountability; Updating Property Standards and Instituting Energy Efficiency Standards | • This proposed rule would update HUD’s program regulations to reflect current legal requirements with respect to HOME projects. |

**Aggregate Costs and Benefits**

Executive Order 12866, as amended, requires the agency to provide its best estimate of the combined aggregate costs and benefits of all regulations included in the agency's regulatory plan that will be made effective in calendar year 2011. HUD expects that neither the total economic costs nor the total efficiency gains will exceed $100 million. None of the rules on HUD’s regulatory plan is anticipated to have an economically significant impact. The revisions proposed to be made to HUD’s HECM program are anticipated to strengthen the program, keep seniors in their homes, and protect the FHA Insurance Fund, but the proposed changes are prospective and are not expected to result in an economic impact of $100 million or more annually. The changes proposed to be made to the SEMAP program are similarly designed to strengthen the program and are intended to have the Housing Choice Voucher program be administered more effectively and efficiently but will also not result in an economic impact of $100 million.
or more. Implementation of the new project rental assistance authority in the Section 811 program, as authorized by the Melville Act, will open up another source of financing for supportive housing for persons with disabilities but not at a level of $100 million or more.

**The Priority Regulations That Comprise HUD’s Regulatory Plan**

A more detailed description of the priority regulations that comprise HUD’s regulatory plan follows.

<table>
<thead>
<tr>
<th>HUD—Office of Housing (OH)</th>
<th>PROPOSED RULE STAGE</th>
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<tbody>
<tr>
<td><strong>82. FEDERAL HOUSING ADMINISTRATION (FHA): STRENGTHENING THE HOME EQUITY CONVERSION MORTGAGES (HECM) PROGRAM TO PROMOTE SUSTAINED HOMEOWNERSHIP</strong> (FR–5353)</td>
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</table>

**Priority:**

Other Significant

**Legal Authority:**

12 USC 1715b, 1715z to 1720; 42 USC 3535(d)

**CFR Citation:**


**Legal Deadline:**

None

**Abstract:**

HUD is taking another step to reform and strengthen the mortgage insurance functions and responsibilities of the Federal Housing Administration (FHA), and concomitantly protect the individuals and families that use FHA-mortgage products. This proposed rule would revise the regulations governing FHA's Home Equity Conversion Mortgage (HECM) program, which is FHA's reverse mortgage program that enables senior homeowners who have equity in their homes to withdraw a portion of the accumulated equity. Most significantly, this rule proposes to require FHA-approved mortgagees that originate HECM
mortgages (HECM mortgagees) to perform a financial capacity and credit history assessment of prospective HECM mortgagors prior to loan approval and closing. Mortgagees will be required to evaluate whether the HECM mortgagor's cash flow and credit history support the mortgagor's ability to comply with the obligations of the HECM and are sufficient to meet recurring living expenses. A mortgagee may deny the HECM loan application if the prospective mortgagor fails either the financial capacity or credit history assessment. As an alternative to declining the HECM loan application, the mortgagee may require the establishment of a principal limit set-aside for payment of property charges. The proposed rule would also cap the amount of insurance benefits paid in connection with a claim involving amounts advanced by the mortgagee on behalf of a HECM mortgagor who fails to pay such property charges when the HECM proceeds have been exhausted and establish a new property inspection requirement to insure that home secured with a HECM mortgage are adequately maintained and meet applicable property standards. The proposed rule would also make several non-substantive changes to reflect the statutory flexibility provided to HUD in establishing the mortgage insurance premiums for FHA-insured mortgages, conform the regulations to existing HUD interpretations and industry practices regarding HECM program requirements, and reduce administrative paperwork.

**Statement of Need:**

HUD does not currently require HECM mortgagees to verify the mortgagor's income, assets, and debt obligations. Neither do the HECM regulations require a mortgagee to assess the mortgagor's credit history and capacity to pay future living expenses and meet all other future financial obligations related to the property under the HECM loan. Such a financial capacity and credit history assessment is a prudent underwriting practice currently required by mortgagees for FHA forward mortgage products. Based on data available to HUD, HECM delinquencies are growing and occurring soon after origination. This data also indicates that these delinquencies are largely the result of the failure of mortgagors to pay recurring property charges. The proposed rule would address these concerns by requiring that mortgagees determine whether the potential mortgagor has the capacity to pay recurring property charges and meet recurring living expenses.

**Summary of Legal Basis:**
The HECM program is authorized under section 255 of the National Housing Act (12 U.S.C. 1715z to 1720). This rulemaking is undertaken pursuant to the general rulemaking authority granted to the Secretary under section 7(d) of the Department of HUD Act (42 U.S.C. 35335(d)), which authorizes the Secretary to make "such rules and regulations as may be necessary to carry out his functions, powers, and duties." In addition, the National Housing Act at 12 U.S.C. 1701c(a) uses the exact wording in conferring general rulemaking authority to the Secretary for implementing the insured mortgage programs authorized under the National Housing Act.

**Alternatives:**

Rulemaking is required to ensure that the financial capacity and credit history requirements are generally applicable and enforceable by HUD. Where appropriate, HUD will provide mortgagees with flexibility in determining the method for conducting the required assessments and for considering additional factors in determining and verifying the financial capacity and credit history of prospective HECM mortgagors.

**Anticipated Cost and Benefits:**

The benefits of this rule would be the reduced transaction costs and externalities associated with foreclosure. The costs of the rule would be the additional administrative and financial costs associated with carrying out the required assessments.

**Risks:**

This rule poses no risk to public health, safety, or the environment.

**Timetable:**

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<td>NPRM</td>
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Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

Agency Contact:
This proposed rule commences the rulemaking process to implement the project rental assistance authority as provided under the Frank Melville Supportive Housing Investment Act of 2010 (Pub. L. 111-374) (Melville Act), which was enacted on January 4, 2011. The Melville Act amended section 811 of the Cranston-Gonzalez National Affordable Housing Act (42 U.S.C. 8013), which authorizes the supportive housing program for persons with disabilities (Section 811 program). The Melville Act made significant changes to the Section 811 program, with one of the most significant changes being the establishment of
new project rental assistance authority. This new authority allows HUD to make Section 811 program operating assistance available to State housing agencies and similar organizations for the purposes of granting funds to the development of supportive housing for persons with disabilities and overseeing compliance with the requirements applicable to such housing. This proposed rule establishes the requirements and procedures that would govern the eligibility and use of project rental assistance in HUD's supportive housing program for persons with disabilities.

**Statement of Need:**

The Melville Act makes many important reforms and improvements to the Section 811 program. One of the most significant new features introduced by the Melville Act is the establishment of new project rental assistance authority (section 811(b)(3) of the Cranston-Gonzalez National Affordable Housing Act, as amended by the Melville Act) that is separate from the existing project rental assistance under the Section 811 program that is available to cover operating costs. Although the Melville Act establishes the prerequisite statutory framework, the full and successful implementation of the new project rental assistance authority requires rulemaking. This proposed rule addresses the need for rulemaking by establishing the necessary policies, procedures, and other requirements that will govern the eligibility and use of project rental assistance. HUD intends to implement other changes made by the Melville Act through separate rulemaking.

**Summary of Legal Basis:**

As noted, the Melville Act amended section 811 of the Cranston-Gonzalez National Affordable Housing Act to establish new project rental assistance authority. This rulemaking is undertaken pursuant to the general rulemaking authority granted to the Secretary under section 7(d) of the Department of HUD Act (42 U.S.C. 35335(d)), which authorizes the Secretary to make “such rules and regulations as may be necessary to carry out his functions, powers, and duties.”

**Alternatives:**

Rulemaking is required to ensure that the new requirements and procedures governing the eligibility and use of project rental assistance are generally applicable to participants in HUD's supportive housing program for persons with disabilities and enforceable by HUD.

**Anticipated Cost and Benefits:**
The new project rental assistance authority offers another method of financing for supportive housing for persons with disabilities for projects that do not receive capital advances. The new authority is designed to promote and facilitate the creation of integrated supportive housing units, which is achieved by making funds available to State housing agencies and other appropriate entities. While there may be incremental costs associated with compliance with the new requirements, to the extent that program participants incur such costs, it will be as a result of their voluntary participation in the project rental assistance component of the Section 811 program. The benefits are increased affordability of providing housing for persons with disabilities.

**Risks:**

This rule poses no risk to public health, safety, or the environment

**Timetable:**

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<tr>
<td>NPRM</td>
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</table>

**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Agency Contact:**

Benjamin T. Metcalf
Senior Advisor, Office of Multifamily Housing Programs
Department of Housing and Urban Development
Office of Housing
451 7th Street SW
Washington, DC 20410
Phone: 202 708–2495

**RIN:** 2502–AJ10
84. TENANT–BASED RENTAL ASSISTANCE; IMPROVING PERFORMANCE THROUGH A
STRENGTHENED SECTION 8 MANAGEMENT ASSESSMENT PROGRAM (FR–5201)

Priority:
Other Significant

Legal Authority:
42 USC 1437a, 1437c, 1437f; 42 USC 3535(d)

CFR Citation:
24 CFR 985

Legal Deadline:
None

Abstract:
SEMAP establishes the management indicators used by HUD to measure the performance of public
housing agencies (PHA) in key areas of the Section 8 rental assistance programs and to assign
performance ratings. The proposed rule would revise the indicator that measures Section 8 voucher use
to encourage PHAs to maximize the number of Section 8 families served. Specifically, under this revised
indicator, HUD will not only consider the number of vouchers available to a PHA, but also the funds
available to the PHA, including budget authority and a portion of reserves. HUD also proposes to assume
responsibility for conducting the inspections used to measure a PHA's compliance with housing quality
standards (HQS). Currently, HUD measures HQS compliance through a reporting requirement for PHA
self-conducted inspections. The proposed rule would also establish a new deconcentration indicator that
will evaluate the ability of Section 8 families with children to access neighborhoods with below-average
poverty rates or neighborhoods with above-average schools.

Statement of Need:
While the SEMAP is currently an effective oversight tool, HUD's experience indicates that modifications
are needed to increase its utility and to better reflect policy priorities. The proposed regulatory
amendments address these needs. For example, the change to the voucher utilization indicator will allow HUD to better assess whether PHAs are maximizing their use of available voucher authority and funds to assist families. By assuming responsibility for HQS inspections, HUD will be in a better position to assess their quality and accuracy. The new deconcentration indicator addresses one of HUD's highest priorities; namely, improving the housing and educational opportunities afforded to families receiving HUD assistance.

**Summary of Legal Basis:**

The Section 8 rental assistance programs are authorized under section 8 of the United States Housing Act of 1937 (42 U.S.C. 1437f). This rulemaking is undertaken pursuant to the general rulemaking authority granted to the Secretary under section 7(d) of the Department of HUD Act (42 U.S.C. 35335(d)), which authorizes the Secretary to make “such rules and regulations as may be necessary to carry out his functions, powers, and duties.”

**Alternatives:**

Rulemaking is required to ensure that revised SEMAP indicators are generally applicable to all PHAs administering Section 8 programs, and are enforceable by HUD. Moreover, the current SEMAP requirements are codified in regulation and, therefore, notice and comment rulemaking is required for their revision.

**Anticipated Cost and Benefits:**

There may be some incremental administrative costs borne by PHAs as a result of revised indicators. The benefits are the cost savings of no longer having to conduct HQS inspections, resulting in a net economic benefit. HUD will assume the costs of conducting these inspections, but these costs will be balanced by the management and operational benefits resulting from the proposed SEMAP enhancements. Moreover, HUD is considering whether HQS inspections should be conducted less frequently than on an annual basis, in order to allow for the best use of departmental resources.

**Risks:**

This rule poses no risk to public health, safety, or the environment.

**Timetable:**

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Statement of Regulatory Priorities

The Department of the Interior (DOI) is the principal Federal steward of our Nation’s public lands and resources, including many of our cultural treasures. DOI serves as trustee to Native Americans and Alaska natives and is responsible for relations with the island territories under United States jurisdiction. The Department manages more than 500 million acres of Federal lands, including 397 park units, 555 wildlife refuges, and approximately 1.7 billion of submerged offshore acres. This includes some of the highest quality renewable energy resources available to help the United States achieve the President’s goal of energy independence, including geothermal, solar, and wind.
The Department protects and recovers endangered species; protects natural, historic, and cultural resources; manages water projects that are a lifeline and economic engine for many communities in the West; manages forests and fights wildfires; manages Federal energy resources; regulates surface coal mining operations; reclaims abandoned coal mines; educates children in Indian schools; and provides recreational opportunities for over 400 million visitors annually in the Nation’s national parks, public lands, national wildlife refuges, and recreation areas.

The DOI will continue to review and update its regulations and policies to ensure that they are effective and efficient, and that they promote accountability and sustainability. The DOI will emphasize regulations and policies that:

- Promote environmentally responsible, safe, and balanced development of renewable and conventional energy on our public lands and the Outer Continental Shelf (OCS);

- Use the best available science to ensure that public resources are protected, conserved, and used wisely;

- Adopt performance approaches focused on achieving cost-effective, timely results;

- Improve the nation-to-nation relationship with American Indian tribes;

- Promote partnerships with States, tribes, local governments, other groups, and individuals to achieve common goals;

- Promote transparency, fairness, accountability, and the highest ethical standards while maintaining performance goals.
Major Regulatory Areas

The DOI bureaus implement congressionally mandated programs through their regulations. Some of these regulatory programs include:

- Developing onshore and offshore energy, including renewable, minerals, oil and gas, and other energy resources;
- Regulating surface coal mining and reclamation operations on public and private lands;
- Managing migratory birds and preserving marine mammals and endangered species;
- Managing dedicated lands, such as national parks, wildlife refuges, National Landscape Conservation System lands, and American Indian trust lands;
- Managing public lands open to multiple use;
- Managing revenues from American Indian and Federal minerals;
- Fulfilling trust and other responsibilities pertaining to American Indians;
- Managing natural resource damage assessments; and
- Managing assistance programs.

Regulatory Policy
How DOI regulatory priorities support the President’s energy, resource management, environmental sustainability, and economic recovery goals

The DOI's regulatory programs seek to operate programs transparently, efficiently, and cooperatively while maximizing protection of our land, resources, and environment in a fiscally responsible way by:

(1) Protecting Natural, Cultural, and Heritage Resources.

The Department's mission includes protecting and providing access to our Nation's natural and cultural heritage and honoring our trust responsibilities to tribes. We are committed to this mission and to applying laws and regulations fairly and effectively. Our priorities include protecting public health and safety, restoring and maintaining public lands, protecting threatened and endangered species, ameliorating land- and resource-management problems on public lands, and ensuring accountability and compliance with Federal laws and regulations.

The Bureau of Land Management (BLM) Wildlife Program continues to focus on maintaining and managing wildlife habitat to ensure self-sustaining populations and a natural abundance and diversity of wildlife resources on public lands. The BLM-managed lands are vital to game species and hundreds of species of non-game mammals, reptiles, and amphibians. In order to provide for long-term protection of wildlife resources, especially given other mandated land use requirements, the Wildlife Program supports aggressive habitat conservation and restoration activities, many funded by partnerships with Federal, State, and non-governmental organizations. For instance, the Wildlife Program is restoring wildlife habitat across a multi-state region to support species that depend upon sagebrush vegetation. Projects are tailored to address regional issues such as fire (as in the western portion of the sagebrush biome) or habitat degradation and loss (as in the eastern portion of the sagebrush biome). Additionally, BLM undertakes habitat improvement projects in partnership with a variety of stakeholders and consistent with State fish and game wildlife action plans and local working group plans.
The National Park Service (NPS) is working with BLM and the U.S. Fish and Wildlife Service (FWS) to finalize a rule implementing Public Law 106-206, which directs the Secretary to establish a system of location fees for commercial filming and still photography activities on public lands. While commercial filming and still photography are generally allowed on Federal lands, managing this activity through a permitting process will minimize damage to cultural or natural resources and interference with other visitors to the area. This regulation would standardize location fee rates and collection for all DOI agencies.

The NPS is proposing a new winter use rule for Yellowstone National Park. This rule is proposed to replace an interim rule that expired at the end of the 2010 to 2011 winter season and that was recently reauthorized for the current (2011-2012) winter season. It would allow a variety of winter uses for visitors while protecting park resources by establishing maximum numbers of snowmobiles and snowcoaches permitted in the Park on a given day. It would also require most snowmobiles and snowcoaches operating in the Park to meet air and sound emission requirements and would require a commercial guide. The NPS intends to publish a final rule by mid-November 2012.

The NPS is prepared to publish final rules for Off Road Vehicle use at Cape Hatteras National Seashore and bicycle routes at Mammoth Cave National Park. Proposed rules for bicycle routes are pending for other park areas. These rules would manage use to protect and preserve natural and cultural resources, and natural processes, and provide a variety of safe visitor experiences while minimizing conflicts among various users.

(2) Sustainably Using Energy, Water, and Natural Resources.

The BLM has identified approximately 20.6 million acres of public land with wind energy potential in the 11 western States and approximately 29.5 million acres with solar energy potential in the six southwestern States. There are over 140 million acres of public land in western States and Alaska with geothermal resource potential. There is also significant wind and wave potential in our offshore waters.
The National Renewable Energy Lab, a Department of Energy national laboratory, has identified more than 1,000 gigawatts of wind potential off the Atlantic coast—roughly equivalent to the Nation’s existing installed electric generating capacity—and more than 900 gigawatts of wind potential off the Pacific Coast. Because public lands are extensive and widely distributed, the Department has an important role, in consultation with Federal, State, regional, and local authorities, in approving and building new transmission lines that are crucial to deliver renewable energy to America’s homes and businesses.

Since the beginning of the Obama Administration, the Department has focused on renewable energy issues and has established priorities for environmentally responsible development of renewable energy on public lands and the OCS. Industry has started to respond by investing in development of wind farms off the Atlantic seacoast and solar, wind, and geothermal energy facilities throughout the west. Power generation from these new energy sources produces virtually no greenhouse gases and, when done in an environmentally sensitive manner, harnesses with minimum impact abundant renewable energy that nature itself provides. The Department will continue its intra- and inter-departmental efforts to move forward with the environmentally responsible review and permitting of renewable energy projects on public lands.

The Secretary issued his first Secretarial Order on March 11, 2009, making renewable energy on public lands and the OCS top priorities at the Department. These remain top priorities. In implementing these priorities through its regulations, the Department will continue to create jobs and contribute to a healthy economy while protecting our signature landscapes, natural resources, wildlife, and cultural resources.

(3) Empowering People and Communities.

The Department strongly encourages public participation in the regulatory process. For example, every year the FWS establishes migratory bird hunting seasons in partnership with flyway councils composed of State fish and wildlife agencies. The FWS also holds a series of public meetings to give
other interested parties, including hunters and other groups, opportunities to participate in establishing the upcoming season's regulations.

Similarly, the BLM uses Resource Advisory Councils made up of affected parties to help prepare land management plans and regulations.

The NPS has begun revising its rules on non-Federal development of gas and oil in units of the National Park System. Of the approximately 700 gas and oil wells in 13 NPS units, 55 percent, or 385 wells, are exempt from current regulations. The NPS is revising the regulations to improve protection of NPS resources. The NPS actively sought public input into designing the rule and published an Advance Notice of Proposed Rulemaking with a comment period from November 15, 2009, through January 25, 2010. Interested members of the public were able to make suggestions for the content of the rule, which NPS will consider in writing the proposed rule. After developing a proposed rule, NPS will solicit further public comment. The NPS expects to publish a proposed rule in 2012.

In October 2010, NPS published an interim final rule with request for comments revising the former regulations for management of demonstrations and the sale or distribution of printed matter in most areas of the National Park System to allow a small-group exception to permit requirements. In essence, under specific criteria, demonstrations, and the sale or distribution of printed matter involving 25 or fewer persons may be held in designated areas, without first obtaining a permit; i.e. making it easier for individuals and small groups to express their views. The NPS has analyzed the comments and expects to publish a final rule in early 2012.

**Retrospective Review of Regulations**

President Obama’s Executive Order 13563 directs agencies to make the regulatory system work better for the American public. Regulations should “…protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.” DOI’s
plan for retrospective regulatory review identifies specific efforts to relieve regulatory burdens, add jobs to
the economy, and make regulations work better for the American public while protecting our environment
and resources. The DOI plan seeks to strengthen and maintain a culture of retrospective review by
consolidating all regulatory review requirements\(^1\) into DOI’s annual regulatory plan. DOI has selected the
following regulatory efforts to focus on over the next 2 years:

- **Oil and Gas Royalty Valuation Rules (Office of Natural Resources Revenue)**–DOI is
  exploring a simplified market-based approach to arrive at the value of oil and gas for royalty
  purposes that could dramatically reduce accounting and paperwork requirements and costs
  on industry and better ensure proper royalty valuation by creating a more transparent royalty
  calculation method.

- **Endangered Species Act Rules (Fish and Wildlife Service)**–The Fish and Wildlife Service (FWS),
  working in conjunction with the National Marine Fisheries Service, will revise and update the ESA
  implementing regulations and policies to improve conservation effectiveness, reduce administrative
  burden, enhance clarity and consistency for impacted stakeholders and agency staff, and encourage
  partnerships, innovation, and cooperation. FWS has already proposed a rule on May 17, 2011, that
  would minimize the requirements for written descriptions of critical habitat boundaries in favor of map
  and Internet-based descriptions. FWS anticipates issuing the final rule in the spring of 2012.
  Additionally, FWS will develop proposed rules and/or policies to amend existing regulations related to:
  - Habitat conservation plans;
  - Safe harbor agreements;
  - Candidate conservation agreements;
  - The process and procedures for designation of critical habitat;

\(^1\) DOI conducts regulatory review under numerous statutes, Executive orders, memoranda, and policies, including but
not limited to the Regulatory Flexibility Act of 1980 (RFA), the Small Business Regulatory Enforcement Fairness Act
- Section 7 consultation to revise the definition of “destruction or adverse modification” of critical habitat; and
- Issuance of incidental take permits during section 7 consultation.

- **Commercial Filming on Public Land Rules**—This joint effort between the National Park Service (NPS), Fish and Wildlife Service (FWS), Bureau of Land Management (BLM), Bureau of Reclamation (BOR), and Bureau of Indian Affairs (BIA) will create consistent regulations and a unified fee schedule for commercial filming and still photography on public land. It will provide the commercial filming industry with a predictable fee for using Federal lands, while earning the Government a fair return for the use of that land.

- **Offshore Energy Safety and Environmental Rules (BSEE)**—In the wake of the Deepwater Horizon oil spill, DOI immediately instituted regulatory reforms that strengthened the protection of workers’ health and safety and enhanced environmental safeguards. The Bureau of Safety and Environmental Enforcement (BSEE), formerly part of the Bureau of Ocean Energy Management, Regulation, and Enforcement (BOEMRE) is now considering ways to apply “safety case”-type performance standards, such as those widely applied internationally, to the U.S. offshore drilling regulatory regime. A hybrid combination of performance-based and prescriptive standards will provide flexibility to adapt to changing technologies and increasingly complex operational conditions, while maintaining worker and environmental protections.

- **Leasing (BIA)**—BIA is amending its leasing regulations to eliminate the need to follow multiple cross-references in the regulations. The amendments will also delete the requirement for BIA review of permits, which some view as unjustified and excessively burdensome.
• *Land Classification Regulations (BLM)*—BLM is amending its regulations to remove obsolete land classification regulations and consolidate these regulations into the existing planning system regulations. These changes will benefit the public by consolidating all land use decisions into one systematic process.

DOI bureaus work to make our regulations easier to comply with and understand. Our regulatory process ensures that bureaus share ideas on how to reduce regulatory burdens while meeting the requirements of the laws they enforce and improving their stewardship of the environment and resources. Results include:

• Effective stewardship of our Nation’s resources in a way that is responsive to the needs of small businesses;

• Increased benefits per dollars spent by carefully evaluating the economic effects of planned rules; and

• Improved compliance and transparency by use of plain language in our regulations and guidance documents.

**Bureaus and Offices Within DOI**

The focus of DOI’s major regulatory bureaus and offices is summarized below.
The Bureau of Indian Affairs (BIA) administers and manages 56 million acres of land held in trust by the United States for Indians and Indian tribes, providing services to approximately 1.9 million Indians and Alaska Natives, and maintaining a government-to-government relationship with the 565 federally recognized Indian tribes. The BIA’s mission is to enhance the quality of life, to promote economic opportunity, and to carry out the responsibility to protect and improve the trust assets of American Indians, Indian tribes, and Alaska Natives, as well as to provide quality education opportunities to students in Indian schools.

In the coming year, BIA will continue its regulatory focus on improved management of trust responsibilities and promotion of economic development in Indian communities. In addition, BIA will focus on updating Indian education regulations and on other regulatory changes to increase transparency in support of the President’s Open Government Initiative.

With the input of tribal leaders, individual Indian beneficiaries, and other subject matter experts, BIA has been examining better ways to serve its beneficiaries. The American Indian Probate Reform Act of 2004 (AIPRA) made clear that regulatory changes were necessary. BIA has promulgated regulations implementing the probate-related provisions of AIPRA and will now focus on regulations to implement other AIPRA provisions related to managing Indian land.

The focus on promoting economic development in Indian communities is a core component of BIA’s mission. Economic development initiatives can attract businesses to Indian communities that provide jobs and fund services that support the health and well-being of tribal members. Economic development can enable tribes to attain self-sufficiency, strengthen their governments, and reduce crime.
Indian education is a top priority of the Assistant Secretary for Indian Affairs. BIA will review Indian education regulations to ensure that they adequately support efforts to provide students of BIA-funded schools with the best education possible.

Finally, BIA’s regulatory focus on increasing transparency implements the President’s Open Government Initiative. BIA will ensure that all regulations that it drafts or revises meet high standards of readability and accurately and clearly describe BIA processes.

BIA’s regulatory priorities are to:

- Develop regulations to meet the Indian trust reform goals for land consolidation and land use management.

BIA is amending regulations affecting land title and records, conveyances of trust or restricted land, leasing, grazing, trespass, rights-of-way, and energy and minerals. These regulatory changes will help the Department better serve beneficiaries and will standardize procedures for consistent execution of fiduciary responsibilities across the BIA.

- Identify and develop regulatory changes necessary for improved Indian education.

BIA is reviewing regulations addressing grants to tribally controlled community colleges and other Indian education regulations. The review will identify provisions that need to be updated to comply with applicable statutes and ensure that the proper regulatory framework is in place to support students of Bureau-funded schools.

- Develop regulatory changes to reform the process for Federal acknowledgment of Indian tribes.
Over the years, BIA has received significant comments from American Indian groups and members of Congress on the Federal acknowledgment process. Most of these comments claim that the current process is cumbersome and overly restrictive. The BIA is reviewing the Federal acknowledgment regulations to determine if any regulatory changes are appropriate.

- Revise regulations governing administrative appeals and other processes to increase transparency.

The BIA is making a concentrated effort to improve the readability and precision of its regulations. Because trust beneficiaries often turn to the regulations for guidance on how a given BIA process works, BIA is ensuring that each revised regulation is written as clearly as possible and accurately reflects the current organization of the Bureau. A few of the regulations BIA will be focusing this effort on include the regulation governing administrative appeals (25 CFR part 2), the land use management regulations mentioned above, and regulations addressing various Indian services.

The Bureau of Land Management

The BLM manages the 245-million-acre National System of Public Lands, located primarily in the western States, including Alaska, and the 700-million-acre subsurface mineral estate located throughout the Nation. BLM’s complex multiple-use mission affects the lives of a great number of Americans, including those who live near and visit the public lands, as well as millions of Americans who benefit from commodities, such as minerals, energy, or timber, produced from the lands’ rich resources.

The BLM’s multiple-use mission conserves the lands’ natural and cultural resources and sustains the health and productivity of the public lands for the use and enjoyment of present and future generations. The BLM manages such varied uses as energy and mineral development, outdoor recreation, livestock grazing, and forestry and woodlands products.

The BLM has identified the following three areas of regulatory priorities.
The summaries that follow explain how these three areas promote the BLM mission and the priorities of the Department.

Energy Independence

BLM manages more Federal land than any other agency—more than 245 million surface acres and 700 million subsurface acres of mineral estate. Thus, it plays a key role in ensuring that the Nation’s energy needs are met by managing both Federal renewable and non-renewable sources of energy. The BLM is analyzing proposals for increasing renewable energy development on public lands. The BLM will manage these proposals to assure they proceed in an environmentally and fiscally sound way that protects our natural resources and critical wildlife habitat for such species as the sage grouse and lynx. These projects will create environmentally friendly jobs and help sustain the quality of life that Americans enjoy today.

Another BLM priority is siting and authorizing transmission corridors to assist the national effort to move renewable energy from production sites to market. The BLM has already designated more than 5,000 miles of energy transport corridors. The BLM will authorize rights-of-way across public lands through these energy transport corridors to allow development of transmission lines.
Treasured Landscapes

Protecting the landscapes of the National System of Public Lands involves numerous BLM programs as the agency moves toward a holistic, landscape-level approach to managing multiple public land uses. The BLM also engages partners interested in working on a broader scale across jurisdictional lines to achieve a common landscape vision. For the past several years, BLM, which manages the largest amount and the greatest diversity of fish and wildlife habitat of any Federal agency, has focused on restoring healthy landscapes in a number of ways, including:

- Reducing the number of wild horses and burros on public lands, particularly in areas most affected by drought and wildfire. Maintaining the wild horse and burro population at appropriate management levels is critical in the effort to conserve forage resources that also sustain native wildlife and livestock.
- Restoring habitat for sensitive, rare, threatened, and endangered species, such as sage grouse, desert tortoise, and salmon.
- Supporting greater biodiversity through noxious weed and invasive species treatments to bring back native plants.
- Improving water quality by restoring riparian areas and protecting watersheds. Enhanced water quality aids in the restoration of habitat for fish and other aquatic and riparian species.
- Conducting post-fire recovery efforts to promote healthy landscapes and discourage the spread of invasive species.

Native American Nations

BLM consults with Indian tribes on a government-to-government basis under multiple authorities and is continually working to assess and improve its tribal consultation practices. The BLM held listening sessions throughout the West on this important issue in 2009 and 2010 and received many valuable
BLM has continued its efforts to improve its tribal consultation practices by participating with the Department in multiple listening sessions with tribes throughout the country.

The Native American Graves Protection and Repatriation Act (NAGPRA), enacted in 1990, addresses the rights of lineal descendants, Indian tribes, and Native Hawaiian organizations to certain Native American human remains, funerary objects, associated funerary objects, sacred objects, and objects of cultural patrimony with which they are affiliated. The statute and implementing regulations represent a careful balance between the legitimate interests of lineal descendants, Indian tribes, and Native Hawaiian organizations to control the remains of their ancestors and cultural property and the legitimate public interests in scientific and educational information associated with the human remains and cultural items.

BLM is complying with the new NAGPRA regulations, including inventorying and repatriating human remains and other cultural items that are in BLM museum collections. BLM also consults with Indian tribes on implementing appropriate actions when human remains and other cultural items subject to NAGPRA are inadvertently discovered or intentionally excavated on the public lands.

Additionally, BLM, in cooperation with the Bureau of Indian Affairs, helps tribes and individual Indian allottees develop their solid and fluid mineral resources. BLM is responsible for development, product measurement, and inspection and enforcement of extracting operations of the mineral estate on trust properties.

BLM’s Regulatory Priorities

The BLM’s regulatory focus is directed primarily by the priorities of the President and Congress, which include:

- Generating jobs and promoting a healthy economy by facilitating domestic production of various sources of energy, including biomass, wind, solar, and other alternative sources.
- Providing for a wide variety of public uses while maintaining the long-term health and diversity of the land.
• Preserving significant natural, cultural, and historic resource values.

• Understanding the arid, semi-arid, arctic, and other ecosystems that BLM manages.

• Using the best scientific and technical information to make resource management decisions.

• Understanding the needs of the people who use and enjoy BLM-managed public lands and providing them with quality service.

• Securing the recovery of a fair return for using publicly owned resources, and avoiding the creation of long-term liabilities for American taxpayers.

• Resolving problems and implementing decisions in cooperation with other agencies, states, tribal governments, and the public.

In developing regulations, BLM recognizes the need to ensure communication, coordination, and consultation with the public, including affected interests, tribes, and other stakeholders. BLM also works to draft regulations that are easy for the public to understand and that provide clarity to those most affected by them.

The BLM’s specific regulatory priorities include:

• Revising onshore oil and gas operating standards.

The BLM expects to publish rules to revise several existing onshore oil and gas operating orders and propose one new onshore order. Onshore orders establish requirements and minimum standards and provide standard operating procedures. The orders are binding on operating rights owners and operators of Federal and Indian (except the Osage Nation) oil and gas leases and on all wells and facilities on state or private lands committed to Federal agreements. The BLM is responsible for ensuring that oil or gas produced and sold from Federal or Indian leases is accurately measured for quantity and quality. The volume and quality of oil or gas sold from leases is key to determining the proper royalty to be paid by the lessee to the Office of Natural Resources Revenue. Existing
Onshore Orders Number 3, 4, and 5 would be revised to use new industry standards so that they reflect current operating procedures and to require that proper verification and accounting practices are used consistently. New Onshore Order Number 9 would cover waste prevention and beneficial use. The revisions would ensure that proper royalties are paid on oil and gas removed from Federal and Trust lands.

- Revising coal-management regulations.

The BLM plans to publish a proposed rule to amend the coal-management regulations that pertain to the administration of Federal coal leases and logical mining units. The rule would primarily implement provisions of the Energy Policy Act of 2005 that pertain to administering coal leases. The rule also would clarify the royalty rate applicable to continuous highwall mining, a new coal-mining method in use on some Federal coal leases.

- Publishing rules on paleontological resources preservation.

The 2009 omnibus public lands law included provisions on permitting for the collection of paleontological resources. The BLM and the National Park Service are co-leads of a team with the U.S. Forest Service that will be drafting a paleontological resources rule. The rule would address the protection of paleontological resources and how BLM would permit the collection of these resources. The rule would also address other issues such as administering permits, casual collection of rocks and minerals, hobby collection of common invertebrate plants and fossils, and civil and criminal penalties for violation of these rules.

- Amending rules on royalty rate increases for new Federal Onshore Competitive Oil and Gas Leases.
The BLM will consider amending its oil and gas regulations to set higher royalty rates for new Federal onshore competitive oil and gas leases issued on or after the effective date of the rule. This rule would revise existing regulations by increasing royalty rates based on the options set out in the proposed rule.

*The Bureau of Ocean Energy Management, Regulation, and Enforcement*

The Bureau of Ocean Energy Management, Regulation, and Enforcement (BOEMRE) replaced the former Minerals Management Service (MMS). On October 1, 2011, BOEMRE was reorganized and divided into two new Bureaus, under the Assistant Secretary for Land and Minerals Management:

1) The Bureau of Ocean Energy Management (BOEM) now functions as the resource manager for the conventional and renewable energy and mineral resources on the OCS. It fosters environmentally responsible and appropriate development of the OCS for both conventional and renewable energy and mineral resources in an efficient and effective manner that ensures fair market value for the rights conveyed.

2) The Bureau of Safety and Environmental Enforcement (BSEE) applies independent regulation, oversight, and enforcement powers to promote and enforce safety in offshore energy exploration and production operations and ensure that potentially negative environmental impacts on marine ecosystems and coastal communities are appropriately considered and mitigated.

Our regulatory focus for fiscal year 2012 is directed by Presidential and legislative priorities that emphasize contributing to America’s energy supply, protecting the environment, and ensuring a fair return for taxpayers for energy production from Federal and Indian lands.
BOEM's regulatory priorities are to:

- Finalize Regulations for Leasing of Sulphur or Oil and Gas and Bonding Requirements in the Outer Continental Shelf

This final rule updates and streamlines the existing OCS leasing regulations and clarifies implementation of the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996. This final rule reorganizes leasing requirements to communicate more effectively the leasing process, as it has evolved over the years. This final rule makes changes to 30 CFR parts 250, 256, and 260 that relate to the oil and gas leasing and bonding requirements.

BSEE’s regulatory priorities are to:

- Establish Additional Requirements for Safety Measures for Drilling and Other Well Operations for Oil and Gas

This will be an Advance Notice of Proposed Rulemaking to address recommendations from the “Increased Safety Measures for Energy Development on the Outer Continental Shelf” report that were not covered by an Interim Final Rule BOEMRE, BSEE’s predecessor, published on October 14, 2010. The safety measures recommendations include additional requirements for blowout preventers, remotely operated vehicles, secondary control systems, and cement evaluation techniques. Detailed responses to the questions and ideas posed in this Advance Notice of Proposed Rulemaking would allow BSEE to develop more comprehensive regulations, if needed, and have a better understanding of the impacts.

- Revise Regulations on Safety and Environmental Management Programs for Offshore Operations and Facilities
This rulemaking proposes to revise 30 CFR part 250 (subpart S) regulations to require operators to develop and implement additional provisions in their Safety and Environmental Management Systems (SEMS) programs for oil, gas, and sulphur operations in the Outer Continental Shelf (OCS). These revisions pertain to developing and implementing: (1) Stop work authority, (2) ultimate work authority, (3) requiring employee participation in the development and implementation of SEMS programs, and (4) establishing requirements for reporting unsafe working conditions. In addition, this proposed rule (5) requires independent third parties to conduct audits of operators’ SEMS programs and (6) establishes further requirements relating to conducting job safety analyses (JSA) for activities identified in an operator’s SEMS program. BSEE believes that these new requirements will further reduce the likelihood of accidents, injuries, and spills in connection with OCS activities, by requiring OCS operators to specifically address issues associated with human behavior as it applies to their SEMS program.

- Develop additional rules and regulations as a result of ongoing reviews of BSEE’s offshore regulatory regime

Several investigations and reviews of BOEMRE, now BSEE, have been and are being conducted by various agencies and entities—including the Safety Oversight Board, the Office of Inspector General, the President’s Deepwater Horizon Commission, the National Academy of Engineering, and the joint BOEMRE/United States Coast Guard (USCG) investigation of Deepwater Horizon. Some of these investigations and reviews focus narrowly on the Deepwater Horizon explosion; others are broader in focus and include many aspects of the current regulatory system. BSEE expects that recommendations for regulatory changes—both substantive and procedural—will be generated by these investigations and reviews, and will need to be reviewed, analyzed, and potentially incorporated in new or modified regulations. The Secretary established the Ocean Energy Safety Advisory Committee to provide advice on matters related to drilling and workplace safety, and spill containment and response. This Committee is expected to make recommendations for new or modified regulations.
Office of Natural Resources Revenue

The revenue responsibilities of the former MMS now are located in the Office of Natural Resources Revenue (ONRR), which will continue to collect, account for, and disburse revenues from Federal offshore energy and mineral leases and from onshore mineral leases on Federal and Indian lands. The program operates nationwide and is primarily responsible for timely and accurate collection, distribution, and accounting for revenues associated with mineral and energy production. The regulatory program of ONRR seeks to:

- Simplify valuation regulations

ONRR plans to simplify the regulations at 30 CFR part 1206 for establishing the value for royalty purposes of (1) oil and natural gas produced from Federal leases; and (2) coal and geothermal resources produced from Federal and Indian leases. Additionally, the proposed rules would consolidate sections of the regulations common to all minerals, such as definitions and instructions regarding how a payor should request a valuation determination. ONRR published Advance Notices of Proposed Rulemaking (ANPRMs) to initiate the rulemaking process and to obtain input from interested parties.

- Finalize debt collection regulations

ONRR is preparing regulations governing collection of delinquent royalties, rentals, bonuses, and other amounts due under Federal and Indian oil, gas, and other mineral leases. The regulations would include provisions for administrative offset and would clarify and codify the provisions of the Debt Collection Act of 1982 and the Debt Collection Improvement Act of 1996.

- Continue to meet Indian trust responsibilities
ONRR has a trust responsibility to accurately collect and disburse oil and gas royalties on Indian lands. ONRR will increase royalty certainty by addressing oil valuation for Indian lands through a negotiated rulemaking process involving key stakeholders.

Office of Surface Mining Reclamation and Enforcement

The Office of Surface Mining Reclamation and Enforcement (OSM) was created by the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Under SMCRA, OSM has two principal functions. They are:

- The regulation of surface coal mining and reclamation operations; and

- The reclamation and restoration of abandoned coal mine lands.

In enacting SMCRA, Congress directed OSM to "strike a balance between protection of the environment and agricultural productivity and the Nation's need for coal as an essential source of energy." In response to its statutory mandate, OSM has sought to develop and maintain a stable regulatory program that is safe, cost-effective, and environmentally sound. A stable regulatory program ensures that the coal mining industry has clear guidelines for operation and reclamation, and that citizens know how the program is being implemented.

OSM's Federal regulatory program sets minimum requirements for obtaining a permit for surface and underground coal mining operations, sets performance standards for those operations, requires reclamation of lands and waters disturbed by mining, and requires enforcement to ensure that the standards are met.
OSM is the primary regulatory authority for SMCRA enforcement until a State or Indian tribe develops its own regulatory program, which is no less effective than the Federal program. When a State or Indian tribe achieves "primacy," it assumes direct responsibility for permitting, inspection, and enforcement activities under its federally approved regulatory program. Today, 24 of the 26 coal-producing States have primacy. In the 2006 amendments to SMCRA, Indian tribes with coal resources were provided the opportunity to assume primacy. No tribes have done so to date, although three tribes have expressed an interest in submitting a tribal program.

OSM's regulatory priorities for the coming year will focus on:

- **Stream Protection**

  Protect streams from the adverse effects of surface coal mining operations; and

- **Coal Combustion Residues**

  Establish Federal standards for the beneficial use of coal combustion residues on active and abandoned coal mines.

*U.S. Fish and Wildlife Service*

The mission of the U.S. Fish and Wildlife Service (FWS) is to work with others to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people. FWS also helps ensure a healthy environment for people by providing opportunities for Americans to enjoy the outdoors and our shared natural heritage.

FWS fulfills its responsibilities through a diverse array of programs that:
• Protect and recover endangered and threatened species;
• Monitor and manage migratory birds;
• Restore native aquatic populations and nationally significant fisheries;
• Enforce Federal wildlife laws and regulate international trade;
• Conserve and restore wildlife habitat such as wetlands;
• Help foreign governments conserve wildlife through international conservation efforts;
• Distribute Federal funds to States, territories, and tribes for fish and wildlife conservation projects;
• and
• Manage the almost 150-million-acre National Wildlife Refuge System, which includes 555 National Wildlife Refuges and which protects and conserves fish and wildlife and their habitats and allows the public to engage in outdoor recreational activities.

Critical challenges to the work of FWS include global climate change; shortages of clean water suitable for wildlife; invasive species that are harmful to our fish, wildlife, and plant resources and their habitats; and the alienation of children and adults from the natural world. To address these challenges, FWS has identified six priorities:

• The National Wildlife Refuge System—conserving our lands and resources;
• Landscape conservation—working with others;
• Migratory birds—conservation and management;
• Threatened and endangered species—achieving recovery and preventing extinction;
• Connecting people with nature—ensuring the future of conservation; and
• Aquatic species—the National Fish Habitat Action Plan (a plan that brings public and private partners together to restore U.S. waterways to sustainable health).

To carry out these priorities, FWS has a large regulatory agenda that will, among other things:

• List, delist, and reclassify species on the Lists of Endangered and Threatened Wildlife and Plants and designate critical habitat for certain listed species;
• Update our regulations to carry out the Convention on International Trade in Wild Fauna and Flora;
• Manage migratory bird populations;
• Administer the subsistence program for harvest of fish and wildlife in Alaska;
• Update our regulations governing the Wildlife and Sport Fish Restoration Program; and
• Set forth hunting and sport fishing regulations for the National Wildlife Refuge System.

Additionally, FWS is working with the National Oceanic and Atmospheric Administration and the Environmental Protection Agency, via a contract with the National Research Council (NRC), to review scientific issues associated with the Federal Insecticide, Fungicide, and Rodenticide Act. Once the NRC's report is completed, the agencies will work together to develop an approach that produces efficient, scientifically defensible biological evaluations protective of listed species.

Further, the FWS' Regional Directors and/or Ecological Services State Supervisors or Project leaders will be meeting with their State counterparts to discuss the role of State agencies in ESA initiatives to enhance their involvement in implementing the ESA’s provisions.

National Park Service

The NPS preserves unimpaired the natural and cultural resources and values within almost 400 units of the National Park System encompassing nearly 84 million acres of lands and waters for the enjoyment, education, and inspiration of this and future generations. The NPS also cooperates with partners to extend the benefits of natural and resource conservation and outdoor recreation throughout the United States and the world.

To achieve this mission the NPS adheres to the following guiding principles:

• Excellent Service: Providing the best possible service to park visitors and partners.
• **Productive Partnerships**: Collaborating with Federal, State, tribal, and local governments, private organizations, and businesses to work toward common goals.

• **Citizen Involvement**: Providing opportunities for citizens to participate in the decisions and actions of the National Park Service.

• **Heritage Education**: Educating park visitors and the general public about their history and common heritage.

• **Outstanding Employees**: Empowering a diverse workforce committed to excellence, integrity, and quality work.

• **Employee Development**: Providing developmental opportunities and training so employees have the "tools to do the job" safely and efficiently.

• **Wise Decisions**: Integrating social, economic, environmental, and ethical considerations into the decisionmaking process.

• **Effective Management**: Instilling a performance management philosophy that fosters creativity, focuses on results, and requires accountability at all levels.

• **Research and Technology**: Incorporating research findings and new technologies to improve work practices, products, and services.

The NPS Division of Regulations and Special Park Uses provides agency coordination for a variety of activities that directly affect the management of visitor use and resource protection within the National Park System to carry out this mission. Our regulatory priorities include among other issues:

Revising existing regulations pertaining to:

• **Commercial Film and Related Activities**

• **Solid Waste Disposal**

• **Non-Federal Oil and Natural Gas Rights**

• **Rights-of-Way**

Establishing rules related to:

• **Collection of Natural Products by Members of Federally Recognized Tribes for Traditional and Cultural Purposes**
Managing Winter Use at Yellowstone NP

Managing Off Road Vehicle Use and Bicycling

Implementation of the Native American Graves Protection and Repatriation Act

Establishing Standards and Procedures for Disposition of Archeological Materials

Bureau of Reclamation

The Bureau of Reclamation’s mission is to manage, develop, and protect water and related resources in an environmentally and economically sound manner in the interest of the American public. To accomplish this mission, Reclamation employs management, engineering, and science to achieve effective and environmentally sensitive solutions.

Reclamation projects provide: Irrigation water service, municipal and industrial water supply, hydroelectric power generation, water quality improvement, groundwater management, fish and wildlife enhancement, outdoor recreation, flood control, navigation, river regulation and control, system optimization, and related uses. Reclamation has continued to focus on increased security at its facilities.

The Reclamation regulatory program focus in fiscal year 2012 is to ensure that its mission and laws that require regulatory actions are carried out expeditiously, efficiently, and with an emphasis on cooperative problem solving by implementing two newly authorized programs:

- Rural Water Supply Program

Title I of Public Law 109-451 authorizes the establishment of a rural water supply program to enable the Bureau of Reclamation to coordinate with rural communities throughout the Western United States to identify their potable water supply needs and evaluate options for meeting those needs. Under the Act, Reclamation is finalizing a rule that will define how it will identify and work with eligible rural communities. Reclamation published an interim final rule on November 17, 2008, and expects
to publish a Second Notice of Proposed Rulemaking in 2012 that will address comments received from the public.

- Loan Guarantees

Title II of Public Law 109-451 authorizes the Secretary of the Interior, through the Bureau of Reclamation, to issue loan guarantees to assist in financing: (a) Rural water supply projects, (b) extraordinary maintenance and rehabilitation of Reclamation project facilities, and (c) improvements to infrastructure directly related to Reclamation projects. This new program will provide an additional funding option to help western communities and water managers to cost effectively meet their water supply and maintenance needs. Under the Act, Reclamation is working with the Office of Management and Budget to publish a rule that will establish criteria for administering the loan guarantee program. Reclamation published a proposed rule on October 6, 2008, and expects to publish a Second Notice of Proposed Rulemaking in 2012 that will address comments received from the public.

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DEPARTMENT OF JUSTICE (DOJ)

Statement of Regulatory Priorities

The mission of the Department of Justice is to enforce the law and defend the interests of the United States according to the law, to ensure public safety against threats foreign and domestic, to provide Federal leadership in preventing and controlling crime, to seek just punishment for those guilty of unlawful behavior, and to ensure fair and impartial administration of justice for all Americans. In carrying out its mission, the Department is guided by four core values: (1) equal justice under the law; (2) honesty and integrity; (3) commitment to excellence; and (4) respect for the worth and dignity of each human being. The Department of Justice is primarily a law-enforcement agency, not a regulatory agency; it carries out
its principal investigative, prosecutorial, and other enforcement activities through means other than the regulatory process.

The Department of Justice’s key regulatory priority is the Prison Rape Elimination Act (PREA) rulemaking which will establish national standards for the prevention, detection, reduction, and punishment of prison rape. The regulatory priorities of the Department also include initiatives in the areas of civil rights, criminal justice, and immigration. These initiatives are summarized below. In addition, several other components of the Department carry out important responsibilities through the regulatory process. Although their regulatory efforts are not separately discussed in this overview of the regulatory priorities, those components have key roles in implementing the Department's anti-terrorism and law enforcement priorities.

Prison Rape Elimination

Pursuant to the Prison Rape Elimination Act of 2003 (PREA or the “Act”), 42 U.S.C. section 15601 et seq., the Department is drafting regulations to adopt national standards for the prevention, detection, reduction, and punishment of prison rape. On February 3, 2011, the Department published for public comment a Notice of Proposed Rulemaking setting forth comprehensive national standards for the detection, prevention, reduction, and punishment of prison rape in prisons, jails, lockups, community confinement facilities, and juvenile facilities operated by Department of Justice, State, local, and private agencies. See 76 FR 6248 (Feb. 3, 2011). In developing these proposed standards, the Department benefited from the findings and recommendations of the National Prison Rape Elimination Commission (NPREC), which had undertaken a comprehensive legal and factual study of the penological, physical, mental, medical, social, and economic impacts of prison sexual assaults on government functions and on the communities and social institutions in which they operate. The Department received over 1,300 public comments in response to the proposed rule, reviewed and analyzed those comments, and drafted
the final rule for submission to OMB. PREA mandates that the national standards shall be based upon the independent judgment of the Attorney General, after giving due consideration to the recommended national standards provided by the Commission … and being informed by such data, opinions, and proposals that the Attorney General determines to be appropriate to consider.” The Act further provides that the Department “shall not establish a national standard … that would impose substantial additional costs compared to the costs presently expended by Federal, State, and local prison authorities.”

The Department worked with an outside contractor to assess the costs imposed by its proposed rule and to support a Regulatory Impact Assessment that will accompany the final rule. Once the rulemaking process has been completed, the Department’s PREA standards will constitute the most comprehensive and assertive approach ever undertaken in this country to combating sexual abuse against persons who are incarcerated

Civil Rights

In September 2010, the Department published its final rules amending its regulations implementing title II and title III of the Americans with Disabilities Act (ADA). Title II prohibits disability based discrimination by public entities. Title III prohibits disability based discrimination by public accommodations and certain testing entities, and requires commercial facilities to be constructed or altered in compliance with the ADA accessibility standards. These key regulations adopt revised ADA Standards for Accessible Design and address certain important policy issues. During the course of this rulemaking, the Department became aware of the need to promulgate regulations in four additional subject matter areas— the accessibility of emergency call center services (Next Generation 9-1-1), captioning and video description in movie theaters, use of accessible web sites, and accessible equipment and furniture. On July 26, 2010, the Department published an advance notice of proposed
rulemaking (ANPRM) for each of these subject areas. The comment period for these ANPRMs closed on January 24, 2011. In addition to soliciting written public comments, the Department held public hearings on the ANPRMs in November and December 2010 and January 2011. The subject matter of these ANPRMs will be the focus of the Civil Rights Division’s regulatory activities for FY 2012, as well as FY 2013. The Department also plans to propose amendments to its ADA regulations and its section 504 regulations to implement the ADA Amendments Act of 2008, which took effect on January 1, 2009.

The subjects addressed in the ANPRMs published on July 26, 2010, included:

**Next Generation 9-1-1.** This ANPRM sought information on possible revisions to the Department’s regulation to ensure direct access to Next Generation 9-1-1 (NG 9-1-1) services for individuals with disabilities. In 1991, the Department of Justice published a regulation to implement title II of the Americans with Disabilities Act of 1990 (ADA). That regulation requires public safety answering points (PSAPs) to provide direct access to persons with disabilities who use analog telecommunication devices for the deaf (TTYs), 28 CFR 35.162. Since that rule was published, there have been major changes in the types of communications technology used by the general public and by people who have disabilities that affect their hearing or speech. Many individuals with disabilities now use the Internet and wireless text devices as their primary modes of telecommunications. At the same time, PSAPs are planning to shift from analog telecommunications technology to new Internet-Protocol (IP)-enabled NG 9-1-1 services that will provide voice and data (such as text, pictures, and video) capabilities. As PSAPs transition from the analog systems to the new technologies, it is essential people with communication disabilities will be able to use the new systems. Therefore, the Department published this ANPRM to begin to develop appropriate regulatory guidance for PSAPs that are making this transition. The Department is in the process of completing its review of the approximately 146 public comments it received in response to its NG 9-1-1 ANPRM and expects to publish an NPRM addressing accessibility of NG 9-1-1 in FY 2012.
Captioning and Video Description in Movie Theaters. Title III of the ADA requires public accommodations to take "such steps as may be necessary to ensure that no individual with a disability is treated differently because of the absence of auxiliary aids and services, unless the covered entity can demonstrate that taking such steps would cause a fundamental alteration or would result in an undue burden." 42 U.S.C. section 12182(b)(2)(A)(iii). Both open and closed captioning and audio recordings are examples of auxiliary aids and services that should be provided by places of public accommodations, 28 CFR section 36.303(b)(1)-(2). The Department stated in the preamble to its 1991 rule that "[m]ovie theaters are not required…to present open-captioned films," 28 CFR part 36, app. C (2011), but it did not address closed captioning and video description in movie theaters.

Since 1991, there have been many technological advances in the area of closed captioning and video description for first-run movies. In June 2008, the Department issued a Notice of Proposed Rulemaking (NPRM) to revise the ADA title III regulation, 73 FR 34466, in which the Department stated that it was considering options for requiring that movie theater owners or operators exhibit movies that are captioned or that provide video (narrative) description. The Department received numerous comments urging the Department to issue captioning and video description regulations. The Department is persuaded that such regulations are appropriate. The Department issued an ANPRM on July 26, 2010, to obtain more information regarding issues raised by commenters; to seek comment on technical questions that arose from the Department’s research; and to learn more about the status of digital conversion. In addition, the Department sought information regarding whether other technologies or areas of interest (e.g., 3D) have developed or are in the process of development that either would replace or augment digital cinema or make any regulatory requirements for captioning and video description more difficult or expensive to implement. The Department received approximately 1171 public comments in response to its movie captioning and video description ANPRM. The Department is in the process of completing its review of these comments and expects to publish an NPRM addressing captioning and video description in movie theaters in FY 2012.
Web Site Accessibility. The Internet as it is known today did not exist when Congress enacted the ADA, yet today the World Wide Web plays a critical role in the daily personal, professional, civic, and business life of Americans. The ADA’s expansive nondiscrimination mandate reaches goods and services provided by public accommodations and public entities using Internet web sites. Being unable to access web sites puts individuals at a great disadvantage in today’s society, which is driven by a dynamic electronic marketplace and unprecedented access to information. On the economic front, electronic commerce, or “e-commerce,” often offers consumers a wider selection and lower prices than traditional, “brick-and-mortar” storefronts, with the added convenience of not having to leave one’s home to obtain goods and services. For individuals with disabilities who experience barriers to their ability to travel or to leave their homes, the Internet may be their only way to access certain goods and services. Beyond goods and services, information available on the Internet has become a gateway to education, socializing, and entertainment.

The Internet is also dramatically changing the way that governmental entities serve the public. Public entities are increasingly providing their constituents access to government services and programs through their web sites. Through government web sites, the public can obtain information or correspond with local officials without having to wait in line or be placed on hold. They can also pay fines, apply for benefits, renew State-issued identification, register to vote, file taxes, request copies of vital records, and complete numerous other everyday tasks. The availability of these services and information online not only makes life easier for the public but also often enables governmental entities to operate more efficiently and at a lower cost.

The ADA’s promise to provide an equal opportunity for individuals with disabilities to participate in and benefit from all aspects of American civic and economic life will be achieved in today’s technologically advanced society only if it is clear to State and local governments, businesses, educators, and other public accommodations that their web sites must be accessible. Consequently, the Department is
considering amending its regulations implementing title II and title III of the ADA to require public entities and public accommodations that provide products or services to the public through Internet web sites to make their sites accessible to and usable by individuals with disabilities.

In particular, the Department’s ANPRM on web site accessibility sought public comment regarding what standards, if any, it should adopt for web site accessibility, whether the Department should adopt coverage limitations for certain entities, like small businesses, and what resources and services are available to make existing web sites accessible to individuals with disabilities. The Department also solicited comments on the costs of making web sites accessible and on the existence of any other effective and reasonably feasible alternatives to making web sites accessible. The Department received approximately 440 public comments and is in the process of reviewing these comments. The Department anticipates publishing separate NPRMs addressing web site accessibility pursuant to titles II and III of the ADA in FY 2013.

*Equipment and Furniture.* Both title II and title III of the ADA require covered entities to make reasonable modifications in their programs or services to facilitate participation by persons with disabilities. In addition, covered entities are required to ensure that people are not excluded from participation because facilities are inaccessible or because the entity has failed to provide auxiliary aids. The use of accessible equipment and furniture is often critical to an entity’s ability to provide a person with a disability equal access to its services. Changes in technology have resulted in the development and improved availability of accessible equipment and furniture that benefit individuals with disabilities. Consequently, it is easier now to specify appropriate accessibility standards for such equipment and furniture, as the 2010 ADA Standards do for several types of fixed equipment and furniture, including ATMs, washing machines, dryers, tables, benches, and vending machines. To the extent that ADA standards apply requirements for fixed equipment and furniture, the Department will look to those standards for guidance on accessibility standards for equipment and furniture that are not fixed. The
ANPRM sought information about other categories of equipment, including beds in accessible guest rooms, and medical equipment and furniture. The Department received approximately 420 comments in response to its ANPRM and is in the process of reviewing these comments. The Department has decided to publish in FY 2012 a separate NPRM pursuant to title III of the ADA on beds in accessible guest rooms and a more detailed ANPRM pursuant to titles II and III of the ADA that focuses solely on accessible medical equipment and furniture. The remaining items of equipment and furniture addressed in the 2010 ANPRM will be the subject of an NPRM that the Department anticipates publishing in FY 2013.

Federal Habeas Corpus Review Procedures in Capital Cases

Pursuant to the USA PATRIOT Improvement and Reauthorization Act of 2005, on December 11, 2008, the Department promulgated a final rule to implement certification procedures for States seeking to qualify for the expedited Federal habeas corpus review procedures in capital cases under chapter 154 of title 28 of the United States Code. On February 5, 2009, the Department published in the Federal Register a notice soliciting further public comment on all aspects of the December 2008 final rule. (74 FR 6131) As the Department reviewed the comments submitted in response to the February 2009 notice, it considered further the statutory requirements governing the regulatory implementation of the chapter 154 certification procedures. The Attorney General determined that chapter 154 reasonably could be construed to allow the Attorney General greater discretion in making certification determinations than the December 2008 regulations allowed. Accordingly, the Department published a notice in the Federal Register on May 25, 2010, proposing to remove the December 2008 regulations pending the completion of a new rulemaking process. The Department finalized the removal of the December 2008 regulations on November 23, 2010. The Department published an NPRM in the Federal Register on March 3, 2011, proposing a new rule and seeking public input on the certification procedure for chapter 154 and the
standards the Attorney General will apply in making certification decisions. The comment period for the proposed new rule closed on June 1, 2011.

Criminal Law Enforcement

For the most part, the Department’s criminal law enforcement components do not rely on the rulemaking process to carry out their assigned missions. The Federal Bureau of Investigation (FBI), for example, is responsible for protecting and defending the United States against terrorist and foreign intelligence threats, upholding and enforcing the criminal laws of the United States, and providing leadership and criminal justice services to Federal, State, municipal, and international agencies and partners. Only in very limited contexts does the FBI rely on rulemaking. For example, the FBI is currently updating its National Instant Criminal Background Check System regulations to allow criminal justice agencies to conduct background checks prior to the return of firearms.

Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) Initiatives. ATF issues regulations to enforce the Federal laws relating to the manufacture and commerce of firearms and explosives. ATF’s mission and regulations are designed to, among other objectives, curb illegal traffic in, and criminal use of, firearms, and to assist State, local, and other Federal law enforcement agencies in reducing crime and violence. ATF will continue, as a priority during fiscal year 2012, to seek modifications to its regulations governing commerce in firearms and explosives. ATF plans to issue final regulations implementing the provisions of the Safe Explosives Act, title XI, subtitle C, of Public Law 107-296, the Homeland Security Act of 2002 (enacted Nov. 25, 2002).

Pursuant to Executive Order 13563 “Improving Regulation and Regulatory Review,” ATF is initiating a rulemaking proceeding to amend existing regulations and extend the term of import permits for firearms,
ammunition, and defense articles from 1 year to 2 years. The additional time will allow importers sufficient time to complete the importation of an authorized commodity before the permit expires and eliminate the need for importers to submit new and duplicative import applications. ATF believes that extending the term of import permits will result in substantial cost and time savings for both ATF and industry. ATF also has begun a rulemaking process that will lead to promulgation of a revised set of regulations (27 CFR part 771) governing the procedure and practice for disapproval of applications for explosives licenses or permits.

**Drug Enforcement Administration (DEA) Initiatives.** DEA is the primary agency responsible for coordinating the drug law enforcement activities of the United States. DEA also assists in the implementation of the President’s National Drug Control Strategy. DEA’s mission is to enforce U.S. controlled substance laws and regulations and bring to the criminal and civil justice system those organizations and individuals involved in the growing, manufacturing, or distribution of controlled substances and listed chemicals appearing in or destined for illicit traffic in the United States, including organizations that use drug trafficking proceeds to finance terrorism. A strategic component of the DEA’s law enforcement mission is the diversion control program (DCP). The DCP carries out the mandates of the Controlled Substances and Chemical Diversion and Trafficking Acts. DEA drafts and publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA, together with these regulations, are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply of controlled substances and listed chemicals for legitimate medical, scientific, research, and industrial purposes.

In 2011, the President declared a national epidemic of prescription drug abuse, which has emphasized the importance of the Department’s regulatory role with respect to controlled substances. DEA has initiated National Take-Back events to purge America’s home medicine cabinets of unwanted and unused
drugs, as well as assisting in other strategies and increased enforcement to address doctor shopping and pill mills. DEA schedules new and emerging substances for control under the CSA to protect public health and safety. During fiscal year 2012, among other regulatory reviews and initiatives, DEA plans to propose regulations implementing the Secure and Responsible Drug Disposal Act of 2010 (Pub. L. 111-273). DEA also plans to issue final regulations on electronic prescriptions for controlled substances subsequent to an Interim Final Rule currently in effect, which provides practitioners with the option of writing prescriptions for controlled substances electronically and permits pharmacies to receive, dispense, and archive electronic prescriptions for controlled substances.

_Bureau of Prisons Initiatives._ The Federal Bureau of Prisons issues regulations to enforce the Federal laws relating to its mission: to protect society by confining offenders in the controlled environments of prisons and community-based facilities that are safe, humane, cost-efficient, and appropriately secure, and that provide work and other self-improvement opportunities to assist offenders in becoming law-abiding citizens. During the next 12 months, in addition to other regulatory objectives aimed at accomplishing its mission, the Bureau will continue its ongoing efforts to: streamline regulations, eliminating unnecessary language and improving readability; improve disciplinary procedures through a revision of the subpart relating to the disciplinary process; reduce the introduction of contraband through various means, such as clarifying drug and alcohol surveillance testing programs; protect the public from continuing criminal activity committed within prison; and enhance the Bureau’s ability to more closely monitor the communications of high-risk inmates.

**Immigration**

On March 1, 2003, pursuant to the Homeland Security Act of 2002 (HSA), the responsibility for immigration enforcement and for providing immigration-related services and benefits, such as naturalization and work authorization, was transferred
from the Justice Department’s Immigration and Naturalization Service (INS) to the Department of Homeland Security (DHS). However, the immigration judges and the Board of Immigration Appeals (Board) in the Executive Office for Immigration Review (EOIR) remain part of the Department of Justice. The immigration judges adjudicate approximately 300,000 cases each year to determine whether aliens should be removed from the United States or should be granted some form of relief from removal. The Board has jurisdiction over appeals from the decisions of immigration judges, as well as other matters. Accordingly, the Attorney General has a continuing role in the conduct of removal hearings, the granting of relief from removal, and custody determinations regarding the detention of aliens pending completion of removal proceedings. The Attorney General also is responsible for civil litigation and criminal prosecutions relating to the immigration laws.

In several pending rulemaking actions, the Department is working to revise and update the regulations relating to removal proceedings in order to improve the efficiency and effectiveness of the hearings. In furtherance of these goals, the Department is drafting a regulation to improve the recognition and accreditation process for organizations and representatives that appear in immigration proceedings. With the assistance of DHS, the Department is also drafting a regulation pursuant to the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 to implement procedures that take into account the specialized needs of unaccompanied alien children in removal proceedings. In addition, the Department is considering regulatory action to address mental incompetency issues in removal proceedings. Finally, in response to Executive Order 13653, the Department is retrospectively reviewing EOIR’s regulations to eliminate regulations that unnecessarily duplicate DHS’s regulations and update outdated references to the pre-2002 immigration system.

**Retrospective Review of Existing Regulations**
Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review" (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final Justice Department plan can be found at: http://www.justice.gov/open/doj-rr-final-plan.pdf.

<table>
<thead>
<tr>
<th>RIN</th>
<th>Title</th>
<th>Description</th>
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<tbody>
<tr>
<td>1140-A</td>
<td>Importation of Arms, Ammunition and Implements of War and Machine Guns,</td>
<td>The regulations in 27 C.F.R. 447 and 479 generally provide that firearms, ammunition, and defense articles may not be imported into the United States except pursuant to a permit. Section 447.43 provides that import permits are valid for one year from their issuance date. I ATF will consider whether these regulations could be revised to achieve the same regulatory objective in a manner that is less burdensome for both industry and ATF.</td>
</tr>
<tr>
<td>AA42</td>
<td>Destructive Devices, and Certain Other Firearms; Extending the Term of Import Permits&quot;</td>
<td></td>
</tr>
<tr>
<td>1117-A</td>
<td>Establishment of Quotas Required by the Controlled Substances Act&quot;</td>
<td>The regulations in 21 C.F.R. parts 1303 and 1315 apply quotas to registered manufacturers of Schedule I and II controlled substances and certain List I chemicals. The quotas are intended to control the available quantities of the basic ingredients needed for the manufacture of certain substances, to reduce the risk of diversion while ensuring</td>
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</table>
sufficient availability to satisfy the legitimate needs of the United States. DEA will explore strategies to modernize the quota system to achieve greater efficiency and effectiveness and reduce the burden on applicants. Although the Department expects that manufacturers and the DEA will benefit from enhanced efficiency and a reduction in paperwork, it cannot quantify the burden and cost reductions until the working group identifies the specific changes it will implement.

<table>
<thead>
<tr>
<th>DOJ—Legal Activities (LA)</th>
<th>FINAL RULE STAGE</th>
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<tbody>
<tr>
<td>85. NATIONAL STANDARDS TO PREVENT, DETECT, AND RESPOND TO PRISON RAPE</td>
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<tr>
<td><strong>Priority:</strong></td>
<td>Economically Significant. Major under 5 USC 801.</td>
</tr>
<tr>
<td><strong>Legal Authority:</strong></td>
<td>5 USC 301; 28 USC 509; 28 USC 510; 42 USC 15607</td>
</tr>
<tr>
<td><strong>CFR Citation:</strong></td>
<td>28 CFR 115</td>
</tr>
<tr>
<td><strong>Legal Deadline:</strong></td>
<td>Final, Statutory, June 23, 2010.</td>
</tr>
<tr>
<td><strong>Abstract:</strong></td>
<td>42 U.S.C. section 15607 directed the Attorney General to promulgate a final rule within 1 year after receiving the report and recommendations of the National Prison Rape Elimination Commission.</td>
</tr>
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</table>
In the Prison Rape Elimination Act of 2003 (PREA), Public Law No. 108-79, codified at 42 U.S.C. sections 15601 to 15609, Congress directed the Attorney General to "publish a final rule adopting national standards for the detection, prevention, reduction, and punishment of prison rape." 42 U.S.C. section 15607(a)(1). The statute further directed that the Attorney General "shall not establish a national standard . . . that would impose substantial additional costs compared to the costs presently expended by Federal, State, and local prison authorities." 42 U.S.C. section 15607(a)(3). In accordance with PREA, the Department is drafting a final rule setting forth national standards for enhancing the prevention, detection, and response to sexual abuse in confinement settings. The Department published a Notice of Proposed Rulemaking on February 3, 2011 (see 76 FR 6248), identifying the proposed standards, and it received over 1,300 public comments in response.

Statement of Need:

Many of the evidentiary and public policy bases for the final rule are set forth in the statute, in which Congress set forth 15 findings relating to the prevalence of prison rape and its impact on society. See 42 U.S.C. section 15601. In summary, prison rape is a widespread problem that causes significant harm to its victims and imposes significant costs to society as a whole. Given the violent, destructive, reprehensible, and illegal nature of rape and sexual abuse in any setting, strong measures are needed to combat its prevalence in correctional settings. Tolerance of sexual abuse of prisoners in the government's custody is incompatible with American values.

Summary of Legal Basis:

PREA states that the Attorney General “shall publish a final rule adopting national standards for the detection, prevention, reduction, and punishment of prison rape.” 42 U.S.C. section 15607(a)(1). The standards “shall be based upon the independent judgment of the Attorney General, after giving due consideration to the recommended national standards provided by the [National Prison Rape Elimination] Commission . . ., and being informed by such data, opinions, and proposals that the Attorney General determines to be appropriate to consider.” Id. section 15607(a)(2) and (a)(3). In June 2009, the Commission forwarded to the Attorney General a lengthy report describing its findings and recommending national standards.

Alternatives:
Given the specific direction of Congress, the Department is obligated to issue a rule that promulgates national standards to combat prison rape. PREA also gives the Attorney General the option of “providing a list of improvements for consideration by correctional facilities,” to the extent that a particular national standard would impose substantial additional costs compared to the costs presently expended by Federal, State, and local prison authorities. 42 U.S.C. section 15607(a)(3). The Department has received input from numerous stakeholders concerning the development of the national standards and, as part of the development process, considered a wide range of proposals and alternatives. These proposals include the standards recommended by the Commission, as well as alternative approaches proposed by various public stakeholders.

**Anticipated Cost and Benefits:**

In directing the Attorney General to promulgate national standards that would “eliminate” prison rape by enhancing its prevention, detection, reduction, and punishment, Congress understood that Federal, State, and local agencies (as well as private entities) that operate inmate confinement facilities and that adopt the standards would likely have to incur costs to come into, and remain in, compliance with the standards. However, any such costs more than outweighed by the benefits of avoiding prison rape. Prevention of prison rape has benefits that can be monetized, as well as benefits that cannot be monetized. The monetized benefits inure primarily to the victims of prison sexual abuse (which number over 200,000 per year) and include the costs of medical and mental health care treatment as well as pain, suffering, and diminished quality of life, among other factors. For the most serious category of prison sexual abuse, the Department’s Initial Regulatory Impact Assessment (IRIA) accompanying the Notice of Proposed Rulemaking estimated the cost per adult victim as ranging from $200,000 to $300,000. Correspondingly, the IRIA estimated that if all affected agencies adopt the standards, full compliance with the standards would cost, in the aggregate, over half a billion dollars a year when annualized over 15 years. Using a breakeven analysis, this means that the standards would have to result in the avoidance of approximately 2 percent or less of the baseline number of annual prison sexual abuse victims for the costs of full compliance to break-even with the monetized benefits of the standards. This does not include the many non-monetizable benefits of prison rape avoidance, which include benefits for victims, for inmates who
are not victims, for families of inmates, for prison administrators and staff, and for society at large. The final rule will include a final Regulatory Impact Assessment.

Risks:
The final rule is intended to carry out the intent of Congress to eliminate prison rape. The risks from the failure to promulgate the final rule are primarily that inmates in Federal, State, and local facilities would continue to be at a higher risk of sexual assault than they would be if the final rule is not promulgated.

Timetable:

<table>
<thead>
<tr>
<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<tbody>
<tr>
<td>ANPRM</td>
<td>03/10/10</td>
<td>75 FR 11077</td>
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<tr>
<td>ANPRM Comment Period End</td>
<td>05/10/10</td>
<td></td>
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<tr>
<td>NPRM</td>
<td>02/03/11</td>
<td>76 FR 6248</td>
</tr>
<tr>
<td>NPRM Comment Period End</td>
<td>04/04/11</td>
<td></td>
</tr>
<tr>
<td>Final Action</td>
<td>02/00/12</td>
<td></td>
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</tbody>
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Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Governmental Jurisdictions, Organizations

Government Levels Affected:
Federal, Local, State

Federalism:
This action may have federalism implications as defined in EO 13132.

URL For Public Comments:
regulations.gov

Agency Contact:
Robert Hinchman
Senior Counsel, Office of Legal Policy
Department of Justice
The Department of Labor’s fall 2011 agenda continues Secretary Solis’ vision of Good Jobs for Everyone. It also renews the Labor Department’s commitment to efficient and effective regulation through the review and modification of our existing regulations, consistent with Executive Order 13563 (“E.O. 13563”).

The Labor Department's vision of a "good job" includes jobs that:

- Increase workers’ incomes and narrow wage and income inequality;
- Assure workers are paid their wages and overtime;
- Are in safe and healthy workplaces, and fair and diverse workplaces;
- Provide workplace flexibility for family and personal care-giving;
- Improve health benefits and retirement security for all workers; and
- Assure workers have a voice in the workplace.

The Department continues to use a variety of mechanisms to achieve the goal of Good Jobs for Everyone, including increased enforcement actions, increased education and outreach, and regulatory actions that foster compliance. At the same time, the Department is enhancing the efficiency and
effectiveness of its efforts through targeted regulatory actions designed to improve compliance while reducing regulatory burdens. The Department’s Plan/Prevent/Protect and Openness and Transparency compliance strategies and the implementation of E.O. 13563 create unifying themes that seek to foster a new calculus that strengthens protections for workers. By requiring employers and other regulated entities to take full ownership over their adherence to Department regulations and promoting greater openness and transparency to put workers in a better position to judge whether their workplace is one that values health and safety, work-life balance, and diversity, the Department seeks to significantly increase compliance. The increased effectiveness of this compliance strategy will enable the Department to achieve the Good Jobs for Everyone goal in a regulatory environment that is more efficient and less burdensome.

**Plan/Prevent/Protect Compliance Strategy**

The Department has already published several regulatory actions toward the completion of requirements that employers develop programs to address specific issues of worker protection, security, and equity. Some of these issues have included controlling the spread of infectious diseases, examining work areas in underground coal mines for mandatory violations, and identifying patterns of violations in mines. The collection of regulatory actions in the Department’s Plan/Prevent/Protect strategy is designed to ensure employers and other regulated entities are in full compliance with the law every day, not just when Department inspectors come calling. As announced with the spring 2010 regulatory agenda, this strategy requires employers and other regulated entities to:

"Plan": Create a plan for identifying and remediating risks of legal violations and other risks to workers; for example, a plan to inspect their workplaces for safety hazards that might injure or kill workers. Workers will be given opportunities to participate in the creation of the plans. In addition, the plans would be made available to workers so they can fully understand them and help to monitor their implementation.
“Prevent”: Thoroughly and completely implement the plan in a manner that prevents legal violations. The plan cannot be a mere paper process. This will not be an exercise in drafting a plan only to put it on a shelf. The plan must be fully implemented.

“Protect”: Verify on a regular basis that the plan's objectives are being met. The plan must actually protect workers from health and safety risks and other violations of their workplace rights.

Employers and other regulated entities who fail to take these steps to comprehensively address the risks, hazards, and inequities in their workplaces will be considered out of compliance with the law and, may be subject to remedial action. However, employers, unions, and others who follow the Department's Plan/Prevent/Protect strategy will assure compliance with employment laws before Labor Department enforcement personnel arrive at their doorsteps. Most important, they will assure that workers get the safe, healthy, diverse, family-friendly, and fair workplaces they deserve.

In the fall 2011 regulatory agenda, the Occupational Safety and Health Administration (OSHA), Mine Safety and Health Administration (MSHA), and the Office of Federal Contract Compliance Programs (OFCCP) will all propose regulatory actions furthering the Department's implementation of the Plan/Prevent/Protect strategy.

Openness and Transparency: Tools for Achieving Compliance

Greater openness and transparency continues to be central to the Department's compliance and regulatory strategies. The fall 2011 regulatory plan demonstrates the Department's continued commitment to conducting the people's business with openness and transparency, not only as good Government and stakeholder engagement strategies, but as important means to achieve compliance with the employment laws administered and enforced by the Department. Openness and transparency will not only enhance agencies’ enforcement actions but will encourage greater levels of compliance by the regulated community and enhance awareness among workers of their rights and benefits. When employers, unions, workers, advocates, and members of the public have greater access to information
concerning workplace conditions and expectations, then we all become partners in the endeavor to create

*Good Jobs for Everyone.*

**Worker Protection Responsiveness**

The Department believes Plan/Prevent/Protect and increased Openness and Transparency will result in improvements to worker health and safety. However, when the Department identifies specific hazards and risks to worker health, safety, security, or fairness, we will utilize our regulatory powers to limit the risk to workers. The fall 2011 regulatory plan includes examples of such regulatory initiatives to address such specific concerns.

MSHA is planning regulatory initiatives to respond to specific health and safety needs of workers: (1) MSHA plans to finalize the standard Lowering Miners’ Exposure to Coal Mine Dust, including Continuous Personal Dust Monitors in April 2012; and (2) MSHA plans to finalize the rule covering Examinations of Work Areas in Underground Coal Mines in March 2012.

Workers across many industries face serious hazards from vehicles perform backing maneuvers and from equipment that can pin, crush, or strike. OSHA and MSHA will both publish regulatory actions concerning these hazards.

Crystalline silica exposure is one of the most serious hazards workers face. OSHA and MSHA are both proposing to address worker exposures to crystalline silica through the promulgation and enforcement of a comprehensive health standard.

**Retrospective Review of Existing Rules**

*Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan.*
However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final agency plans can be found at: http://www.dol.gov/regulations/EO13563Plan.pdf

<table>
<thead>
<tr>
<th>Regulatory Identifier Number</th>
<th>Title of Rulemaking</th>
<th>Whether It Is Expected to Significantly Reduce Burdens on Small Businesses</th>
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<tbody>
<tr>
<td>1218-AC20</td>
<td>Hazard Communication</td>
<td>Yes</td>
</tr>
<tr>
<td>1218-AC34</td>
<td>Bloodborne Pathogens</td>
<td>No</td>
</tr>
<tr>
<td>1218-AC64; 1218-AC65</td>
<td>Updating OSHA Standards Based on National Consensus Standards—Acetylene and Personal Protective Equipment</td>
<td>No</td>
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<tr>
<td>1218-AC67</td>
<td>Standard Improvement Project—Phase IV (SIP IV)</td>
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<td>1218-AC75</td>
<td>Cranes and Derricks in Construction: Revision to Digger Derricks’ Requirements</td>
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<tr>
<td>1218-AC74</td>
<td>Review/Lookback of OSHA</td>
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The fall 2011 regulatory agenda aims to achieve more efficient and less burdensome regulation through our renewed commitment to conduct retrospective reviews of regulations. On January 18, 2011, the President issued Executive Order (E.O.) 13563 entitled “Improving Regulation and Regulatory Review.” The E.O. aims to “strike the right balance” between what is needed to protect health, welfare, safety, and the environment for all Americans, and what we need to foster economic growth, job creation, and competitiveness.

In August 2011, as part of a Governmentwide response to E.O. 13563, the Department published its Plan for Retrospective Analysis of Existing Rules, which identifies several burden-reducing review projects. For example, OSHA’s Standards Improvement Project III (SIP III) rulemaking achieved a 1.9 million burden hour reduction, and we anticipate that OSHA’s SIP IV project will similarly yield savings for employers. OSHA’s Hazard Communication/Globally Harmonized System for Classification and Labeling

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<tr>
<th>Chemical Standards</th>
<th>1219-AB72</th>
<th>Criteria and Procedures for Proposed Assessment of Civil Penalties (Part 100)</th>
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<td>1250-AA05</td>
<td>Sex Discrimination Guidelines</td>
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<td>Equal Employment Opportunity in Apprenticeship and Training, Amendment of Regulations</td>
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of Chemicals proposal has estimated savings for employers ranging from $585 million to $792.7 million. Based on preliminary estimates, EBSA’s Abandoned Plan Program amendments may reduce costs by approximately $1.12 million. These projects estimate monetized savings that would eliminate roughly between $580 to $790 million in annual regulatory burdens.

The Plan also formalizes the development of this semiannual regulatory agenda as a system through which the Department identifies potential regulations for review. This regulatory agenda provides public notice of the Department’s intention to initiate or continue work on approximately 10 review projects; more than 13 percent of all of the Department’s planned regulatory actions.

**Occupational Safety and Health Administration (OSHA)**

OSHA’s regulatory program is designed to help workers and employers identify hazards in the workplace, prevent the occurrence of injuries and adverse health effects, and communicate with the regulated community regarding hazards and how to effectively control them. Long-recognized health hazards and emerging hazards place American workers at risk of serious disease and death and are initiatives on OSHA’s regulatory agenda. In addition to targeting specific hazards, OSHA is focusing on systematic processes that will modernize the culture of safety in America's workplaces and retrospective review projects that will update regulations and reduce burdens on regulated communities. OSHA’s retrospective review projects under E.O.13563 include consideration of the Bloodborne Pathogens standard, updating consensus standards, phase IV of OSHA’s standard improvement project (SIP IV), and reviewing various permissible exposure levels.

*Plan/Prevent/Protect*

**Infectious Diseases**

OSHA is considering the need for regulatory action to address the risk to workers exposed to infectious diseases in healthcare and other related high-risk environments. OSHA is interested in all routes of infectious disease transmission in healthcare settings not already covered by its bloodborne
pathogens standard (e.g. contact, droplet, and airborne). The Agency is particularly concerned by studies that indicate that transmission of infectious diseases to both patients and healthcare workers may be occurring as a result of incomplete adherence to recognized, but voluntary, infection control measures. The Agency is considering an approach that would combine elements of the Department’s Plan/Prevent/Protect strategy with established infection control practices. The Agency received strong stakeholder participation in response to its May 2010 request for information and July 2011 stakeholder meetings.

In 2007, the healthcare and social assistance sector as a whole had 16.5 million employees. Healthcare workplaces can range from small, private practices of physicians to hospitals that employ thousands of workers. In addition, healthcare is increasingly being provided in other settings such as nursing homes, free-standing surgical and outpatient centers, emergency care clinics, patients’ homes, and pre-hospitalization emergency care settings. OSHA is concerned with the movement of healthcare delivery from the traditional hospital setting, with its greater infrastructure and resources to effectively implement infection control measures, into more diverse and smaller workplace settings with less infrastructure and fewer resources, but with an expanding worker population.

Injury and illness Prevention Program (12P2)

OSHA’s Injury and Illness Prevention Program is the prototype for the Department’s Plan/Prevent/Protect strategy. OSHA’s first step in this important rulemaking was to hold stakeholder meetings. Stakeholder meetings were held in East Brunswick, New Jersey; Dallas, Texas; Washington, DC; and Sacramento, California, beginning in June 2010 and ending in August 2010. More than 200 stakeholders participated in these meetings, and in addition, nearly 300 stakeholders attended as observers. The proposed rule will explore requiring employers to provide their employees with opportunities to participate in the development and implementation of an injury and illness prevention program, including a systematic process to proactively and continuously address workplace safety and health hazards. This rule will involve planning, implementing, evaluating, and improving processes and
activities that promote worker safety and health hazards. OSHA has substantial evidence showing that employers that have implemented similar injury and illness prevention programs have significantly reduced injuries and illnesses in their workplaces. The new rule would build on OSHA’s existing Safety and Health Program Management Guidelines and lessons learned from successful approaches and best practices that have been applied by companies participating in OSHA’s Voluntary Protection Program and Safety and Health Achievement Recognition Program, and similar industry and international initiatives.

Openness and Transparency

Modernizing Recordkeeping

OSHA held informal meetings to gather information from experts and stakeholders regarding the modification of its current injury and illness data collection system that will help the agency, employers, employees, researchers, and the public prevent workplace injuries and illnesses, as well as support President Obama’s Open Government Initiative. Under the proposed rule, OSHA will explore requiring employers to electronically submit to the Agency data required by part 1904 (Recording and Reporting Occupational Injuries). The proposed rule will enable OSHA to conduct data collections ranging from the periodic collection of all part 1904 data from a handful of employers to the annual collection of summary data from many employers. OSHA learned from stakeholders that most large employers already maintain their part 1904 data electronically; as a result, electronic submission will constitute a minimal burden on these employers, while providing a wealth of data to help OSHA, employers, employees, researchers, and the public prevent workplace injuries and illnesses. The proposed rule also does not add to or change the recording criteria or definitions in part 1904. The proposed rule only modifies employers’ obligations to transmit information from these records to OSHA.

Whistleblower Protection Regulations

The ability of workers to speak out and exercise their legal rights without fear of retaliation is essential to many of the legal protections and safeguards that all Americans value. Whether the goal is the safety of our food, drugs, or workplaces, the integrity of our financial system, or the security of our
transportation systems, whistleblowers have been essential to ensuring that our laws are fully and fairly executed. In the fall regulatory agenda, OSHA proposes to issue procedural rules that will establish consistent and transparent procedures for the filing of whistleblower complaints under eight statutes. They include procedures for handling employee retaliation complaints filed under the:

- National Transit System Security Act, and Federal Railroad Safety Act, as amended by the Implementing Recommendations of the 9/11 Commission Act
- Surface Transportation Assistance Act, as amended by the Implementing Recommendations of the 9/11 Commission Act
- Consumer Product Safety Improvement Act
- Consumer Financial Protection Act of 2010, and section 1057 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010
- Sarbanes Oxley Act, as amended by section 922 (b) and (c) and section 929A of the Dodd-Frank Wall Street Reform and Consumer Protection Act
- Affordable Care Act
- Seaman’s Protection Act
- FDA Food Safety Modernization Act

These procedural rules will strengthen OSHA’s enforcement of its whistleblower program by providing specific timeframes and guidance for filing a complaint with OSHA, issuing a finding, avenues of appeal, and allowable remedies. OSHA is committed to its whistleblower program and to ensuring that all America’s workers have a voice in the workplace.

Addressing Targeted Hazards

Silica

In order to target one of the most serious hazards workers face, OSHA is proposing to address worker exposures to crystalline silica through the promulgation and enforcement of a comprehensive health standard. Exposure to silica causes silicosis, a debilitating respiratory disease, and may cause cancer, other chronic respiratory diseases, and renal and autoimmune disease as well. The
seriousness of the health hazards associated with silica exposure is demonstrated by the large number of fatalities and disabling illnesses that continue to occur. Over 2 million workers are exposed to crystalline silica in general industry, construction, and maritime industries. Reducing these hazardous exposures through promulgation and enforcement of a comprehensive health standard will contribute to OSHA’s goal of reducing occupational fatalities and illnesses. As a part of the Secretary’s strategy for securing safe and healthy workplaces, MSHA will also utilize information provided by OSHA to undertake regulatory action related to silica exposure in mines.

Preventing Backover Injuries and Fatalities

Workers across many industries face a serious hazard when vehicles perform backing maneuvers, especially vehicles with an obstructed view to the rear. OSHA is collecting information on this hazard and researching emerging technologies that may help to reduce this risk. NIOSH reports, for example, that one-half of the fatalities involving construction equipment occur while the equipment is backing. Backing accidents cause at least 60 occupational deaths per year. Emerging technologies that address the risks of backing operations include cameras, radar, and sonar—to help view or detect the presence of workers on foot in blind areas—and new monitoring technology, such as tag-based warning systems that use radio frequency (RFID) and magnetic field generators on equipment to detect electronic tags worn by workers. Along with MSHA, which is developing regulations concerning Proximity Detection Systems, and based on information collected and the Agency’s review and research, the Agency may consider rulemaking as an appropriate measure to address this source of employee risk.

E.O. 13563

Hazard Communication/Globally Harmonized System for Classification and Labeling of Chemicals

The proposed modifications in its NPRM concerning the HCS are expected to benefit employers in two primary ways. First, the harmonization of hazard classifications, safety data sheet (SDSs) formats, and warning labels will yield substantial savings to businesses, once the standard is fully implemented. On the producer side, fewer different SDSs will have to be produced for affected chemicals, and many
SDSs will be able to be produced at lower cost due to harmonization and standardization. Second, for users, OSHA expects that they will see reductions in operating costs due to the decreased number of SDSs, the standardization of SDSs that will make it easier to locate information and determine handling requirements, and other factors related to simplification and uniformity that will improve workplace efficiency. Finally, OSHA estimates that the revisions to the HCS will result in reductions in the cost of training employees on the HCS in future periods because standardized SDS and label formats will reduce the amount of time needed to familiarize employees with the HCS and fewer systems will have to be taught since all producers will be using the same system.

OSHA’s preliminary estimate is that establishing a harmonized system for the classification and labeling of chemicals will create a substantial annualized savings for employers ranging from $585 million to $792.7 million. The majority of these benefits will be realized through increases in productivity for health and safety managers, as well as for logistics personnel with savings ranging from $475.2 million to $569 million. Simplifying requirements for hazard communication training are estimated to provide savings up to $285.3 million. Additionally, establishing uniform safety data sheets and labels will save between $16 million and $32.2 million. OSHA plans to publish the final rule in 2012. This rulemaking is economically significant with an estimated annual cost of over $200 million.

Bloodborne Pathogens

OSHA will undertake a review of the Bloodborne Pathogen Standard in accordance with the requirements of the Regulatory Flexibility Act, section 5 of Executive Order 12866, and E.O. 13563. The review will consider the continued need for the rule; whether the rule overlaps, duplicates, or conflicts with other Federal, State or local regulations; and the degree to which technology, economic conditions, or other factors may have changed since the rule was evaluated.
Updating OSHA Standards Based on National Consensus Standards--Acetylene and Personal Protective Equipment Standards

Under section 6(a) of the OSH Act, during the first 2 years of the Act, the Agency was directed to adopt national consensus standards as OSHA standards. In the more than 40 years since these standards were adopted by OSHA, the organizations responsible for these consensus standards have issued updated versions of these standards. However, in most cases, OSHA has not revised its regulations to reflect later editions of the consensus standards. This project is part of a multi-year project to update OSHA standards that are based on consensus standards.

Standard Improvement Project--Phase IV (SIP IV)

OSHA’s Standards Improvement Projects (SIPs) are intended to remove or revise duplicative, unnecessary, and inconsistent safety and health standards. The Agency has published three earlier final standards to remove unnecessary provisions, thus reducing costs or paperwork burden on affected employers. The Agency believes that these standards have reduced the compliance costs and eliminated or reduced the paperwork burden for a number of its standards. The Agency only considers such changes to its standards so long as they do not diminish employee protections. The Agency is initiating a fourth rulemaking effort to identify unnecessary or duplicative provisions or paperwork requirements that is limited solely to its construction standards in 29 CFR 1926.

Cranes and Derricks in Construction: Revision to Digger Derricks’ Requirements

OSHA published its final Cranes and Derricks in Construction Standard in August 2010. Edison Electric Institute (EEI) filed a petition for review challenging several aspects of the standard, including the scope of the exemption for digger derricks. As part of the settlement agreement with EEI, OSHA agreed to publish a direct final rule expanding the scope of a partial exemption for work by digger derricks. In the direct final rule, OSHA will revise the scope provision on digger derricks as an exemption for all work done by digger derricks covered by subpart V of 29 CFR 1926.

Review-Lookback of OSHA Chemical Standards
The majority of OSHA’s Permissible Exposure Limits (PELs) were adopted in 1971 under section 6(a) of the OSH Act, and only a few have been successfully updated since that time. There is widespread agreement among industry, labor, and professional occupational safety and health organizations that OSHA’s PELs are outdated and need revising in order to take into account newer scientific data that indicates that significant occupational health risks exist at levels below OSHA’s current PELs. In 1989, OSHA issued a final standard that lowered PELs for over 200 chemicals and added PELs for 164. However, the final rule was challenged and ultimately vacated by the 11th Circuit Court of Appeals in 1991 citing deficiencies in OSHA’s analyses. Since that time, OSHA has made attempts to examine its outdated PELs in light of the Court’s 1991 decision. Most recently, OSHA sought input through a stakeholder meeting and web forum to discuss various approaches that might be used to address its outdated PELs. As part of the Department’s Regulatory Review and Lookback Efforts, OSHA is developing a Request for Information (RFI), seeking input from the public to help the Agency identify effective ways to address occupational exposure to chemicals.

Mine Safety and Health Administration (MSHA)

The Mine Safety and Health Administration is the worker protection agency focused on the prevention of death, disease, and injury from mining and the promotion of safe and healthful workplaces for the Nation’s miners. The Department believes that every worker has a right to a safe and healthy workplace. Workers should never have to sacrifice their lives for their livelihood, and all workers deserve to come home to their families at the end of their shift safe and whole. MSHA’s approach to reducing workplace fatalities and injuries includes promulgating and enforcing mandatory health and safety standards. MSHA’s retrospective review projects under E.O.13563 addresses revising the process for proposing civil penalties.

Plan/Prevent/Protect
Examinations of Work Areas in Underground Coal Mines for Violations of Mandatory Health or Safety Standards

MSHA plans to issue a proposed rule to address section 303(d) of the Federal Mine Safety and Health Act that requires mine operators to conduct examinations, in areas where miners work or travel, to address violations of standards. The final rule would assure that underground coal mine operators find and fix violations during pre-shift, supplemental, on-shift, and weekly examinations, thereby improving health and safety for miners.

Respirable Crystalline Silica Standard

The Agency’s regulatory actions also exemplify a commitment to protecting the most vulnerable populations while assuring broad-based compliance. Health hazards are pervasive in both coal and metal/nonmetal mines, including surface and underground mines and large and small mines. As mentioned previously, as part of the Secretary’s strategy for securing safe and healthy workplaces, both MSHA and OSHA will be undertaking regulatory actions related to silica. Overexposure to crystalline silica can result in some miners developing silicosis, an irreversible but preventable lung disease, which ultimately may be fatal. In its proposed rule, MSHA plans to follow the recommendations of the Secretary of Labor’s Advisory Committee on the Elimination of Pneumoconiosis Among Coal Mine Workers, the National Institute for Occupational Safety and Health (NIOSH), and other groups to address the exposure limit for respirable crystalline silica. As another example of intra-departmental collaboration, MSHA intends to consider OSHA’s work on the health effects of occupational exposure to silica and OSHA’s risk assessment in developing the appropriate standard for the mining industry.

Proximity Detection Systems for Continuous Mining Machines in Underground Coal Mines

MSHA published a proposed rule to address the danger that miners face when working near continuous mining machines in underground coal mines. MSHA has concluded, from investigations of accidents involving mobile equipment and other reports, that action was necessary to protect miners. From 1984 to 2011, there have been 31 fatalities resulting from crushing and pinning accidents involving continuous mining machines. Continuous mining machines can pin, crush, or strike a miner
working near the equipment. Proximity detection technology can prevent these types of accidents. Proximity detection systems can be installed on mining machinery to detect the presence of personnel or equipment within a certain distance of the machine. The rule would strengthen the protection for underground miners by reducing the potential for pinning, crushing, or striking hazards associated with working close to continuous mining machines.

Proximity Detection Systems for Mobile Machines in Underground Mines

MSHA plans to publish a proposed rule to require underground coal mine operators to equip shuttle cars, coal hauling machines, continuous haulage systems, and scoops with proximity detection systems. Miners working near these machines face pinning, crushing, and striking hazards that have resulted, and continue to result, in accidents involving life threatening injuries and death. The proposal would strengthen protections for miners by reducing the potential for pinning, crushing, or striking accidents in underground mines.

Openness and Transparency

Pattern of Violations

MSHA has determined that the existing pattern criteria and procedures contained in 30 CFR part 104 do not reflect the statutory intent for section 104(e) of the Federal Mine Safety and Health Act of 1977 (Mine Act). The legislative history of the Mine Act explains that Congress intended the pattern of violations to be an enforcement tool for operators who have demonstrated a disregard for the health and safety of miners. These mine operators, who have a chronic history of persistent significant and substantial (S&S) violations, needlessly expose miners to the same hazards again and again. This indicates a serious safety and health management problem at a mine. The goal of the pattern of violations final rule is to compel operators to manage health and safety conditions so that the root causes of S&S violations are found and fixed before they become a hazard to miners. The final rule would reflect statutory intent, simplify the pattern of violations criteria, and improve consistency in
applying the pattern of violations criteria.

MSHA developed an online service that enables mine operators, miners, and others to monitor a mining operation to determine if the mine could be approaching a potential pattern of violations. The web tool contains the specific criteria that MSHA uses to review a mine for a potential pattern of violations. The pattern of violations monitoring tool promotes openness and transparency in government.

Notification of Legal Identity

The existing requirements do not provide sufficient information for MSHA to identify all of the mine “operators” responsible for operator safety and health obligations under the Federal Mine Safety and Health Act of 1977, as amended. This proposed regulation would expand the information required to be submitted to MSHA to create more transparent and open records that would allow the Agency to better identify and focus on the most egregious or persistent violators and more effectively deter future violations by imposing penalties and other remedies on those violators.

Addressing Targeted Hazards

Lowering Miners’ Exposure to Coal Mine Dust, including Continuous Personal Dust Monitors

MSHA will continue its regulatory action related to preventing Black Lung disease. Data from the NIOSH indicate increased prevalence of coal workers pneumoconiosis (CWP) “clusters” in several geographical areas, particularly in the Southern Appalachian Region. MSHA published a notice of proposed rulemaking to address continued risk to coal miners from exposure to respirable coal mine dust. This regulatory action is part of MSHA’s Comprehensive Black Lung Reduction Strategy for reducing miners’ exposure to respirable dust. This strategy includes enhanced enforcement, education and training, and health outreach and collaboration.

E.O. 13563
Criteria and Procedures for Proposed Assessment of Civil Penalties (Part 100)

MSHA plans to publish a proposed rule to revise the process for proposing civil penalties. The assessment of civil penalties is a key component in MSHA’s strategy to enforce safety and health standards. The Congress intended that the imposition of civil penalties would induce mine operators to be proactive in their approach to mine safety and health, and take necessary action to prevent safety and health hazards before they occur. MSHA believes that the procedures for assessing civil penalties can be revised to improve the efficiency of the Agency’s efforts and to facilitate the resolution of enforcement issues.

Office of Federal Contract Compliance Programs (OFCCP)

Through the work of the Office of Federal Contract Compliance Programs, DOL ensures that contractors and subcontractors doing business with the Federal Government at nearly 200,000 establishments take affirmative action to create fair and diverse workplaces. OFCCP also combats discrimination based on race, color, religion, sex, national origin, disability, or status as a protected veteran by ensuring that Federal contractors recruit, hire, train, promote, terminate, and compensate workers in a non-discriminatory manner. DOL, through OFCCP, protects workers, promotes diversity and enforces civil rights laws.

Plan/Prevent/Protect

Construction Contractor Affirmative Action Requirements

OFCCP will publish a proposed rule that would enhance the effectiveness of the affirmative action programs of Federal and federally assisted construction contractors and subcontractors. The proposed rule would strengthen affirmative action programs particularly in the areas of recruitment, training, and apprenticeships. The proposed rule would also provide contractors and subcontractors the tools to assess their progress and appropriately tailor their affirmative action plans. The proposed rule would also allow contractors and subcontractors to focus on their affirmative action obligations earlier in the
contracting process. OFCCP is coordinating with the Employment and Training Administration (ETA), which is developing a proposed regulation revising the equal opportunity regulatory framework under the National Apprenticeship Act.

**E.O. 13563**

**Sex Discrimination Guidelines**

The Office of Federal Contract Compliance Programs (OFCCP) is charged with enforcing Executive Order 11246, as amended, which prohibits Federal Government contractors and subcontractors from discriminating against individuals in employment on the basis of race, color, sex, religion, or national origin, and requires them to take affirmative action. OFCCP regulations at 41 CFR part 60-20 set forth the interpretations and guidelines for implementing Executive Order 11246, as amended, in regard to promoting and ensuring equal opportunities for all persons employed or seeking employment with Government contractors and subcontractors without regard to sex. This nondiscrimination requirement also applies to contractors and subcontractors performing under federally assisted construction contracts. The guidance in part 60-20 is more than 30 years old and warrants a regulatory lookback. OFCCP will issue a Notice of Proposed Rulemaking to create sex discrimination regulations that reflect the current state of the law in this area.

**Employee Benefits Security Administration (EBSA)**

The Employee Benefits Security Administration (EBSA) is responsible for administering and enforcing the fiduciary, reporting and disclosure, and health coverage provisions of title I of the Employee Retirement Income Security Act of 1974 (ERISA). This includes recent amendments and additions to ERISA enacted in the Pension Protection Act of 2006, as well as new health coverage provisions under the Patient Protection and Affordable Care Act of 2010 (the Affordable Care Act). EBSA’s regulatory plan initiatives are intended to improve health benefits and retirement security for
workers in every type of job at every income level. EBSA is charged with protecting approximately 140 million Americans covered by an estimated 718,000 private retirement plans, 2.5 million health plans, and similar numbers of other welfare benefit plans, which together hold $6.7 trillion in assets.

EBSA will continue to issue guidance implementing the health reform provisions of the Affordable Care Act to help provide better quality health care for American workers and their families. EBSA's regulations reduce discrimination in health coverage, promote better access to quality coverage, and protect the ability of individuals and businesses to keep their current health coverage. Many regulations are joint rulemakings with the Departments of Health and Human Services and the Treasury.

Using regulatory changes to produce greater openness and transparency is an integral part of EBSA's contribution to a departmentwide compliance strategy. These efforts will not only enhance EBSA's enforcement toolbox but will encourage greater levels of compliance by the regulated community and enhance awareness among workers of their rights and benefits. Several proposals from the EBSA agenda expand disclosure requirements, substantially enhancing the availability of information to employee benefit plan participants and beneficiaries and employers, and strengthening the retirement security of America's workers. EBSA's retrospective review project under E.O.13563 is Abandoned Plan Program amendments.

Addressing Targeted Issues of Employee Benefits

Health Reform Implementation

Since the passage of health care reform, EBSA has helped put the employment-based health provisions into action. Working with HHS and Treasury, EBSA has issued regulations covering issues such as the elimination of preexisting condition exclusions for children under age 19, internal and external appeals of benefit denials, the extension of coverage for children up to age 26, and a ban on rescissions (which are retroactive terminations of health care coverage). These regulations will eventually impact up to 138 million Americans in employer-sponsored plans. EBSA will continue its
work in this regard, to ensure a smooth implementation of the legislation’s market reforms, minimizing disruption to existing plans and practices, and strengthening America’s health care system.

Enhancing Participant Protections

EBSA will re-propose amendments to its regulations to clarify the circumstances under which a person will be considered a “fiduciary” when providing investment advice to retirement plans and other employee benefit plans and participants and beneficiaries of such plans. The amendments would take into account current practices of investment advisers and the expectations of plan officials and participants who receive investment advice. This initiative is intended to assure retirement security for workers in all jobs regardless of income level by ensuring that financial advisers and similar persons are required to meet ERISA’s standards of care when providing the investment advice that is relied upon by millions of plan sponsors and workers.

Lifetime Income Options

EBSA, in 2010, published a request for information concerning steps it can take by regulation, or otherwise, to encourage the offering of lifetime annuities or similar lifetime benefit distribution options for participants and beneficiaries of defined contribution plans. EBSA also held a hearing with the Department of the Treasury and Internal Revenue Service to further explore these possibilities. This initiative is intended to assure retirement security for workers in all jobs regardless of income level by helping to ensure that participants and beneficiaries have the benefit of their plan savings throughout retirement. EBSA now has established a public record which supports further consideration or action in a number of areas including pension benefit statements, participant education, and fiduciary guidance. With regard to pension benefit statements specifically, EBSA is working on a proposed rule under ERISA section 105 that would require or facilitate the presentation of a participant’s accrued benefits; i.e., the participant’s account balance, as a lifetime income stream of payments, in addition to presenting the benefits as an account balance.
Promoting Openness and Transparency

In addition to its health care reform and participant protection initiatives discussed above, EBSA is pursuing a regulatory program that, as reflected in the Unified Agenda, is designed to encourage, foster, and promote openness, transparency, and communication with respect to the management and operations of pension plans, as well as participant rights and benefits under such plans. Among other things, EBSA will be issuing a final rule addressing the requirement that administrators of defined benefit pension plans annually disclose the funding status of their plan to the plan's participants and beneficiaries (RIN I210-AB18). In addition, EBSA will be finalizing amendments to the disclosure requirements applicable to plan investment options, including Qualified Default Investment Alternatives, to better ensure that participants understand the operations and risks associated with investments in target date funds (RIN 1210-AB38). A complete listing of EBSA's regulatory initiatives (both Plan and non-Plan items) is provided in the Unified Agenda portion of this document.

E.O. 13563

Abandoned Plan Program Amendment

In 2006, the Department published regulations that facilitate the termination and winding up of 401(k)-type retirement plans that have been abandoned by their plan sponsors. The regulation establishes a streamlined program under which plans are terminated with very limited involvement of EBSA regional offices. EBSA now has 6 years of experience with this program and believes certain changes would improve the overall efficiency of the program and increase its usage.

EBSA intends to revise the regulations to expand the program to include plans of businesses in liquidation proceedings to reflect recent changes in the U.S. Bankruptcy Code. The Department believes that this expansion has the potential to substantially reduce burdens on these plans and bankruptcy trustees. Plans of businesses in liquidation currently do not have the option of using the streamlined termination and winding-up procedures under the program. This is true even though
bankruptcy trustees, pursuant to the Bankruptcy Code, can have a legal duty to administer the plan. Thus, bankruptcy trustees, who often are unfamiliar with applicable fiduciary requirements and plan-termination procedures, presently have little in the way of a blueprint or guide for efficiently terminating and winding up such plans. Expanding the program to cover these plans will allow eligible bankruptcy trustees to use the streamlined termination process to better discharge its obligations under the law. The use of streamlined procedures will reduce the amount of time and effort it would take ordinarily to terminate and wind up such plans. The expansion also will eliminate Government filings ordinarily required of terminating plans. Participation in the program will reduce the overall cost of terminating and winding up such plans, which will result in larger benefit distributions to participants and beneficiaries in such plans.

EBSA preliminarily estimates that approximately 165 additional plans will benefit from the amended abandoned plans regulation and accompanying class exemption. EBSA expects that the cost burden reduction that will result from this initiative will be approximately $1.12 million.

Please note that this preliminary estimate only reflects short-term burden reduction costs for bankruptcy trustees to terminate plans under the rule. EBSA expects substantial benefits will accrue to participants and beneficiaries covered by these plans, because their account balances will be maximized for two primary reasons. First, prompt, efficient termination of these plans will eliminate future administrative expenses charged to the plans that otherwise would diminish plan assets. Second, by following the specific standards and procedures set forth in the rule, the Department expects that overall plan termination costs will be reduced due to increased efficiency.

Office of Labor-Management Standards (OLMS)

The Office of Labor-Management Standards (OLMS) administers and enforces most provisions of the Labor-Management Reporting and Disclosure Act of 1959 (LMRDA). The LMRDA promotes labor-management transparency by requiring unions, employers, labor-relations consultants, and others to file reports, which are publicly available. The LMRDA includes provisions protecting union member rights to
participate in their union's governance, to run for office and fully exercise their union citizenship, as well as procedural safeguards to ensure free and fair union elections. Besides enforcing these provisions, OLMS also ensures the financial accountability of unions, their officers and employees, through enforcement and voluntary compliance efforts. Because of these activities, OLMS better ensures that workers have a more effective voice in the governance of their unions, which in turn affords them a more effective voice in their workplaces. OLMS also administers Executive Order 13496, which requires Federal contractors to notify their employees concerning their rights to organize and bargain collectively under Federal labor laws.

Openness and Transparency

Persuader Agreements: Employer and Labor Relations Consultant Reporting under the LMRDA

OLMS published a proposed regulatory initiative in June 2011, which is a transparency regulation intended to provide workers with information critical to their effective participation in the workplace. The proposed regulations would better implement the public disclosure objectives of the LMRDA in situations where an employer engages a consultant in order to persuade employees concerning their rights to organize and bargain collectively. Under LMRDA section 203, an employer must report any agreement or arrangement with a consultant to persuade employees concerning their rights to organize and collectively bargain, or to obtain certain information concerning activities of employees or a labor organization in connection with a labor dispute involving the employer. The consultant is also required to report such an agreement or arrangement with an employer. Statutory exceptions to these reporting requirements are set forth in LMRDA section 203(c), which provides, in part, that employers and consultants are not required to file a report by reason of the consultant's giving or agreeing to give "advice" to the employer. The Department in its proposal reconsidered the current policy concerning the scope of the "advice" exception. When workers have the necessary information about arrangements that have been made by their employer to persuade them whether or not to form, join, or assist a union, they are better able to make a more informed choice about representation.
OLMS published a final rule in October 2011 revising the Form LM-30 Labor Organization Officer and Employee Report, which discloses actual or likely conflicts between the financial interests of a union official and the interests of the union. In addition to seeking greater transparency of actual or likely conflicts of interest, this rule is also a burden reduction regulation.

**Employment and Training Administration (ETA)**

The Employment and Training Administration (ETA) administers and oversees programs that prepare workers for good jobs at good wages by providing high quality job training, employment, labor market information, and income maintenance services through its national network of One-Stop centers. The programs within ETA promote pathways to economic independence for individuals and families. Through several laws, ETA is charged with administering numerous employment and training programs designed to assist the American worker in developing the knowledge, skills, and abilities that are sought after in the 21st century's economy. ETA plans a retrospective review of the Rounding Rule for the Total Unemployment Rate Benefits Trigger.

**Addressing Targeted Concerns of Workers**

Temporary Non Agricultural Employment of H-2B Aliens in the United States

As part of the Department’s foreign labor certification responsibilities, ETA certifies whether U.S. workers capable of performing the jobs for which employers are seeking foreign workers are available and whether the employment of foreign workers will adversely affect the wages and working conditions of U.S. workers similarly employed. Through the Wage and Hour Division (WHD), the Department enforces compliance with the conditions of an approved temporary labor certification.
This rulemaking seeks to ensure that only those employers who demonstrate a real temporary need for foreign workers will have access to H-2B workers. The rule also will seek to provide U.S. workers with greater access to the jobs employers wish to fill with temporary H-2B workers through more robust recruitment by employers to demonstrate the unavailability of U.S. workers and through the creation of a national, electronic job registry. The rule will explore strengthening existing worker enforcement to ensure adequate protections for both U.S. and H-2B workers. The rulemaking will include greater transparency and openness to provide U.S. workers with greater information and access to job opportunities.

E.O. 13563

Equal Employment Opportunity in Apprenticeship and Training, Amendment of Regulations

The revision of the National Apprenticeship Act Equal Opportunity in Apprenticeship and Training (EEO) regulations is a critical element in the Department’s vision to promote and expand registered apprenticeship opportunities in the 21st Century while safeguarding the welfare and safety of all apprentices. In October 2008, ETA issued a final rule updating 29 CFR part 29, the regulatory framework for registration of apprenticeship programs and apprentices, and administration of the National Apprenticeship System. The companion EEO regulations, 29 CFR part 30, have not been amended since 1978. ETA proposes to update part 30 EEO in the Apprenticeship and Training regulations to ensure that they act in concert with the 2008 revised part 29 rule. The proposed EEO regulations also will further Secretary Solis' vision of good jobs for everyone by ensuring that apprenticeship program sponsors develop and fully implement nondiscrimination and affirmative action efforts that provide equal opportunity for all applicants to apprenticeship and apprentices, regardless of race, gender, national origin, color, religion, or disability.
86. CONSTRUCTION CONTRACTORS’ AFFIRMATIVE ACTION REQUIREMENTS

Priority:

Other Significant

Legal Authority:

sec 201, 202, 205, 211, 301, 302, and 303 of EO 11246, as amended; 30 FR 12319; 32 FR 14303, as amended by EO 12086

CFR Citation:

41 CFR 60–1; 41 CFR 60–4

Legal Deadline:

None

Abstract:

The regulations implementing the affirmative action obligations of construction contractors under Executive Order 11246, as amended, were last revised in 1980. Recent data show that disparities in the representation of women and racial minorities continue to exist in on-site construction occupations in the construction industry. This Notice of Proposed Rulemaking (NPRM) would revise 41 CFR part 60-1 and 60-4 by removing outdated regulatory provisions, proposing a new method for establishing affirmative action goals, and proposing other revisions to the affirmative action requirements that reflect the realities of the labor market and employment practices in the construction industry today.

Statement of Need:

These regulations, last revised in 1980, have proven ineffective at making meaningful progress in the employment of women and certain minorities in the construction industry. Analysis of 2006 to 2008 ACS data for 27 on-site construction occupations reveals a significant disparity between the percentage of women in construction occupations in the construction industry and the percentage of women in construction occupations in all other industries. The representation of African Americans in the construction industry is substantially less than would be expected given their representation in all other industries. For example, in 23 of the 27 occupations analyzed, disparities were found in the representation of African Americans. The NPRM would remove outdated regulatory provisions, propose a
new method for establishing affirmative action goals, and propose other revisions to the affirmative action requirements that reflect the realities of the labor market and employment practices in the construction industry today.

**Summary of Legal Basis:**
This action is not required by statute or court order. Legal Authority: Sections 201, 202, 205, 211, 301, 302, and 303 of E.O. 11246, as amended; 30 FR 12319; 32 FR 14303, as amended by E.O. 12086.

**Alternatives:**
Regulatory alternatives will be addressed as the NPRM is developed.

**Anticipated Cost and Benefits:**
The proposed rule would adopt a new framework for implementing affirmative action requirements in the construction industry and proposes standards for designating projects “mega construction projects.” There may be some additional costs to contractors as a result of the increased scope of required actions. The benefits would likely include increased diversity in construction workplaces and increased opportunities for women and minorities to obtain on-site construction jobs. Recent reports on the national unemployment rate show significantly higher unemployment in these populations than in others. The African American unemployment rate is at record high numbers. More detailed cost and benefit analyses will be made as the NPRM is developed. Data all show significant underrepresentation of these groups in the construction industry.

**Risks:**
Failure to provide updated regulations may impede the equal opportunity rights of some workers in protected classes.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Undetermined

**Government Levels Affected:**
None
Federalism:
Undetermined

Agency Contact:
Debra A. Carr
Director, Division of Policy, Planning, and Program Development
Department of Labor
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Washington, DC 20210
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TDD Phone: 202 693–1337
Fax: 202 693–1304
Email: ofccp-public@dol.gov

Related RIN: Previously reported as 1215–AB81
RIN: 1250–AA01

<table>
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<th>DOL—Office of Labor-Management Standards (OLMS)</th>
<th>FINAL RULE STAGE</th>
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<tr>
<td>87. PERSUADER AGREEMENTS: EMPLOYER AND LABOR RELATIONS CONSULTANT REPORTING UNDER THE LMRDA</td>
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Priority:
Other Significant

Legal Authority:
29 USC 433; 29 USC 438

CFR Citation:
29 CFR 405; 29 CFR 406
Abstract:
The Department published a notice and comment rulemaking seeking consideration of a revised
interpretation of section 203(c) of the Labor-Management Reporting and Disclosure Act (LMRDA). That
statutory provision creates an “advice” exemption from reporting requirements that apply to employers
and other persons in connection with persuading employees about the right to organize and bargain
collectively. A revised interpretation would narrow the scope of the advice exemption.

Statement of Need:
The Department of Labor proposed a regulatory initiative to better implement the public disclosure
objectives of the Labor-Management Reporting and Disclosure Act (LMRDA) regarding employer-
consultant agreements to persuade employees concerning their rights to organize and bargain
collectively. Under LMRDA section 203, an employer must report any agreement or arrangement with a
third party consultant to persuade employees as to their collective bargaining rights or to obtain certain
information concerning the activities of employees or a labor organization in connection with a labor
dispute involving the employer. The consultant also is required to report concerning such an agreement
or arrangement with an employer. Statutory exceptions to these reporting requirements are set forth in
LMRDA section 203(c), which provides, in part, that employers and consultants are not required to file a
report by reason of the consultant’s giving or agreeing to give “advice” to the employer. The Department’s
proposal stated that its current policy concerning the scope of the “advice exception” is overbroad and
that a narrower construction would better allow for the employer and consultant reporting intended by the
LMRDA. The proposal stated that regulatory action is needed to provide workers with information critical
to their effective participation in the workplace.

Summary of Legal Basis:
This proposed rulemaking is authorized under U.S.C. sections 433 and 438 and applies to regulations at

Alternatives:
Alternatives will be developed and considered in the course of notice and comment rulemaking.
Anticipated Cost and Benefits:

Anticipated costs and benefits of this proposed regulatory initiative have not been assessed and will be determined at a later date, as appropriate.

Risks:

This action does not affect public health, safety, or the environment.

Timetable:

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Regulatory Flexibility Analysis Required:

No

Government Levels Affected:

None

URL For More Information:

www.olms.dol.gov

URL For Public Comments:

www.regulations.gov

Agency Contact:

Andrew R. Davis

Chief, Division of Interpretations and Standards, Office of Labor–Management Standards

Department of Labor

Office of Labor–Management Standards

Room N–5609

FP Building
DOL—Employment and Training Administration

(ETA)

PROPOSED RULE STAGE

88. EQUAL EMPLOYMENT OPPORTUNITY IN APPRENTICESHIP AMENDMENT OF REGULATIONS

Priority:
Other Significant

Legal Authority:
sec 1, 50 Stat 664, as amended (29 USC 50; 40 USC 276c; 5 USC 301); Reorganization Plan No 14 of 1950, 64 Stat 1267 (5 USC app p 534)

CFR Citation:
29 CFR 30 (Revision)

Legal Deadline:
None

Abstract:
Revisions to the equal opportunity regulatory framework for the National Apprenticeship Act are a critical element in the Department's vision to promote and expand Registered Apprenticeship opportunities in the 21st century while continuing to safeguard the welfare and safety of apprentices. In October 2008, the Agency issued a Final Rule updating regulations for Apprenticeship Programs and Labor Standards for Registration. These regulations, codified at title 29 Code of Federal Regulations (CFR) part 29, had not
been updated since 1977. The companion regulations, 29 CFR part 30, Equal Employment Opportunity (EEO) in Apprenticeship and Training, have not been amended since 1978.

The Agency now proposes to update 29 CFR part 30 to ensure that the National Registered Apprenticeship System is consistent and in alignment with EEO law, as it has developed since 1978, and recent revisions to 29 CFR part 29. This second phase of regulatory updates will ensure that Registered Apprenticeship is positioned to continue to provide economic opportunity for millions of Americans while keeping pace with these new requirements.

**Statement of Need:**
Federal regulations for Equal Employment Opportunity (EEO) in Apprenticeship have not been updated since 1978. Updates to these regulations are necessary to ensure that DOL regulatory requirements governing the National Registered Apprenticeship System are consistent with the current state of EEO law and recent revisions to 29 CFR part 29.

**Summary of Legal Basis:**
These regulations are authorized by the National Apprenticeship Act of 1937 (29 U.S.C. 50) and the Copeland Act (40 U.S.C. 276c). These regulations will set forth policies and procedures to promote equality of opportunity in apprenticeship programs registered with the U.S. Department of Labor or in State Apprenticeship Agencies recognized by the U.S. Department of Labor.

**Alternatives:**
The public will be afforded an opportunity to provide comments on the proposed amendment to Apprenticeship EEO regulations when the Department publishes a Notice of Proposed Rulemaking (NPRM) in the Federal Register. A Final Rule will be issued after analysis and incorporation of public comments to the NRPM.

**Anticipated Cost and Benefits:**
The proposed changes are thought to raise "novel legal or policy issues" but are not economically significant within the context of Executive Order 12866 and are not a “major rule” under section 804 of the Small Business Regulatory Enforcement Fairness Act.

**Risks:**
This action does not affect the public health, safety, or the environment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, State, Tribal

**Federalism:**

This action may have federalism implications as defined in EO 13132.

**Agency Contact:**

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**RIN:** 1205–AB59
89. LABOR CERTIFICATION PROCESS AND ENFORCEMENT FOR TEMPORARY EMPLOYMENT IN OCCUPATIONS OTHER THAN AGRICULTURE OR REGISTERED NURSING IN THE UNITED STATES (H–2B WORKERS)

Priority: Other Significant

Legal Authority:
8 USC 1101(a)(15)(H)(ii)(B)); 8 USC 1184(c)(1); 8 CFR 214.2(h)

CFR Citation:
20 CFR 655

Legal Deadline:
None

Abstract:
The Department published a Notice of Proposed Rulemaking (NPRM) on March 18, 2011. The public comment period closed on May 17, 2011. The Department of Homeland Security (DHS) regulations require employers to apply for a temporary labor certification from the Department of Labor before H-2B petitions may be approved. DOL certifies that there are not sufficient U.S. worker(s) who are capable of performing the temporary services or labor at the time of an application for a visa, and that the employment of the H-2B workers will not adversely affect the wages and working conditions of similarly employed U.S. workers. This NPRM proposed to re-engineer the H-2B program in order to enhance transparency and strengthen program integrity and protections of both U.S. workers and H-2B workers.

Statement of Need:
The Department has determined that a new rulemaking effort is necessary for the H-2B program. The policy underpinnings of the current regulation; e.g., streamlining the H-2B process to defer many determinations of program compliance until after an application has been adjudicated do not provide an adequate level of protection for either U.S. or foreign workers. The proposed rule seeks to enhance worker protections and increase the availability of job opportunities to qualified U.S. workers.

Summary of Legal Basis:
The Department of Labor’s authority to revise these regulations derives from 8 U.S.C. 1101(a)(15)(H)(ii)(B), 8 U.S.C. 1184(c)(1), and 8 CFR 214.2(h).

Alternatives:
The public was afforded an opportunity to provide comments on the proposed regulatory changes when the Department published the NPRM in the Federal Register. A final rule will be issued after analysis of, and response to, public comments.

Anticipated Cost and Benefits:
Preliminary estimates of the anticipated costs of this regulatory action have been provided in the NPRM. The Department of Labor sought information on potential additional or actual costs from employers and other interested parties through the NPRM in order to better assess the costs and benefits of the proposed provisions of the program. The proposed changes are thought to raise “novel legal or policy issues” but are not economically significant within the context of Executive Order 12866 and are not a “major rule” under section 804 for the Small Business Regulatory Enforcement Fairness Act.

Risks:
This action does not affect the public health, safety, or the environment.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Government Levels Affected:
State

Agency Contact:
William L. Carlson Ph.D.
Administrator, Office of Foreign Labor Certification
Department of Labor
90. DEFINITION OF “FIDUCIARY”

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
29 USC 1002; ERISA sec 3(21); 29 USC 1135; ERISA sec 505

CFR Citation:
29 CFR 2510.3–21(c)

Legal Deadline:
None

Abstract:
This rulemaking would amend the regulatory definition of the term “fiduciary” set forth at 29 CFR 2510.3-21 (c) to more broadly define as employee benefit plan fiduciaries persons who render investment advice to plans for a fee within the meaning of section 3(21) of ERISA. The amendment would take into account current practices of investment advisers and the expectations of plan officials and participants who receive investment advice.

Statement of Need:
This rulemaking is needed to bring the definition of “fiduciary” into line with investment advice practices and to recast the current regulation to better reflect relationships between investment advisers and their employee benefit plan clients. The current regulation may inappropriately limit the types of investment advice relationships that should give rise to fiduciary duties on the part of the investment adviser.

Summary of Legal Basis:

Section 505 of ERISA provides that the Secretary may prescribe such regulations as she finds necessary and appropriate to carry out the provisions of title I of the Act. Regulation 29 CFR 2510.3-21(c) defines the term fiduciary for certain purposes under section 3(21) of ERISA.

Alternatives:

Alternatives will be considered following a determination of the scope and nature of the regulatory guidance needed by the public.

Anticipated Cost and Benefits:

Preliminary estimates of the anticipated costs and benefits will be developed, as appropriate, following a determination regarding the alternatives to be considered.

Timetable:

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Regulatory Flexibility Analysis Required:

Undetermined

Government Levels Affected:

Undetermined

Agency Contact:

Jeffrey J. Turner

Chief, Division of Regulations, Office of Regulations and Interpretations

Department of Labor

Employee Benefits Security Administration
Current standards limit exposures to quartz (crystalline silica) in respirable dust. The metal and nonmetal mining industry standard is based on the 1973 American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values formula: 10 mg/m³ divided by the percentage of quartz plus 2. Overexposure to crystalline silica can result in some miners developing silicosis, an irreversible but preventable lung disease, which ultimately may be fatal. The formula is designed to limit exposures to 0.1 mg/m³ (100 ug) of silica. NIOSH recommends a 50 ug/m³ exposure limit for respirable crystalline silica. MSHA will publish a proposed rule to address miners' exposure to respirable crystalline silica.
MSHA standards are outdated; current regulations may not protect workers from developing silicosis. Evidence indicates that miners continue to develop silicosis. MSHA’s proposed regulatory action exemplifies the Agency’s commitment to protecting the most vulnerable populations while assuring broad-based compliance. MSHA will regulate based on sound science to eliminate or reduce the hazards with the broadest and most serious consequences. MSHA intends to use OSHA’s work on the health effects and risk assessment, adapting it as necessary for the mining industry.

**Summary of Legal Basis:**

Promulgation of this standard is authorized by section 101 of the Federal Mine Safety and Health Act of 1977.

**Alternatives:**

This rulemaking would improve health protection from that afforded by the existing standards. MSHA will consider alternative methods of addressing miners’ exposures based on the capabilities of the sampling and analytical methods.

**Anticipated Cost and Benefits:**

MSHA will prepare estimates of the anticipated costs and benefits associated with the proposed rule.

**Risks:**

For over 70 years, toxicology information and epidemiological studies have shown that exposure to respirable crystalline silica presents potential health risks to miners. These potential adverse health effects include simple silicosis and progressive massive fibrosis (lung scarring). Evidence indicates that exposure to silica may cause cancer. MSHA believes that the health evidence forms a reasonable basis for reducing miners’ exposures to respirable crystalline silica.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Small Entities Affected:**

Businesses, Governmental Jurisdictions
92. CRITERIA AND PROCEDURES FOR PROPOSED ASSESSMENT OF CIVIL PENALTIES

Priority:
Other Significant

Unfunded Mandates:
Undetermined

Legal Authority:
30 USC 815; 30 USC 820; 30 USC 957

CFR Citation:
Abstract:

MSHA will develop a proposed rule to revise the process for proposing civil penalties. The assessment of civil penalties is a key component in MSHA’s strategy to enforce safety and health standards. The Congress intended that the imposition of civil penalties would induce mine operators to be proactive in their approach to mine safety and health, and take necessary action to prevent safety and health hazards before they occur. MSHA believes that the procedures for assessing civil penalties can be revised to improve the efficiency of the Agency's efforts and to facilitate the resolution of enforcement issues.

Statement of Need:

Section 110(a) of the Federal Mine Safety and Health Act of 1977 (Mine Act) requires MSHA to assess a civil penalty for a violation of a mandatory health or safety standard or violation of any provision of the Mine Act. The mine operator has 30 days from receipt of the proposed assessment to contest it before the Federal Mine Safety and Health Review Commission (Commission), an independent adjudicatory agency established under the Mine Act. A proposed assessment that is not contested within 30 days becomes a final order of the Commission. A proposed assessment that is contested within 30 days proceeds to the Commission for adjudication. The proposed rule would promote consistency, objectivity, and efficiency in the proposed assessment of civil penalties.

When issuing citations or orders, inspectors are required to evaluate safety and health conditions and make decisions about the statutory criteria related to assessing penalties. The proposed changes in the measures of the evaluation criteria would result in fewer areas of disagreement and earlier resolution of enforcement issues. The proposal would require conforming changes to the Mine Citation/Order form (MSHA Form 7000-3).

Summary of Legal Basis:
Section 104 of the Mine Act requires MSHA to issue citations or orders to mine operators for any violations of a mandatory health or safety standard, rule, order, or regulation promulgated under the Mine Act. Sections 105 and 110 of the Mine Act provide for assessment of these penalties.

Alternatives:
The proposal would include several alternatives in the preamble and requests comments on them.

Anticipated Cost and Benefits:
MSHA will prepare estimates of the anticipated costs and benefits in a preliminary regulatory economic analysis to accompany the proposed rule.

Risks:
MSHA's existing procedures for assessing civil penalties can be revised to improve the efficiency of the Agency's efforts and to facilitate the resolution of enforcement issues. In the overwhelming majority of contested cases before the Commission, the issue is not whether a violation occurred. Rather, the parties disagree on the gravity of the violation, the degree of mine operator negligence, and other criterion. The proposed changes should result in fewer areas of disagreement and earlier resolution of enforcement issues, which should result in fewer contests of violations or proposed assessments.

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Regulatory Flexibility Analysis Required:
Undetermined

Small Entities Affected:
Businesses

Government Levels Affected:
None

URL For More Information:
www.msha.gov/regsinfo.htm

URL For Public Comments:
www.regulations.gov
Agency Contact:
Roslyn B. Fontaine
Acting Director, Office of Standards, Regulations, and Variances
Department of Labor
Mine Safety and Health Administration
1100 Wilson Boulevard, Room 2350
Arlington, VA 22209–3939
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RIN: 1219–AB72

DOL—MSHA

93. • PROXIMITY DETECTION SYSTEMS FOR MOBILE MACHINES IN UNDERGROUND MINES

Priority:
Other Significant

Legal Authority:
30 USC 811

CFR Citation:
Not Yet Determined

Legal Deadline:
None

Abstract:
MSHA will develop a proposed rule to address the hazards that miners face when working near mobile equipment in underground mines. MSHA has concluded, from investigations or accidents involving mobile equipment and other reports, that action is needed to protect miner safety. Mobile equipment can pin, crush, or strike a miner working near the equipment. Proximity detection technology can prevent these
types of accidents. The proposed rule would strengthen the protection for underground miners by reducing the potential of pinning, crushing, or striking hazards associated with working close to mobile equipment. As part of the Secretary's strategy for securing safe and healthy workplaces, the OSHA will also undertake regulatory action related to reducing injuries and fatalities to workers in close proximity to moving equipment and vehicles.

**Statement of Need:**
Mining is one of the most hazardous industries in this country. Miners continue to be injured or killed resulting from pinning, crushing, or striking accidents involving mobile equipment. Equipment is available to help prevent accidents that cause debilitating injuries and accidental death.

**Summary of Legal Basis:**
Promulgation of this standard is authorized by section 101(a) of the Federal Mine Safety and Health Act of 1977, as amended by the Mine Improvement and New Emergency Response Act of 2006.

**Alternatives:**
No reasonable alternatives to this regulation would be as comprehensive or as effective in eliminating hazards and preventing injuries.

**Anticipated Cost and Benefits:**
MSHA will develop a preliminary regulatory economic analysis to accompany the proposed rule.

**Risks:**
The lack of proximity detection systems on mobile equipment in underground mines contributes to a higher incidence of debilitating injuries and accidental deaths.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
No

**Small Entities Affected:**
Businesses

Government Levels Affected:
None

URL For More Information:
www.msha.gov/regsinfo.htm

URL For Public Comments:
www.regulations.gov

Agency Contact:
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Mine Safety and Health Administration
1100 Wilson Boulevard, Room 2350
Arlington, VA 22209–3939
Phone: 202 693–9440
Fax: 202 693–9441
Email: fontaine.roslyn@dol.gov

Related RIN: Related to 1219–AB65

RIN: 1219–AB78

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<td>94. LOWERING MINERS' EXPOSURE TO COAL MINE DUST, INCLUDING CONTINUOUS PERSONAL DUST MONITORS</td>
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Priority:
Other Significant

Legal Authority:
30 USC 811; 30 USC 813(h)
Abstract:
The Federal Coal Mine Health and Safety Act of 1969 established the first comprehensive respirable dust standards for coal mines. These standards were designed to reduce the incidence of coal workers' pneumoconiosis (CWP or black lung) and silicosis and eventually eliminate these diseases. While significant progress has been made toward improving the health conditions in our Nation's coal mines, miners continue to be at risk of developing occupational lung disease, according to the National Institute for Occupational Safety and Health (NIOSH). In September 1995, NIOSH issued a Criteria Document in which it recommended that the respirable coal mine dust permissible exposure limit (PEL) be cut in half. In February 1996, the Secretary of Labor convened a Federal Advisory Committee on the Elimination of Pneumoconiosis Among Coal Miners (Advisory Committee) to assess the adequacy of MSHA's current program and standards to control respirable dust in underground and surface coal mines, as well as other ways to eliminate black lung and silicosis among coal miners. The Committee represented the labor, industry and academic communities. The Committee submitted its report to the Secretary of Labor in November 1996, with the majority of the recommendations unanimously supported by the Committee members. The Committee recommended a number of actions to reduce miners' exposure to respirable coal mine dust. This final rule is an important element in MSHA's Comprehensive Black Lung Reduction Strategy (Strategy) to “End Black Lung Now.”

Summary of Legal Basis:
Promulgation of this regulation is authorized by the Federal Mine Safety and Health Act of 1977 as amended by the Mine Improvement and New Emergency Response Act of 2006.

Alternatives:
MSHA is considering amendments, revisions, and additions to existing standards.

Anticipated Cost and Benefits:
MSHA will develop a regulatory economic analysis to accompany the final rule.

Risks:
Respirable coal dust is one of the most serious occupational hazards in the mining industry. Occupational exposure to excessive levels of respirable coal mine dust can cause coal workers’ pneumoconiosis and silicosis, which are potentially disabling and can cause death. MSHA is pursuing both regulatory and nonregulatory actions to eliminate these diseases through the control of coal mine respirable dust levels in mines and reduction of miners’ exposure. MSHA developed a risk assessment to accompany the proposed rule.

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**URL For More Information:**

www.msha.gov

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Roslyn B. Fontaine

Acting Director, Office of Standards, Regulations, and Variances

Department of Labor

Mine Safety and Health Administration

1100 Wilson Boulevard, Room 2350
Abstract:
The Mine Safety and Health Administration (MSHA) will develop a final rule to address hazards that miners face when working near continuous mining machines in underground coal mines. MSHA has concluded, from investigations of accidents involving continuous mining machines and other reports, that action is necessary to protect miners. Continuous mining machines can pin, crush, or strike a miner working near the equipment. Proximity detection technology can prevent these types of accidents. The final rule would strengthen the protection for underground coal miners by reducing the potential of pinning, crushing, or striking hazards associated with working close to continuous mining machines. As a part of the Secretary's strategy for securing safe and healthy workplaces, the OSHA will also undertake
regulatory action related to reducing injuries and fatalities to workers in close proximity to moving equipment and vehicles.

**Statement of Need:**

Mining is one of the most hazardous industries in this country. Miners continue to be injured or killed resulting from pinning, crushing, or striking accidents involving mobile equipment. Equipment is available to help prevent accidents that cause debilitating injuries and accidental death.

**Summary of Legal Basis:**

Promulgation of this standard is authorized by section 101(a) of the Federal Mine Safety and Health Act of 1977, as amended by the Mine Improvement and New Emergency Response Act of 2006.

**Alternatives:**

No reasonable alternatives to this regulation would be as comprehensive or as effective in eliminating hazards and preventing injuries.

**Anticipated Cost and Benefits:**

MSHA will develop a regulatory economic analysis to accompany the final rule.

**Risks:**

The lack of proximity detection systems on continuous mining machines in underground coal mines contributes to a higher incidence of debilitating injuries and accidental deaths.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**
Businesses

Government Levels Affected:
None

URL For More Information:
www.msha.gov/reginfo.htm

URL For Public Comments:
www.regulations.gov

Agency Contact:
Roslyn B. Fontaine
Acting Director, Office of Standards, Regulations, and Variances
Department of Labor
Mine Safety and Health Administration
1100 Wilson Boulevard, Room 2350
Arlington, VA 22209–3939
Phone: 202 693–9440
Fax: 202 693–9441
Email: fontaine.roslyn@dol.gov

RIN: 1219–AB65

DOL—MSHA

96. PATTERN OF VIOLATIONS

Priority:
Other Significant

Legal Authority:
30 USC 814(e); 30 USC 957

CFR Citation:
30 CFR 104
Legal Deadline:
None

Abstract:
MSHA is preparing a final rule to revise the Agency's existing regulation for pattern of violations contained in 30 CFR part 104. MSHA has determined that the existing pattern criteria and procedures do not reflect the statutory intent for section 104(e) of the Federal Mine Safety and Health Act of 1977 (Mine Act) that operators manage health and safety conditions at mines so that the root causes of significant and substantial (S&S) violations are addressed before they become a hazard to the health and safety of miners. The legislative history of the Mine Act explains that Congress intended the pattern of violations tool to be used for operators who have demonstrated a disregard for the health and safety of miners. The final rule would reflect statutory intent, simplify the pattern of violations criteria, and improve consistency in applying the patterns of violations criteria.

Statement of Need:
The pattern of violations provision was a new enforcement tool in the Mine Act. The Mine Act places the ultimate responsibility for ensuring the safety and health of miners on mine operators. The goal of the pattern of violations proposed rule is to compel operators to manage health and safety conditions so that the root causes of S&S violations are found and fixed before they become a hazard to miners. MSHA's existing regulation is not consistent with the language, purpose, and legislative history of the Mine Act and hinders the Agency's use of pattern of violations to identify chronic violators who thumb their noses at the law by a continuing cycle of citation and abatement.

Summary of Legal Basis:
Promulgation of this standard is authorized by sections 104(e) and 508 of the Federal Mine Safety and Health Act of 1977.

Alternatives:
MSHA will consider alternative criteria for determining when a pattern of significant and substantial violations exists in order to improve health and safety conditions in mines and provide protection for miners. Congress provided the Secretary with broad discretion in determining criteria, recognizing that MSHA may need to modify the criteria as Agency experience dictates.
**Anticipated Cost and Benefits:**

MSHA will develop a regulatory economic analysis to accompany the final rule.

**Risks:**

Mine operators with a chronic history of persistent serious violations needlessly expose miners to the same hazards again and again. These operators demonstrate a disregard for the safety and health of miners; this indicates a serious safety and health management problem at the mine. The existing regulation has not been effective in reducing repeated risks to miners at these mines.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**URL For More Information:**
97. EXAMINATION OF WORK AREAS IN UNDERGROUND COAL MINES FOR VIOLATIONS OF MANDATORY HEALTH OR SAFETY STANDARDS

Priority:
Other Significant

Legal Authority:
30 USC 811; 30 USC 961

CFR Citation:
30 CFR 75

Legal Deadline:
None

Abstract:
In the ever changing mine environment, it is critical that hazardous conditions be recognized and abated quickly. Additionally, other conditions that could develop into a hazard if left uncorrected must also be eliminated. Operator examinations for hazards and violations of mandatory health or safety standards are mandated in the Mine Act and are a critical component of an effective safety and health program for underground mines. While this requirement was previously included in regulations, the 1992 final rule addressing ventilation in underground coal mines only included the requirement that the mine examiners look for hazardous conditions. The 1992 rule omitted from the standard the text taken from the Mine Act requiring examinations for violations of mandatory health or safety standards during preshift examinations. The final rule will revise existing standards for preshift, supplemental, on-shift, and weekly examinations to address violations of mandatory health or safety standards.

**Statement of Need:**

Underground coal mines usually present harsh and hostile working environments, and the ventilation system is the most vital life support system in underground mining. A properly operating ventilation system is essential for maintaining a safe and healthful working environment. Examinations of work areas that include the ventilation system are the first line of defense for miners working in underground coal mines and are necessary to protect miners. Conditions in underground coal mines change rapidly—roof that appears adequately supported can quickly deteriorate and fall; stoppings can crush out and short-circuit air currents; conveyor belts can become misaligned or belt roller bearings can fail, resulting in an ignition source; and methane can accumulate in areas where it may not have been detected.

Diligent compliance with safety and health standards and safety-conscious work practices provide a substantial measure of protection against mine accidents and emergencies. To assure optimum safety of miners, it is imperative that operators find violations of health or safety standards, correct them, and record corrective actions taken.

**Summary of Legal Basis:**

Promulgation of this regulation is authorized by sections 101 and 303 (d)(1) and (f) of the Federal Mine Safety and Health Act of 1977.

**Alternatives:**
The proposal included several alternatives in the preamble and requested comments on them.

**Anticipated Cost and Benefits:**

MSHA estimated that the proposed rule would cost $15.3 million yearly and result in net benefits of $6.0 million yearly.

**Risks:**

Failure to conduct adequate examinations to identify, report, and correct hazardous conditions and violations of health and safety standards has resulted in serious accidents and fatalities. Lack of adequate ventilation in underground mines has resulted in fatalities from asphyxiation and explosions.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

None

**URL For More Information:**

www.msha.gov/regsinfo.htm
DOL—Occupational Safety and Health Administration (OSHA) PRERULE STAGE

98. INFECTION DISEASES

Priority:
Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:
Undetermined

Legal Authority:
5 USC 533; 29 USC 657 and 658; 29 USC 660; 29 USC 666; 29 USC 669; 29 USC 673; . . .

CFR Citation:
29 CFR 1910

Legal Deadline:
None

Abstract:
Employees in health care and other high-risk environments face long-standing infectious diseases hazards such as tuberculosis (TB), varicella disease (chickenpox, shingles), and measles (rubeola), as well as new and emerging infectious disease threats, such as Severe Acute Respiratory Syndrome (SARS) and pandemic influenza. Health care workers and workers in related occupations, or who are exposed in other high-risk environments, are at increased risk of contracting TB, SARS, MRSA, and other infectious diseases that can be transmitted through a variety of exposure routes. OSHA is concerned about the ability of employees to continue to provide health care and other critical services without unreasonably jeopardizing their health.

OSHA is considering the need for a standard to ensure that employers establish a comprehensive infection control program and control measures to protect employees from infectious disease exposures to pathogens that can cause significant disease. Workplaces where such control measures might be necessary include: Health care, emergency response, correctional facilities, homeless shelters, drug treatment programs, and other occupational settings where employees can be at increased risk of exposure to potentially infectious people. A standard could also apply to laboratories, which handle materials that may be a source of pathogens, and to pathologists, coroners’ offices, medical examiners, and mortuaries.

OSHA published an RFI on May 6, 2010, the comment period closed on August 4, 2010.

**Statement of Need:**

In 2007, the healthcare and social assistance sector as a whole had 16.5 million employees. Healthcare workplaces can range from small private practices of physicians to hospitals that employ thousands of workers. In addition, healthcare is increasingly being provided in other settings such as nursing homes, free-standing surgical and outpatient centers, emergency care clinics, patients’ homes, and prehospitalization emergency care settings. The Agency is particularly concerned by studies that indicate that transmission of infectious diseases to both patients and healthcare workers may be occurring as a result of incomplete adherence to recognized, but voluntary, infection control measures. Another concern is the movement of healthcare delivery from the traditional hospital setting, with its greater infrastructure
and resources to effectively implement infection control measures, into more diverse and smaller workplace setting with less infrastructure and fewer resources, but with an expanding worker population.

**Summary of Legal Basis:**

The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women (29 U.S.C. 651).

**Alternatives:**

The alternative to the proposed rulemaking would be to take no regulatory action.

**Anticipated Cost and Benefits:**

The estimates of the costs and benefits are still under development.

**Risks:**

Analysis of risks is still under development.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:**

Undetermined

**Agency Contact:**

Dorothy Dougherty

Acting Director, Directorate of Evaluation and Analysis
99. INJURY AND ILLNESS PREVENTION PROGRAM

Priority:
Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:
Undetermined

Legal Authority:
29 USC 653; 29 USC 655(b); 29 USC 657

CFR Citation:
Not Yet Determined

Legal Deadline:
None

Abstract:
OSHA is developing a rule requiring employers to implement an Injury and Illness Prevention Program. It involves planning, implementing, evaluating, and improving processes and activities that protect employee safety and health. OSHA has substantial data on reductions in injuries and illnesses from employers who have implemented similar effective processes. The Agency currently has voluntary Safety
and Health Program Management Guidelines (54 FR 3904 to 3916), published in 1989. An injury and illness prevention rule would build on these guidelines as well as lessons learned from successful approaches and best practices under OSHA’s Voluntary Protection Program Safety and Health Achievement Recognition Program and similar industry and international initiatives such as American National Standards Institute/American Industrial Hygiene Association Z10 and Occupational Health and Safety Assessment Series 18001.

**Statement of Need:**
There are approximately 5,000 workplace fatalities and approximately 3.5 million serious workplace injuries every year. There are also many workplace illnesses caused by exposure to common chemical, physical, and biological agents. OSHA believes that an injury and illness prevention program is a universal intervention that can be used in a wide spectrum of workplaces to dramatically reduce the number and severity of workplace injuries. Such programs have been shown to be effective in many workplaces in the United States and internationally.

**Summary of Legal Basis:**
The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women (29 U.S.C. 651).

**Alternatives:**
The alternatives to this rulemaking would be to issue guidance, recognition programs, or allow for the States to develop individual regulations. OSHA has used voluntary approaches to address the need, including publishing Safety and Health Program Management Guidelines in 1989. In addition, OSHA has two recognition programs, the Voluntary Protection Program (known as VPP), and the Safety and Health Achievement Recognition Program (known as SHARP). These programs recognize workplaces with effective safety and health programs. Several States have issued regulations that require employers to establish effective safety and health programs.

**Anticipated Cost and Benefits:**
The scope of the proposed rulemaking and the costs and benefits are still under development for this regulatory action.
Risks:
A detailed risk analysis is underway.

Timetable:

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Regulatory Flexibility Analysis Required:
Undetermined

Small Entities Affected:
Businesses

Government Levels Affected:
Undetermined

Federalism:
Undetermined

Agency Contact:
Dorothy Dougherty
Acting Director, Directorate of Evaluation and Analysis
Department of Labor
Occupational Safety and Health Administration
Room N–3641, FP Building
200 Constitution Avenue NW.
Washington, DC 20210
Phone: 202 693–2400
Fax: 202 693–1641
Email: dougherty.dorothy@dol.gov

RIN: 1218–AC48
Crystalline silica is a significant component of the earth's crust, and many workers in a wide range of industries are exposed to it, usually in the form of respirable quartz or, less frequently, cristobalite. Chronic silicosis is a uniquely occupational disease resulting from exposure of employees over long periods of time (10 years or more). Exposure to high levels of respirable crystalline silica causes acute or accelerated forms of silicosis that are ultimately fatal. The current OSHA permissible exposure limit (PEL) for general industry is based on a formula proposed by the American Conference of Governmental Industrial Hygienists (ACGIH) in 1968 (PEL=10mg/cubic meter/(% silica + 2), as respirable dust). The current PEL for construction and shipyards (derived from ACGIH's 1970 Threshold Limit Value) is based on particle counting technology, which is considered obsolete. NIOSH and ACGIH recommend 50µg/m3 and 25µg/m3 exposure limits, respectively, for respirable crystalline silica.

Both industry and worker groups have recognized that a comprehensive standard for crystalline silica is needed to provide for exposure monitoring, medical surveillance, and worker training. ASTM International has published recommended standards for addressing the hazards of crystalline silica. The Building Construction Trades Department of the AFL-CIO has also developed a recommended comprehensive
program standard. These standards include provisions for methods of compliance, exposure monitoring, training, and medical surveillance.

**Statement of Need:**

Workers are exposed to crystalline silica dust in general industry, construction, and maritime industries. Industries that could be particularly affected by a standard for crystalline silica include: Foundries, industries that have abrasive blasting operations, paint manufacture, glass and concrete product manufacture, brick making, china and pottery manufacture, manufacture of plumbing fixtures, and many construction activities including highway repair, masonry, concrete work, rock drilling, and tuckpointing. The seriousness of the health hazards associated with silica exposure is demonstrated by the fatalities and disabling illnesses that continue to occur. In 2005, the most recent year for which data is available, silicosis was identified on 161 death certificates as an underlying or contributing cause of death. It is likely that many more cases have occurred where silicosis went undetected. In addition, the International Agency for Research on Cancer has designated crystalline silica as carcinogenic to humans, and the National Toxicology Program has concluded that respirable crystalline silica is a known human carcinogen. Exposure to crystalline silica has also been associated with an increased risk of developing tuberculosis and other nonmalignant respiratory diseases, as well as renal and autoimmune diseases. Exposure studies and OSHA enforcement data indicate that some workers continue to be exposed to levels of crystalline silica far in excess of current exposure limits. Congress has included compensation of silicosis victims on Federal nuclear testing sites in the Energy Employees' Occupational Illness Compensation Program Act of 2000. There is a particular need for the Agency to modernize its exposure limits for construction and shipyard workers, and to address some specific issues that will need to be resolved to propose a comprehensive standard.

**Summary of Legal Basis:**

The legal basis for the proposed rule is a preliminary determination that workers are exposed to a significant risk of silicosis and other serious disease and that rulemaking is needed to substantially reduce the risk. In addition, the proposed rule will recognize that the PELs for construction and maritime are outdated and need to be revised to reflect current sampling and analytical technologies.

**Alternatives:**
Over the past several years, the Agency has attempted to address this problem through a variety of non-regulatory approaches, including initiation of a Special Emphasis Program on silica in October 1997, sponsorship with NIOSH and MSHA of the National Conference to Eliminate Silicosis, and dissemination of guidance information on its Web site.

**Anticipated Cost and Benefits:**

The scope of the proposed rulemaking and estimates of the costs and benefits are still under development.

**Risks:**

A detailed risk analysis is under way.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal

**Federalism:**

This action may have federalism implications as defined in EO 13132.

**Agency Contact:**

Dorothy Dougherty

Acting Director, Directorate of Evaluation and Analysis
**DOL—OSHA**

101. IMPROVE TRACKING OF WORKPLACE INJURIES AND ILLNESSES

**Priority:**
Other Significant. Major status under 5 USC 801 is undetermined.

**Unfunded Mandates:**
Undetermined

**Legal Authority:**
29 USC 657

**CFR Citation:**
29 CFR 1904

**Legal Deadline:**
None

**Abstract:**
OSHA is proposing changes to its reporting system for occupational injuries and illnesses. An updated and modernized reporting system would enable a more efficient and timely collection of data and would improve the accuracy and availability of the relevant records and statistics. This proposal involves
modification to 29 CFR part 1904.41 to expand OSHA's legal authority to collect and make available injury and illness information required under part 1904.

**Statement of Need:**
The collection of establishment specific injury and illness data in electronic format on a timely basis is needed to help OSHA, employers, employees, researchers, and the public more effectively prevent workplace injuries and illnesses, as well as support President Obama's Open Government Initiative to increase the ability of the public to easily find, download, and use the resulting dataset generated and held by the Federal Government.

**Summary of Legal Basis:**
The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to develop and maintain an effective program of collection, compilation, and analysis of occupational safety and health statistics (29 U.S.C. 673).

**Alternatives:**
The alternative to the proposed rulemaking would be to take no regulatory action.

**Anticipated Cost and Benefits:**
The estimates of the costs and benefits are still under development.

**Risks:**
Analysis of risks is still under development.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
No

**Government Levels Affected:**
None

**Agency Contact:**
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RIN: 1218–AC49

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<thead>
<tr>
<th>DOL—OSHA</th>
<th>FINAL RULE STAGE</th>
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<tr>
<td>102. HAZARD COMMUNICATION</td>
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Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
29 USC 655(b); 29 USC 657

CFR Citation:

Legal Deadline:
None

Abstract:
OSHA’s Hazard Communication Standard (HCS) requires chemical manufacturers and importers to evaluate the hazards of the chemicals they produce or import, and prepare labels and material safety data sheets to convey the hazards and associated protective measures to users of the chemicals. All employers with hazardous chemicals in their workplaces are required to have a hazard communication program, including labels on containers, material safety data sheets (MSDS), and training for employees. Within the United States (U.S.), there are other Federal agencies that also have requirements for classification and labeling of chemicals at different stages of the life cycle. Internationally, there are a number of countries that have developed similar laws that require information about chemicals to be prepared and transmitted to affected parties. These laws vary with regard to the scope of substances covered, definitions of hazards, the specificity of requirements (e.g., specification of a format for MSDSs), and the use of symbols and pictograms. The inconsistencies between the various laws are substantial enough that different labels and safety data sheets must often be used for the same product when it is marketed in different nations.

The diverse and sometimes conflicting national and international requirements can create confusion among those who seek to use hazard information. Labels and safety data sheets may include symbols and hazard statements that are unfamiliar to readers or not well understood. Containers may be labeled with such a large volume of information that important statements are not easily recognized. Development of multiple sets of labels and safety data sheets is a major compliance burden for chemical manufacturers, distributors, and transporters involved in international trade. Small businesses may have particular difficulty in coping with the complexities and costs involved.

As a result of this situation, and in recognition of the extensive international trade in chemicals, there has been a long-standing effort to harmonize these requirements and develop a system that can be used around the world. In 2003, the United Nations adopted the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Countries are now adopting the GHS into their national regulatory systems. OSHA published the NPRM on September 30, 2009, and held public hearings in Washington, DC, and Pittsburgh, PA, in March 2010. The record closed on June 1, 2010.
Statement of Need:
Multiple sets of requirements for labels and safety data sheets present a compliance burden for U.S. manufacturers, distributors, and transports involved in international trade. The comprehensibility of hazard information and worker safety will be enhanced as the GHS will: (1) Provide consistent information and definitions for hazardous chemicals; (2) address stakeholder concerns regarding the need for a standardized format for material safety data sheets; and (3) increase understanding by using standardized pictograms and harmonized hazard statements. The increase in comprehensibility and consistency will reduce confusion and thus improve worker safety and health. In addition, the adoption of the GHS would facilitate international trade in chemicals, reduce the burdens caused by having to comply with differing requirements for the same product, and allow companies that have not had the resources to deal with those burdens to be involved in international trade. This is particularly important for small producers who may be precluded currently from international trade because of the compliance resources required to address the extensive regulatory requirements for classification and labeling of chemicals. Thus, every producer is likely to experience some benefits from domestic harmonization, in addition to the benefits that will accrue to producers involved in international trade. Several nations, including the European Union, have adopted the GHS with an implementation schedule through 2015. U.S. manufacturers, employers, and employees will be at a disadvantage in the event that our system of hazard communication is not in compliance with the GHS.

Summary of Legal Basis:
The Occupational Safety and Health Act of 1970 authorizes the Secretary of Labor to set mandatory occupational safety and health standards to assure safe and healthful working conditions for working men and women (29 U.S.C. 651).

Alternatives:
The alternative to the proposed rulemaking would be to take no regulatory action.

Anticipated Cost and Benefits:
The estimates of the costs and benefits are still under development.

Risks:
OSHA’s risk analysis is under development.
### Timetable:

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**Regulatory Flexibility Analysis Required:**

No

**Government Levels Affected:**

Local, State

**Federalism:**

This action may have federalism implications as defined in EO 13132.

**Agency Contact:**

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DEPARTMENT OF TRANSPORTATION (DOT)

Introduction: Department Overview and Summary of Regulatory Priorities

The Department of Transportation (DOT) consists of 10 operating administrations and the Office of the Secretary, each of which has statutory responsibility for a wide range of regulations. DOT regulates safety in the aviation, motor carrier, railroad, motor vehicle, commercial space, and pipeline transportation areas. DOT also regulates aviation consumer and economic issues and provides financial assistance for programs involving highways, airports, public transportation, the maritime industry, railroads, and motor vehicle safety. The Department writes regulations to carry out a variety of statutes ranging from the Americans With Disabilities Act to the Uniform Time Act. Finally, DOT develops and implements a wide range of regulations that govern internal programs such as acquisitions and grants, access for the disabled, environmental protection, energy conservation, information technology, occupational safety and health, property asset management, seismic safety, and the use of aircraft and vehicles.

The Department’s Regulatory Priorities

The Department’s regulatory priorities respond to the challenges and opportunities we face. Our mission generally is as follows:

The national objectives of general welfare, economic growth and stability, and the security of the United States require the development of transportation policies and programs that contribute to
providing fast, safe, efficient, and convenient transportation at the lowest cost consistent with those and other national objectives, including the efficient use and conservation of the resources of the United States.

To help us achieve our mission, we have five strategic goals:

• Safety: Improve public health and safety by reducing transportation-related fatalities and injuries.

• State of Good Repair: Ensure the U.S. proactively maintains its critical transportation infrastructure in a state of good repair.

• Economic Competitiveness: Promote transportation policies and investments that bring lasting and equitable economic benefits to the Nation and its citizens.

• Livable Communities: Foster livable communities through place-based policies and investments that increase transportation choices and access to transportation services.

• Environmental Sustainability: Advance environmentally sustainable policies and investments that reduce carbon and other harmful emissions from transportation sources.

In identifying our regulatory priorities for the next year, the Department considered its mission and goals and focused on a number of factors, including the following:

• The relative risk being addressed
• Requirements imposed by statute or other law
• Actions on the National Transportation Safety Board “Most Wanted List”
• The costs and benefits of the regulations
• The advantages of nonregulatory alternatives
• Opportunities for deregulatory action
• The enforceability of any rule, including the effect on agency resources

This regulatory plan identifies the Department’s regulatory priorities—the 16 pending rulemakings chosen from among the dozens of significant rulemakings listed in the Department’s broader regulatory agenda that the Department believes will merit special attention in the upcoming year. The rules included in the regulatory plan embody the Department’s focus on our strategic goals.

The regulatory plan reflects the Department’s primary focus on safety—a focus that extends across several modes of transportation. For example:

• The Federal Aviation Administration (FAA) will continue its efforts to implement safety management systems.
• The Federal Motor Carrier Safety Administration (FMCSA) continues its work to strengthen the requirements for Electronic On-Board Recorders.
• The FMCSA will continue its work to revise motor carrier safety fitness procedures.
• The National Highway Traffic Safety Administration (NHTSA) will continue its rulemaking to reduce death and injury resulting from incidents involving motorcoaches.

We are taking actions to address other important issues. For example:
• The NHTSA is engaged in a major rulemaking to address fuel economy standards for passenger cars and light trucks.

• The Office of the Secretary of Transportation (OST) remains focused on aviation consumer rulemaking designed to further safeguard the interests of consumers flying the Nation’s skies.

Each of the rulemakings in the regulatory plan is described below in detail. In order to place them in context, we first review the Department’s regulatory philosophy and our initiatives to educate and inform the public about transportation safety issues. We then describe the role of the Department’s regulatory process and other important regulatory initiatives of OST and of each of the Department’s components. Since each transportation “mode” within the Department has its own area of focus, we summarize the regulatory priorities of each mode and of OST, which supervises and coordinates modal initiatives and has its own regulatory responsibilities, such as consumer protection in the aviation industry.

•

• The Department’s Regulatory Philosophy and Initiatives

The Department has adopted a regulatory philosophy that applies to all its rulemaking activities. This philosophy is articulated as follows: DOT regulations must be clear, simple, timely, fair, reasonable, and necessary. They will be issued only after an appropriate opportunity for public comment, which must provide an equal chance for all affected interests to participate, and after appropriate consultation with other governmental entities. The Department will fully consider the comments received. It will assess the risks addressed by the rules and their costs and benefits, including the cumulative effects.
The Department will consider appropriate alternatives, including nonregulatory approaches. It will also make every effort to ensure that regulation does not impose unreasonable mandates.

- The Department stresses the importance of conducting high-quality rulemakings in a timely manner and reducing the number of old rulemakings. To implement this, the Department has required the following actions: (1) Regular meetings of senior DOT officials to ensure effective policy leadership and timely decisions, (2) effective tracking and coordination of rulemakings, (3) regular reporting, (4) early briefings of interested officials, (5) regular training of staff, and (6) adequate allocations of resources. The Department has achieved significant success because of this effort. It allows the Department to use its resources more effectively and efficiently.

- The Department’s regulatory policies and procedures provide a comprehensive internal management and review process for new and existing regulations and ensure that the Secretary and other appropriate appointed officials review and concur in all significant DOT rules. DOT continually seeks to improve its regulatory process. A few examples include: The Department’s development of regulatory process and related training courses for its employees; its use of an electronic, Internet-accessible docket that can also be used to submit comments electronically; a “list serve” that allows the public to sign up for e-mail notification when the Department issues a rulemaking document; creation of an electronic rulemaking tracking and coordination system; the use of direct final rulemaking; the use of regulatory negotiation; a continually expanding Internet page that provides important regulatory information, including “effects” reports and status reports (http://regs.dot.gov/); and the continued exploration and use of Internet blogs and other Web 2.0 technology to increase and enhance public participation in its rulemaking process.
In addition, the Department continues to engage in a wide variety of activities to help cement the partnerships between its agencies and its customers that will produce good results for transportation programs and safety. The Department's agencies also have established a number of continuing partnership mechanisms in the form of rulemaking advisory committees.

- Retrospective Review of Existing Regulations

In accordance with Executive Order (E.O.) 13563 "Improving Regulation and Regulatory Review," the Department actively engaged in a special retrospective review of our existing rules to determine whether they need to be revised or revoked. This review was in addition to those reviews in accordance with section 610 of the Regulatory Flexibility Act, Executive Order 12866, and the Department's Regulatory Policies and Procedures. As part of this effort, we also reviewed our processes for determining what rules to review and ensuring the rules are effectively reviewed. As a result of the review, we identified many rules for expedited review and changes to our retrospective review process. Our retrospective review plan in response to E.O. 13563 can be found at www.regs.dot.gov; the results of the review of our rules can also be found there and in appendix D to our regulatory agenda.

- Each rulemaking initiated as a result of the retrospective review is included in the list below with a Regulation Identification Number (RIN) to assist in following the action through the rulemaking process. Additionally, at the end of each title, existing rulemaking actions will be been identified by adding “RRR” and those that are new will be indicated by “RRR*”.

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<tr>
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<tr>
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<td>Enhanced Flight Vision System (EFVS) (RRR*)</td>
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<td>14 CFR Part 16; Rules of Practice for Federally-Assisted Airport Enforcement Proceedings (RRR*)</td>
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<td>2120-AK01</td>
<td>Combined Drug and Alcohol Testing Programs for Operators Conducting Commercial Air Tours (RRR*)</td>
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<td>2120-AK03</td>
<td>CAT III Definitions (RRR*)</td>
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<td>National Standards for Traffic Control Devices; the Manual on Uniform Traffic Control Devices for Streets and Highways; Engineering Judgments (RRR)</td>
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<td>Federal Motor Vehicle Standard No. 108; Lamps, reflective devices, and associated equipment - Color Boundaries (RRR*)</td>
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<td>Federal Motor Vehicle Safety Standard No. 108; Lamps, reflective devices, and associated equipment - Reconsideration (RRR*)</td>
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<td>FMVSS No. 126, Petition for Reconsideration of Electronic Stability Control (ESC) (RRR*)</td>
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<td>Part 571 FMVSS No. 205, Glazing Materials, GTR (RRR*)</td>
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<td>War Risk Ship Valuation (RRR*)</td>
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<td>2137-AE77</td>
<td>Hazardous Materials: Minor Editorial Corrections and Clarifications (RRR*)</td>
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<td>Hazardous Materials: Miscellaneous Amendments (RRR*)</td>
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<td>2137-AE79</td>
<td>Hazardous Materials: Miscellaneous Amendments; Petitions for Rulemaking (RRR*)</td>
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Hazardous Materials: Miscellaneous Pressure Vessel Requirements (DOT Spec Cylinders) (RRR*)  Y

Hazardous Materials: Reverse Logistics (RRR*)  Y

Hazardous Materials: Incorporation of Certain Special Permits and Competent Authorities into the HMR (RRR*)  Y

*Some of the entries on this list may be completed actions, which do not appear in The Regulatory Plan/Agenda. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for DOT.

The Department will also continue its efforts to use advances in technology to improve its rulemaking management process. For example, the Department created an effective tracking system for significant rulemakings to ensure that either rules are completed in a timely manner or delays are identified and fixed. Through this tracking system, a monthly status report is generated. To make its efforts more transparent, the Department has made this report Internet accessible at www.regs.dot.gov, as well as through a list-serve. By doing this, the Department is providing valuable information concerning our rulemaking activity and is providing information necessary for the public to evaluate the Department's progress in meeting its commitment to completing quality rulemakings in a timely manner.

The Department continues to place great emphasis on the need to complete high-quality rulemakings by involving senior departmental officials in regular meetings to resolve issues expeditiously.

Office of the Secretary of Transportation (OST)

The Office of the Secretary (OST) oversees the regulatory process for the Department. OST implements the Department's regulatory policies and procedures and is responsible for ensuring the
involvement of top management in regulatory decisionmaking. Through the General Counsel's office, OST is also responsible for ensuring that the Department complies with the Administrative Procedure Act, Executive Order 12866 (Regulatory Planning and Review), DOT's Regulatory Policies and Procedures, and other legal and policy requirements affecting rulemaking. Although OST's principal role concerns the review of the Department’s significant rulemakings, this office has the lead role in the substance of projects concerning aviation economic rules and other rules that affect multiple elements of the Department.

• OST provides guidance and training regarding compliance with regulatory requirements and process for use by personnel throughout the Department. OST also plays an instrumental role in the Department’s efforts to improve our economic analyses; risk assessments; regulatory flexibility analyses; other related analyses; and data quality, including peer reviews.

OST also leads and coordinates the Department’s response to the Office of Management and Budget’s (OMB) intergovernmental review of other agencies’ significant rulemaking documents and to Administration and congressional proposals that concern the regulatory process. The General Counsel’s office works closely with representatives of other agencies, OMB, the White House, and congressional staff to provide information on how various proposals would affect the ability of the Department to perform its safety, infrastructure, and other missions.

• During fiscal year 2012, OST will continue to focus its efforts on enhancing airline passenger protections by requiring carriers to adopt various consumer service practices under the following rulemaking initiatives:
  • Accessibility of Carrier Websites and Ticket Kiosks (2105-AD96)
OST will also continue its efforts to help coordinate the activities of several operating administrations that advance various departmental efforts that support the Administration’s initiatives on promoting safety, stimulating the economy and creating jobs, sustaining and building America’s transportation infrastructure, and improving livability for the people and communities who use transportation systems subject to the Department’s policies.

Federal Aviation Administration (FAA)

The Federal Aviation Administration is charged with safely and efficiently operating and maintaining the most complex aviation system in the world. It is guided by Destination 2025—a transformation of the Nation’s aviation system in which air traffic will move safely, swiftly, efficiently, and seamlessly around the globe. Our vision is to develop new systems and to enhance a culture that increases the safety, reliability, efficiency, capacity, and environmental performance of our aviation system. To meet our vision will require enhanced skills, clear communication, strong leadership, effective management, innovative technology, new equipment, advanced system oversight, and global integration.

FAA activities that may lead to rulemaking in fiscal year 2012 include continuing to:

- Promote and expand safety information-sharing efforts, such as FAA-industry partnerships and data-driven safety programs that prioritize and address risks before they lead to accidents. Specifically, FAA will continue implementing Commercial Aviation Safety Team projects related to controlled
flight into terrain, loss of control of an aircraft, uncontained engine failures, runway incursions, weather, pilot decisionmaking, and cabin safety. Some of these projects may result in rulemaking and guidance materials.

- Work cooperatively to harmonize the U.S. aviation regulations with those of other countries, without compromising rigorous safety standards. The differences worldwide in certification standards, practice and procedures, and operating rules must be identified and minimized to reduce the regulatory burden on the international aviation system. The differences between the FAA regulations and the requirements of other nations impose a heavy burden on U.S. aircraft manufacturers and operators, some of which are small businesses. Standardization should help the U.S. aerospace industry remain internationally competitive. The FAA continues to publish regulations based on recommendations of Aviation Rulemaking Committees that are the result of cooperative rulemaking between the U.S. and other countries.

- Develop and implement Safety Management Systems (SMS) where these systems will improve safety of aviation and aviation-related activities. An SMS proactively identifies potential hazards in the operating environment, analyzes the risks of those hazards, and encourages mitigation prior to an accident or incident. In its most general form, an SMS is a set of decisionmaking tools that can be used to plan, organize, direct, and control activities in a manner that enhances safety.

FAA top regulatory priorities for 2011 through 2012 include:

- Qualification, Service, and Use of Crewmembers and Aircraft Dispatchers (2120-AJ00)
- Helicopter Air Ambulance and Commercial Helicopter Safety Initiatives and Miscellaneous Amendments (2120-AJ53)
- Congestion Management for LaGuardia Airport, John F. Kennedy International Airport, and Newark Liberty International Airport (2120-AJ89)

The Crewmember and Aircraft Dispatcher Training rulemaking would:

- Reduce human error and improve performance;
- Enhance traditional training programs through the use of flight simulation training devices for flight crewmembers; and
- Include additional training in areas critical to safety.

The Air Ambulance and Commercial Helicopter rulemaking would:

- Codify current agency guidance
- Address National Transportation Safety Board recommendations;
- Provide certificate holders and pilots with tools and procedures that will aid in reducing accidents, including potential equipage requirements; and
- Amend all part 135 commercial helicopter operations regulations to include pilot training and alternate airport weather minimums.

The Congestion Management rulemaking for LaGuardia Airport, John F. Kennedy International Airport, and Newark Liberty International Airport would:

- Replace the orders limiting scheduled operations at John F. Kennedy International Airport (JFK), limiting scheduled operations at Newark Liberty International Airport (EWR), and limiting scheduled and unscheduled operations at LaGuardia Airport (LGA); and
- Provide a longer-term and comprehensive approach to congestion management at JFK, EWR, and LGA
The Safety Management System for Certificate Holders Operating Under 14 CFR Part 121 rulemaking would:

- Require certain certificate holders to develop and implement an SMS;
- Propose a general framework from which a certificate holder can build its SMS; and
- Conform to International Civil Aviation Organization Annexes and adopt several National Transportation Safety Board recommendations.

Federal Highway Administration (FHWA)

- The Federal Highway Administration (FHWA) carries out the Federal highway program in partnership with State and local agencies to meet the Nation’s transportation needs. The FHWA’s mission is to improve continually the quality and performance of our Nation’s highway system and its intermodal connectors.

Consistent with this mission, the FHWA will continue:

- With ongoing regulatory initiatives in support of its surface transportation programs;
- To implement legislation in the least burdensome and restrictive way possible; and
- To pursue regulatory reform in areas where project development can be streamlined or accelerated, duplicative requirements can be consolidated, recordkeeping requirements can be reduced or simplified, and the decisionmaking authority of our State and local partners can be increased.
FHWA’s top regulatory priority for the fiscal year is to address the rulemaking actions outlined in the DOT Plan for Implementation of Executive Order 13563. In particular, FHWA will undertake two rulemakings that propose changes to the Manual on Uniform Traffic Control Devices (MUTCD). The first of these rulemakings (RIN 2125-AF41, Engineering Judgment) would clarify the use of engineering judgment and studies in the application of traffic control devices. A separate rulemaking (RIN 2125-AF43, Compliance Dates Revision) would revise the compliance dates for certain requirements in the MUTCD. Consistent with the principles outlined in Executive Order 13563, the FHWA anticipates these actions would provide clarity and needed flexibility, as well as reduce burdens on State and local governments. We believe our approach in both rulemakings is consistent with the requirements of Executive Order 13563, including its emphasis on consideration of benefits and costs (sections 1(a) and 1(b)), its requirement of an open exchange of information with stakeholders (section 2(a)), and, in particular, its call for retrospective analysis of existing rules, including streamlining and modification to make such rules less burdensome (section 6). These rulemakings are also consistent with a Presidential Memorandum regarding Administrative Flexibility, which calls for reducing burdens and promoting flexibility for State and local governments.

**Federal Motor Carrier Safety Administration (FMCSA)**

The mission of the Federal Motor Carrier Safety Administration (FMCSA) is to reduce crashes, injuries, and fatalities involving commercial trucks and buses. A strong regulatory program is a cornerstone of FMCSA’s compliance and enforcement efforts to advance this safety mission. FMCSA develops new and more effective safety regulations based on three core priorities: Raising the bar for entry, maintaining high standards, and removing high-risk behavior. In addition to Agency-directed regulations, FMCSA develops regulations mandated by Congress, such as the Safe, Accountable, Flexible, and Efficient

• FMCSA’s regulatory plan for FY 2012 includes completion of a number of rulemakings that are high priorities for the Agency because they would have a positive impact on safety. Among the rulemakings included in the plan are: (1) Carrier Safety Fitness Determination (RIN 2126-AB11) and (2) National Registry of Certified Medical Examiners (RIN 2126-AA97).

Together, these priority rules could help to substantially improve commercial motor vehicle (CMV) safety on our Nation’s highways by improving FMCSA’s ability to provide safety oversight of motor carriers and drivers.

In FY 2012, FMCSA will continue its work on the Comprehensive Safety Analysis (CSA). The CSA initiative will improve the way FMCSA identifies and conducts carrier compliance and enforcement operations over the coming years. CSA’s goal is to improve large truck and bus safety by assessing a wider range of safety performance data from a larger segment of the motor carrier industry through an array of progressive compliance interventions. FMCSA anticipates that the impacts of CSA and its associated rulemaking to put into place a new safety fitness standard will enable the Agency to prohibit “unfit” carriers from operating on the Nation’s highways (the Carrier Safety Fitness Determination(RIN 2126-AB11)) and will contribute further to the Agency’s overall goal of decreasing CMV-related fatalities and injuries.

•
Also in FY 2012, FMCSA plans to issue a final rule on the National Registry of Certified Medical Examiners (RIN 2126-AA97) to establish training and testing requirements for healthcare professionals who issue medical certificates to CMV drivers.

In order to manage its rulemaking agenda, FMCSA continues to involve senior Agency leaders at the earliest stages of its rulemakings and continues to refine its regulatory development process. The Agency also holds senior executives accountable for meeting deadlines for completing rulemakings.

- National Highway Traffic Safety Administration

The statutory responsibilities of the National Highway Traffic Safety Administration (NHTSA) relating to motor vehicles include reducing the number of, and mitigating the effects of, motor vehicle crashes and related fatalities and injuries; providing safety performance information to aid prospective purchasers of vehicles, child restraints, and tires; and improving automotive fuel efficiency. NHTSA pursues policies that encourage the development of nonregulatory approaches when feasible in meeting its statutory mandates. It issues new standards and regulations or amendments to existing standards and regulations when appropriate. It ensures that regulatory alternatives reflect a careful assessment of the problem and a comprehensive analysis of the benefits, costs, and other impacts associated with the proposed regulatory action. Finally, it considers alternatives consistent with the Administration’s regulatory principles.

NHTSA continues to focus on the high-priority vehicle safety issue of motorcoaches and their occupants, and will publish several notices in fiscal year 2012 to that end. NHTSA will issue a final rule to require the installation of lap/shoulder belts in newly manufactured motorcoaches in accordance with NHTSA’s 2007 Motorcoach Safety Plan and DOT’s 2009 departmental Motorcoach Safety Action Plan. NHTSA is also considering proposing new Federal motor vehicle safety standards (FMVSS) for motorcoach rollover structural integrity requirements, as well as requirements for electronic stability
control systems for motorcoaches and truck tractors. Together, these three rulemaking actions will address 12 recommendations issued by the National Transportation Safety Board related to motorcoach safety.

In fiscal year 2012, NHTSA will continue its efforts to reduce domestic dependency on foreign oil in accordance with the Energy Independence and Security Act (EISA) of 2007 by publishing, in conjunction with the Environmental Protection Agency (EPA), a joint final rule setting corporate average fuel economy (CAFE) standards for light trucks and passenger cars for model years 2017 and beyond. To further enhance the safety of passenger vehicles and pedestrians, NHTSA is considering proposing, in response to the Pedestrian Safety Enhancement Act of 2010, a FMVSS to provide a means of alerting blind and other pedestrians of motor vehicle operation.

In addition to numerous programs that focus on the safe performance of motor vehicles, the Agency is engaged in a variety of programs to improve driver and occupant behavior. These programs emphasize the human aspects of motor vehicle safety and recognize the important role of the States in this common pursuit. NHTSA has identified two high-priority areas: Safety belt use and impaired driving. To address these issue areas, the Agency is focusing especially on three strategies—conducting highly visible, well-publicized enforcement; supporting prosecutors who handle impaired driving cases and expanding the use of DWI/Drug Courts, which hold offenders accountable for receiving and completing treatment for alcohol abuse and dependency; and adopting alcohol screening and brief intervention by medical and health care professionals. Other behavioral efforts encourage child safety-seat use; combat excessive speed and aggressive driving; improve motorcycle, bicycle, and pedestrian safety; and provide consumer information to the public.
Federal Railroad Administration (FRA)

- FRA’s current regulatory program contains numerous mandates resulting from the Rail Safety Improvement Act of 2008 (RSIA08), as well as actions supporting the Department's High-Speed Rail Strategic Plan. RSIA08 alone has resulted in at least 20 rulemaking actions, which are competing for limited resources to meet statutory deadlines. FRA has prioritized these rulemakings according to the greatest effect on safety, as well as expressed congressional interest, and will work to complete as many rulemakings as possible prior to their statutory deadlines. Revised timelines for completion of unfinished regulations will be forwarded to Congress for consideration.

- Through the Railroad Safety Advisory Committee (RSAC), FRA is working to complete many of the RSIA08 actions that include developing requirements for train conductor certification, roadway worker protection, track safety, alcohol and drug testing of maintenance-of-way personnel, and training for railroad employees. Other RSAC-supported actions that advance high-speed passenger rail include proposed revisions to the Track Safety Standards dealing with vehicle-track interaction. FRA is also initiating a rulemaking related to the development of railroad risk reduction and system safety programs, which will be a multi-year effort due to the underlying statutory requirements that must be undertaken prior to the issuance of any final rule. Finally, FRA will be engaging in two rulemaking proceedings to address various issues related to the implementation of positive train control systems. FRA expects these regulatory actions to provide substantial benefits to the industry while ensuring the safe and effective implementation of the technology.

Federal Transit Administration (FTA)
FTA helps communities support public transportation by making grants of Federal funding for transit vehicles, construction of transit facilities, and planning and operation of transit and other transit-related purposes. FTA regulatory activity implements the laws that apply to recipients’ uses of Federal funding and the terms and conditions of FTA grant awards. FTA policy regarding regulations is to:

• Provide maximum benefit to the mobility of the Nation’s citizens and the connectivity of transportation infrastructure;
• Provide maximum local discretion;
• Ensure the most productive use of limited Federal resources;
• Protect taxpayer investments in public transportation;
• Incorporate principles of sound management into the grant management process.

As the needs for public transportation have changed over the years, the Federal transit programs have grown in number and complexity. FTA’s regulatory priorities for the coming year will reflect the mandates of the Agency’s authorization statute, including, most notably, the Major Capital Investments (RIN 2132-AB02) “New Starts” program. The New Starts program is the main source of discretionary Federal funding for construction of rapid rail, light rail, commuter rail, and other forms of transit infrastructure. FTA also anticipates amending its regulations governing recipients’ management of major capital projects and its Bus Testing rule.

Maritime Administration (MARAD)

•
The Maritime Administration (MARAD) administers Federal laws and programs to promote and strengthen the U.S. merchant marine to meet the economic and security needs of the Nation. To that end, MARAD’s efforts are focused upon ensuring a strong American presence in the domestic and international trades and to expanding maritime opportunities for American businesses and workers.

MARAD’s regulatory objectives and priorities reflect the Agency’s responsibility for ensuring the availability of a U.S. merchant marine that can provide water transportation services for American shippers and consumers and, in times of war or national emergency, for the U.S. armed forces. Major program areas include the following: Maritime Security, Voluntary Intermodal Sealift Agreement, National Defense Reserve Fleet and the Ready Reserve Force, Maritime Guaranteed Loan Financing, United States Merchant Marine Academy, Mariner Education and Training Support, and Deepwater Port Licensing. Additionally, MARAD will continue its monitoring and enforcement of U.S. cargo preference laws and implementation of MARAD’s newest program, the “America’s Marine Highways Program.” To date, the Department has identified marine corridors, and grants have been awarded under the America’s Marine Highways Program.

MARAD’s primary regulatory activities in fiscal year 2012 will be to update existing cargo preference-related regulations, to continue the update of existing regulations as part of the Department’s Retrospective Regulatory Review effort, and to propose new regulations where appropriate.

Pipeline and Hazardous Materials Safety Administration (PHMSA)

The Pipeline and Hazardous Materials Safety Administration (PHMSA) has responsibility for rulemaking under two programs. Through the Associate Administrator for Hazardous Materials Safety, PHMSA administers
regulatory programs under Federal hazardous materials transportation law and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990. Through the Associate Administrator for Pipeline Safety, PHMSA administers regulatory programs under the Federal pipeline safety laws and the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990.

PHMSA will continue to work toward the reduction of deaths and injuries associated with the transportation of hazardous materials by all transportation modes, including pipeline. We will concentrate on the prevention of high-risk incidents identified through the findings of the National Transportation Safety Board and PHMSA’s evaluation of transportation incident data. PHMSA will use all available Agency tools to assess data; evaluate alternative safety strategies, including regulatory strategies as necessary and appropriate; target enforcement efforts; and enhance outreach, public education, and training to promote safety outcomes.

PHMSA will be considering whether changes are needed to the regulations covering hazardous liquid onshore pipelines. In particular, PHMSA is considering whether it should extend regulation to certain pipelines currently exempt from regulation; whether other areas along a pipeline should either be identified for extra protection or be included as additional high-consequence areas (HCAs) for integrity management (IM) protection; whether to establish and/or adopt standards and procedures for minimum lead detection requirements for all pipelines; whether to require the installation of emergency flow restricting devices (EFRDs) in certain areas; whether revised valve spacing requirements are needed on new construction or existing pipelines; whether repair timeframes should be specified for pipeline segments in areas outside the HCAs that are assessed as part of the IM; and whether to establish and/or adopt standards and procedures for improving the methods of preventing, detecting, assessing, and remediating stress corrosion cracking (SCC) in hazardous liquid pipeline systems.

•
Additionally, PHMSA will consider whether or not to revise the requirements in the pipeline safety regulations addressing integrity management principles for gas transmission pipelines. Specifically, PHMSA will be reviewing the definition of an HCA (including the concept of a potential impact radius), the repair criteria for both HCA and non-HCA areas, requiring the use of automatic and remote-controlled shutoff valves, valve spacing, and whether applying the integrity management program requirements to additional areas would mitigate the need for class location requirements.

Research and Innovative Technology Administration (RITA)

- The Research and Innovative Technology Administration (RITA) seeks to identify and facilitate solutions to the challenges and opportunities facing America’s transportation system through:
  - Coordination, facilitation, and review of the Department's research and development programs and activities;
  - Providing multi-modal expertise in transportation and logistics research, analysis, strategic planning, systems engineering and training;
  - Advancement, and research and development, of innovative technologies, including intelligent transportation systems;
  - Comprehensive transportation statistics research, analysis, and reporting;
  - Managing education and training in transportation and national transportation-related fields; and
  - Managing the activities of the John A. Volpe National Transportation Systems Center.

Through its Bureau of Transportation Statistics, Office of Airline Information, RITA collects, compiles, analyzes, and makes accessible information on the Nation's air transportation system. RITA collects airline financial, traffic, and operating statistical data, including on-time flight performance data that
highlight long tarmac times and chronically late flights. This information gives the Government consistent and comprehensive economic and market data on airline operations that are used in supporting policy initiatives and administering the Department’s mandated aviation responsibilities, including negotiating international bilateral aviation agreements, awarding international route authorities, performing airline and industry status evaluations, supporting air service to small communities, setting Alaskan Bush Mail rates, and meeting international treaty obligations.

Through its Intelligent Transportation Systems Joint Program Office (ITS/JPO), RITA conducts research and demonstrations and, as appropriate, may develop new regulations, in coordination with OST and other DOT operating administrations, to enable deployment of ITS research and technology results. This office collects and disseminates benefits and costs information resulting from ITS-related research along with direct measurement of the deployment of ITS nationwide. These efforts support market assessments for emerging market sectors that would be cost-prohibitive for industry to absorb alone. Such information is widely consumed by the community of stakeholders to determine their deployment needs.

The ITS Architecture and Standards Programs develop and maintain a National ITS Architecture; develop open, non-proprietary interface standards to facilitate rapid and economical adoption of nationally interoperable ITS technologies; and cooperate to harmonize ITS standards internationally. These standards are incorporated into DOT operating administration regulatory activities when appropriate.

Through its Volpe National Transportation Systems Center, RITA provides a comprehensive range of engineering expertise, and qualitative and quantitative assessment services, focused on applying,
maintaining, and increasing the technical body of knowledge to support DOT operating administration regulatory activities.

- Through its Transportation Safety Institute, RITA designs, develops, conducts, and evaluates training and technical assistance programs in transportation safety and security to support DOT operating administration regulatory implementation and enforcement activities.

  RITA’s regulatory priorities are to assist OST and all DOT operating administrations in updating existing regulations by applying research, technology, and analytical results; to provide reliable information to transportation system decisionmakers; and to provide safety regulation implementation and enforcement training.
QUANTIFIABLE COSTS AND BENEFITS OF RULEMAKINGS
ON THE 2011 to 2012 DOT REGULATORY PLAN

(This chart does not account for non-quantifiable benefits, which are often substantial.)

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<th>Agency/RIN Number</th>
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<td>2127-AK56</td>
<td>Seat Belts on Motorcoaches</td>
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<td>2127-AK79</td>
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TOTAL FOR DOT

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Notes:

Costs and benefits of rulemakings may be forecast over varying periods. Although the forecast periods will be the same for any given rulemaking, comparisons between proceedings should be made cautiously.

Costs and benefits are generally discounted at a 7 percent discount rate over the period analyzed.

The Department of Transportation generally assumes that there are economic benefits to avoiding a fatality of $6.2 million. That economic value is included as part of the benefits estimates shown in the chart. As noted above, we have not included the non-quantifiable benefits.

<table>
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<tr>
<th>DOT—Office of the Secretary (OST)</th>
<th>PROPOSED RULE STAGE</th>
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<tbody>
<tr>
<td>103. +ACCESSIBILITY OF CARRIER WEBSITES AND TICKET KIOSKS</td>
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</table>

Priority:

Other Significant

Legal Authority:

49 USC 41702; 49 USC 47105; 49 USC 41712

CFR Citation:

14 CFR 382

Legal Deadline:

None

Abstract:

This rulemaking was divided into two successive Air Carrier Access Act (ACAA) rulemakings. This one, as well as the second rulemaking (2105-AE12), address issues raised in another rulemaking RIN 2105-AD92. This rulemaking would consider: (1) The cost and technical issues involved in requiring carrier website accessibility and (2) whether automated kiosks operated by carriers at airports and elsewhere
should be required to be accessible. After the public comment periods, we intend to consolidate the final decisions in this rulemaking and RIN 2105-AE12 into one document.

**Statement of Need:**

This rulemaking proposes to provide greater accommodations for individuals with disabilities in accessing automated kiosks at U.S. airports and Web sites operated by U.S. and foreign air carriers and their ticket agents. Automated kiosks are widely used by U.S. and foreign air carriers at airports to provide customer services (e.g., boarding pass and bag tag printing). Also, today's passengers increasingly rely on air travel Web sites for information about airline services, making reservations, and obtaining discounted airfares. Currently, neither airlines nor airports are required to make airport kiosks accessible to passengers with disabilities. Also, not all air travel information and services available to the public on Web sites are accessible to people with disabilities. Only DOT can protect air travelers with disabilities as states are preempted from regulating in these areas and no private right of action exists for airline consumers to enforce the Air Carrier Access Act.

**Summary of Legal Basis:**

The legal basis for the proposed rule is the Air Carrier Access Act, which prohibits discrimination in airline service on the basis of disability, and section 504 of the Rehabilitation Act of 1973, which requires accessibility in airport terminal facilities that receive Federal financial assistance.

**Alternatives:**

Since May 2008, the Department has attempted to address the problem of inaccessible Web sites by requiring U.S. and foreign air carriers to make discounted, Web-based fares and amenities available to passengers who self-identify as being unable to use an airline's inaccessible Web site due to their disability. The Department has also tried to address the problem of inaccessible kiosks by requiring U.S. and foreign air carriers to make equivalent service available to passengers with a disability who cannot readily use a carrier's automated kiosk due to their disability. Disability advocacy groups have repeatedly expressed opposition to these interim solutions as they do not enable them to independently access and use airlines' Web sites or kiosks.

**Anticipated Cost and Benefits:**
Preliminary estimates show that the present value of net benefits of the requirement to ensure the accessibility of automated airport kiosks to be $70.4 million over the 10-year period from 2013 through 2022, using a 7 percent discount rate. With respect to the proposed requirements to ensure air travel Web site accessibility, our preliminary regulatory evaluation estimates the expected present value of net benefits at $48.5 million over the period from 2013 through 2022, using the 7 percent discount rate.

Risks:

N/A

Timetable:

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<th>Action</th>
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<td>SNPRM</td>
<td>09/26/11</td>
<td>76 FR 59307</td>
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<td>SNPRM Comment Period End</td>
<td>11/25/11</td>
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<tr>
<td>Extension of Comment Period and Clarification of Proposed Rule</td>
<td>11/21/11</td>
<td>76 FR 71914</td>
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<td>Supplemental NPRM Comment Period End</td>
<td>01/09/12</td>
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</table>

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

Businesses

Government Levels Affected:

None

URL For More Information:

www.regulations.gov

URL For Public Comments:

www.regulations.gov

Agency Contact:
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Deputy Assistant General Counsel for Regulation and Enforcement
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Office of the Secretary
Room W94–302
1200 New Jersey Avenue SE
Washington, DC 20590
Phone: 202 366–4723
TDD Phone: 202 755–7687
Email: bob.ashby@ost.dot.gov

Related RIN: Related to 2105–AE12

RIN: 2105–AD96

DOT—OST

104. • +ENHANCING AIRLINE PASSENGER PROTECTIONS III

Priority:
Other Significant

Legal Authority:
49 USC 41712; 49 USC 40101; 49 USC 41702

CFR Citation:
14 CFR 244; 14 CFR 250; 14 CFR 253; 14 CFR 259; 14 CFR 399

Legal Deadline:
None

Abstract:
This rulemaking would address the following issues: (1) Whether the Department should require a marketing carrier to provide assistance to its code-share partner when a flight operated by the code-share partner experiences a lengthy tarmac delay; (2) whether the Department should enhance disclosure
requirements on code-share operations, including requiring on-time performance data, reporting of certain
data code-share operations, and codifying the statutory amendment of 49 U.S.C. 41712(c) regarding
website schedule disclosure of code-share operations; (3) whether the Department should expand the on-
time performance “reporting carrier” pool to include smaller carriers; (4) whether the Department should
require travel agents to adopt minimum customer service standards in relation to the sale of air
transportation; (5) whether the Department should require ticket agents to disclose the carriers whose
tickets they sell or do not sell and information regarding any incentive payments they receive in
connection with the sale of air transportation; (6) whether the Department should require ticket agents to
disclose any preferential display of individual fares or carriers in the ticket agent's Internet displays; (7)
whether the Department should require additional or special disclosures regarding certain substantial
fees; e.g., oversize or overweight baggage fees; (8) whether the Department should prohibit post-
purchase price increase for all services and products not purchased with the ticket or whether it is
sufficient to prohibit post-purchase prices increases for baggage charges that traditionally have been
included in the ticket price; and (9) whether the Department should require that ancillary fees be
displayed through all sale channels.

Statement of Need:

On April 25, 2011, the Department of Transportation published in the Federal Register a final rule on
Enhancing Airline Passenger Protections (76 FR 23110). Among other requirements, the rule contains
several requirements for U.S. and foreign air carriers, ticket agents, and other sellers of air transportation
to disclose to consumers the cost of certain ancillary services. The rule requires disclosure through
various methods. One issue the rulemaking requested comment on was whether the Department should
require information regarding the cost of airline ancillary services to be displayed through Global
Distribution Systems in order to enhance transparency of such fees to consumers. Because the
Department lacked critical information on the issue, the Department deferred the issue to this rulemaking.
This rulemaking will address that issue as well as several other airline consumer protection proposals.

Summary of Legal Basis:
The Department has authority and responsibility under 49 U.S.C. section 41712, in concert with 49 U.S.C. 40101 and 49 U.S.C. section 41702, to protect consumers from unfair and deceptive practices and to ensure safe and adequate service in air transportation.

**Alternatives:**

One alternative would be to take no regulatory action. Also, various regulatory alternatives will be developed and the public will be afforded an opportunity to provide comments when the Department publishes the proposed rule in the Federal Register.

**Anticipated Cost and Benefits:**

TBD

**Risks:**

The risk of not taking regulatory action would be the continuation of a system where passengers cannot determine the true cost of their air travel.

**Timetable:**

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<tr>
<th>Action</th>
<th>Date</th>
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<tr>
<td>Supplemental NPRM</td>
<td>08/00/12</td>
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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Undetermined

**URL For More Information:**

www.regulations.gov

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Blane A. Workie
Attorney
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<th>DOT—OST</th>
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<tr>
<td><strong>105. • +CARRIER–SUPPLIED MEDICAL OXYGEN, ACCESSIBLE IN–FLIGHT ENTERTAINMENT SYSTEMS, SERVICE ANIMALS, AND ACCESSIBLE LAVATORIES ON SINGLE–AISLE AIRCRAFT</strong></td>
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<td>14 CFR 382</td>
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<td><strong>Legal Deadline:</strong></td>
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<td><strong>Abstract:</strong></td>
<td>This rulemaking is the one of two successive Air Carrier Access Act (ACAA) rulemakings that address issues raised in another rulemaking: RIN 2105-AD92. The second rulemaking is RIN 2105-AD96. This rulemaking action would consider (1) whether there are safety-related reasons for excluding service animals other than dogs that may be specific to foreign carriers; (2) whether the cost of requiring carriers</td>
</tr>
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</table>
to supply free in-flight medical oxygen would create an undue burden; and (3) whether providing high-
contrast captioning on in-flight entertainment displays is technically and economically feasible. It would
also address accessible lavatories on single-aisle aircraft and a rulemaking petition from the Psychiatric
Service Dog Society to eliminate provisions allowing carriers to require documentation and 48 hours
advance notice for users of psychiatric service animals, and miscellaneous service animal issues. After
the public comment periods, we intend to consolidate the final decisions in this rulemaking and RIN 2105-
AD96 into one document.

Statement of Need:
This rulemaking action would examine whether the Department should require carriers to provide in-flight
medical oxygen, captioning on in-flight entertainment (IFE) systems, and accessible lavatories on single-
aisle aircraft to provide individuals with disabilities greater access to air travel. Currently, few airlines
make in-flight medical oxygen available to passengers and as a result individuals who are dependent on
medical oxygen but cannot use portable oxygen concentrators are having difficulty traveling by air. Also,
passengers who are deaf or hard-of-hearing have strongly advocated for captioning of IFE systems,
arguing that the in-flight entertainment that is available to other passengers should also be available to
them. Lavatories on single-aisle aircraft have also become a matter of interest to the Department as more
and more single-aisle aircraft are used for longer flights and the absence of accessible lavatories makes
travel difficult for passengers with disabilities.

This rulemaking action will also address whether to amend the existing regulation, which allows airlines to
require users of psychiatric and emotional support service animals to provide documentation and
advance notice of their planned travel with a service animal. An advocacy group representing users of
psychiatric service dogs has filed a petition for rulemaking stating that the notice and medical
documentation requirements stigmatize and discriminate against people with mental disabilities, and
asking that it be repealed.

Summary of Legal Basis:
This legal basis for the proposed rule is the Air Carrier Access Act (ACAA), which prohibits discrimination
in airline service on the basis of disability.
**Alternatives:**

Regulatory alternatives will be developed and the public will be afforded an opportunity to provide comments when the Department publishes the proposed rule in the Federal Register.

**Anticipated Cost and Benefits:**

Estimates of costs and benefits are under development.

**Risks:**

N/A

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**URL For More Information:**

www.regulations.gov

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Robert C. Ashby
Deputy Assistant General Counsel for Regulation and Enforcement

Department of Transportation

Office of the Secretary

Room W94–302

1200 New Jersey Avenue SE

Washington, DC 20590
DOT—Federal Aviation Administration (FAA) | PROPOSED RULE STAGE

106. +QUALIFICATION, SERVICE, AND USE OF CREWMEMBERS AND AIRCRAFT DISPATCHERS

Priority:
Other Significant

Legal Authority:
49 USC 106(g); 49 USC 40113; 49 USC 40119; 49 USC 44101; 49 USC 44701; 49 USC 44702; 49 USC 44705; 49 USC 44709 to 44711; 49 USC 44713; 49 USC 44716; 49 USC 44717; 49 USC 44722; 49 USC 44901; 49 USC 44903; 49 USC 44904; 49 USC 44912; 49 USC 46105

CFR Citation:
14 CFR 119; 14 CFR 121; 14 CFR 135; 14 CFR 142; 14 CFR 65

Legal Deadline:
None

Abstract:
This rulemaking would amend the regulations for crewmember and dispatcher training programs in domestic, flag, and supplemental operations. The rulemaking would enhance traditional training programs by requiring the use of flight simulation training devices for flight crewmembers and including additional training requirements in areas that are critical to safety. The rulemaking would also reorganize and revise the qualification and training requirements. The changes are intended to contribute to reducing aviation accidents.

Statement of Need:
This rulemaking is part of the FAA’s efforts to reduce fatal accidents in which human error was a major contributing cause. The changes would reduce human error and improve performance among flight crewmembers, flight attendants, and aircraft dispatchers. National Transportation Safety Board (NTSB) investigations identified several areas of inadequate training that were the probable cause of an accident. This rulemaking contains changes to address the causes and factors identified by the NTSB.

Summary of Legal Basis:

The FAA’s authority to issue rules on aviation safety is found in title 49 of the United States Code. This rulemaking is promulgated under the authority described in 49 U.S.C. 44701(a)(5), which requires the Administrator to promulgate regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security.

Alternatives:

During the Notice of Proposed Rulemaking (NPRM) phase, the FAA did not find any significant alternatives in accordance with 5 U.S.C. section 603(d). The FAA will again review alternatives at the final rule phase.

Anticipated Cost and Benefits:

The FAA is developing the costs and benefits of this rulemaking

Risks:

The FAA will review specific risks associated with this rulemaking.

Timetable:

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Supplemental NPRM 07/19/11
Comment Period End
Supplemental NPRM 06/23/11 76 FR 36888
Comment Period Extended
Extended Supplemental NPRM 09/19/11
Comment Period End
Analyzing Comments 01/00/12

Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Businesses

Government Levels Affected:
None

Additional Information:
For flight crewmember information contact James K. Sheppard, for flight attendant information contact Nancy Lauck Claussen, and for aircraft dispatcher information contact Leo Hollis, Air Carrier Training Branch (AFS-210), Flight Standards Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone (202) 267 8166.

URL For More Information:
www.regulations.gov

URL For Public Comments:
www.regulations.gov

Agency Contact:
Nancy L. Claussen
Federal Aviation Administration
Department of Transportation
Federal Aviation Administration
This rulemaking would replace the current temporary orders limiting scheduled operations at LaGuardia Airport, John F. Kennedy International Airport, and Newark Liberty International Airport with a more permanent rule to address the issues of congestion and delay at the New York area’s three major commercial airports, while also promoting fair access and competition. The rulemaking would help ensure that congestion and delays are managed by limiting scheduled and unscheduled operations. The rulemaking would also establish a secondary market for U.S. and foreign air carriers to buy, sell, trade, and lease slots amongst each other at each of the three airports. This would allow carriers serving or
seeking to serve the New York area airports to exchange slots as their business models and strategic goals require.

**Statement of Need:**

This rulemaking would replace the current temporary orders limiting scheduled operations at LaGuardia Airport, John F. Kennedy International Airport, and Newark Liberty International Airport with a more permanent rule to address the issues of congestion and delay at the New York area's three major commercial airports, while also promoting fair access and competition. The rulemaking would help ensure that congestion and delays are managed by limiting scheduled and unscheduled operations. The rulemaking would also establish a secondary market for U.S. and foreign air carriers to buy, sell, trade, and lease slots amongst each other at each of the three airports. This would allow carriers serving or seeking to serve the New York area airports to exchange slots as their business models and strategic goals require.

**Summary of Legal Basis:**

This rulemaking is promulgated under the authority described in subtitle VII, part A, subpart I, sections 40101, 40103, 40105, and 41712. The Secretary of Transportation (Secretary) is the head of the DOT and has broad oversight of significant FAA decisions. See 49 U.S.C. 102 and 106. In addition, under 49 U.S.C. 41712, the Secretary has the authority to investigate and prohibit unfair and deceptive practices and unfair methods of competition in air transportation or the sale of air transportation.

The FAA has broad authority under 49 U.S.C. 40103 to regulate the use of the navigable airspace of the United States. This section authorizes the FAA to develop plans and policy for the use of navigable airspace and to assign the use the FAA deems necessary for safe and efficient utilization. It further directs the FAA to prescribe air traffic rules and regulations governing the efficient utilization of navigable airspace. Not only is the FAA required to ensure the efficient use of navigable airspace, but it must do so in a manner that does not effectively shut out potential operators at the airport and in a manner that acknowledges competitive market forces.

These authorities empower the DOT to ensure the efficient utilization of airspace by limiting the number of scheduled and unscheduled aircraft operations at JFK, EWR, and LGA, while balancing between
promoting competition and recognizing historical investments in the airport and the need to provide continuity. They also authorize the DOT to investigate the transfer of slots and to limit or prohibit anti-competitive transfers.

Alternatives:
The FAA considered two alternatives. The first alternative was to simply extend the existing orders. This alternative was rejected because the FAA wanted to increase competition by making slots available to more operators. The FAA believes these operators are likely to be small entities. The second alternative was to remove the existing orders. This alternative results in unacceptable delay costs from the increase in operations.

Anticipated Cost and Benefits:
TBD

Risks:
The FAA will review specific risks associated with this rulemaking.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
Businesses

Government Levels Affected:
None

URL For More Information:
www.regulations.gov

URL For Public Comments:
www.regulations.gov

Agency Contact:
Molly W. Smith
This rulemaking would change equipment and operating requirements for commercial helicopter operations, including many specifically for helicopter air ambulance operations. This rulemaking is necessary to increase crew, passenger, and patient safety. The intended effect is to implement National Transportation Safety Board, Aviation Rulemaking Committee, and internal FAA recommendations.
Statement of Need:
Since 2002, there has been an increase in fatal helicopter air ambulance accidents. The FAA has undertaken initiatives to address common factors that contribute to helicopter air ambulance accidents, including issuing notices, handbook bulletins, operations specifications, and advisory circulars (ACs). This rule would codify many of those initiatives, as well as several NTSB and part 125/135 Aviation Rulemaking Committee recommendations. In addition, the House of Representatives and the Senate introduced legislation in the 111th Congress and in earlier sessions that would address several of the issues raised in this rulemaking.

Summary of Legal Basis:
This rulemaking is promulgated under the authority described in 49 U.S.C. 44701(a)(4), which requires the Administrator to promulgate regulations in the interest of safety for the maximum hours or periods of service of airmen and other employees of air carriers, and 49 U.S.C. 44701(a)(5), which requires the Administrator to promulgate regulations and minimum standards for other practices, methods, and procedures necessary for safety in air commerce and national security.

Alternatives:
Alternative One: The alternative would change the compliance date from 3 years to 4 years after the effective rule date to install all required pieces of equipment. This would help small business owners cope with the burden of the expenses because they would be able to integrate these pieces of equipment over a longer period of time. This alternative is not preferred because it would delay safety enhancements.

Alternative Two: The alternative would exclude the HTAWS unit from this proposal. Although this alternative would reduce annualized costs to small air ambulance operators by approximately 12 percent and the ratio of annualized cost to annual revenue would decrease from a range of between 1.76 percent and 1.88 percent to a range of between 1.55 percent and 1.65 percent, the annualized cost would still be significant for all 35 small air ambulance operators. The alternative not only does not eliminate the problem for a substantial number of small entities, but also would reduce safety. The HTAWS is an outstanding tool for situational awareness in all aspects of flying, including day, night, and instrument
meteorological conditions. Therefore the FAA believes that this equipment is a significant enhancement for safety.

Alternative Three: The alternative would increase the requirement of certificate holders from 10 to 15 helicopters or more that are engaged in helicopter air ambulance operations to have an Operations Control Center. The FAA believes that operators with 10 or more helicopters engaged in air ambulance operations would cover 66 percent of the total population of the air ambulance fleet in the U.S. The FAA believes that operators with 15 or more helicopters would decrease the coverage of the population to 50 percent. Furthermore, complexity issues arise and considerably increase with operators of more than 10 helicopters.

All alternatives above are not considered to be acceptable by the FAA in accordance with 5 U.S.C. 603(c).

**Anticipated Cost and Benefits:**
The FAA is currently developing costs and benefits.

**Risks:**
Helicopter air ambulance operations have several characteristics that make them unique, including that they are not limited to airport locations for picking up and dropping off patients, but may pick up a person at a roadside accident scene and transport him or her directly to a hospital. Helicopter air ambulance operations are also often time-sensitive. A helicopter air ambulance flight may be crucial to getting a donor organ or critically ill or injured patient to a medical facility as efficiently as possible. Additionally, patients generally are not able to choose the helicopter air ambulance company that provides them with transportation. Despite the fact that there are unique aspects to helicopter air ambulance operations, they remain, at their core, air transportation. Accordingly, the FAA has the responsibility for ensuring the safety of these operations.

**Timetable:**

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DOT—FAA

109. +SAFETY MANAGEMENT SYSTEMS FOR CERTIFICATE HOLDERS (SECTION 610 REVIEW)

Priority:

Other Significant

Legal Authority:
Congress passed Public Law 111-216 that instructs FAA to conduct a rulemaking to require all part 121 air carriers to implement a Safety Management System (SMS). This act further states that FAA shall consider at a minimum each of the following as part of the SMS rulemaking: (1) An Aviation Safety Action Program (ASAP); (2) a Flight Operations Quality Assurance Program (FOQA); (3) a Line Operations Safety Audit (LOSA); and (4) an Advance Qualifications Program.

**Abstract:**

This rulemaking would require each certificate holder operating under 14 CFR part 121 to develop and implement a Safety Management System (SMS) to improve the safety of its aviation related activities. A SMS is a comprehensive, process-oriented approach to managing safety throughout an organization. An SMS includes an organization-wide safety policy; formal methods for identifying hazards, controlling, and continually assessing risk and safety performance; and promotion of a safety culture. SMS stresses not only compliance with technical standards but increased emphasis on the overall safety performance of the organization.

**Statement of Need:**

Passage of the Airline Safety and FAA Extension Act of 2010 (Pub. L. 111-216), section 215 “Safety Management System” directs the Administrator to conduct a rulemaking to require all part 121 air carriers to implement a safety management system (SMS). The Act requires an NPRM within 90 days and a final rule not later than 24 months from enactment of Public Law 111-216.

**Summary of Legal Basis:**

Alternatives:
The Rulemaking Team considered including parts 135 (air carriers) and 145 (repair stations) to the rule but did not because of time restraints.

Anticipated Cost and Benefits:
Costs and benefits of this final rule are still in development. An initial cost estimate for SMS implementation over 3 years is $270,000 (small carrier), $373,950 (medium carrier), and $1,135,500 (large carrier) with total cost for 90 part 121 carriers of $52,276,200. However, given the flexibility of SMS, and expected safety improvements, benefits are expected to exceed costs.

Risks:
Commercial air carrier accident rate in the U.S. has remained relatively constant over the past 10 years. However, the recent trend of hazards include many that could have been mitigated or eliminated had a structured, organization-wide approach to managing air carriers’ operations been in place.

SMS is a comprehensive, process-oriented approach to managing safety throughout an organization, and stresses not only compliance with technical standards but increased emphasis on the overall safety performance of the organization.

The potential reduction of risks would be averted causalities, aircraft damage, and accident investigation costs by identifying safety issues and spotting trends before they result in a near-miss, incident, or accident.

Timetable:

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal

**URL For More Information:**

www.regulations.gov

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Scott VanBuren

Department of Transportation

Federal Aviation Administration

800 Independence Avenue SW

Washington, DC 20591

Phone: 202 494–8417

Email: scott.vanburen@faa.gov

**Related RIN:** Split from 2120–AJ15

**RIN:** 2120–AJ86

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**DOT—Federal Motor Carrier Safety Administration (FMCSA)**

**PROPOSED RULE STAGE**

**110. +CARRIER SAFETY FITNESS DETERMINATION**
Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
Sec 4009 of TEA–21

CFR Citation:
49 CFR 385

Legal Deadline:
None

Abstract:
This rulemaking would revise 49 CFR part 385, Safety Fitness Procedures, in accordance with the Agency’s major new initiative, Comprehensive Safety Analysis (CSA). CSA is a new operational model FMCSA plans to implement that is designed to help the Agency carry out its compliance and enforcement programs more efficiently and effectively. Currently, the safety fitness rating of a motor carrier is determined based on the results of a very labor intensive compliance review conducted at the carrier’s place of business. Aside from roadside inspections and new audits, the compliance review is the Agency’s primary intervention. Under CSA, FMCSA would propose to implement a broader array of progressive interventions, some of which allow FMCSA to make contact with more carriers. Through this rulemaking FMCSA would establish safety fitness determinations based on safety data from crashes, inspections, and violation history rather than just the standard compliance review. This will enable the Agency to assess the safety performance of a greater segment of the motor carrier industry with the goal of further reducing large truck and bus crashes and fatalities.

Statement of Need:
Because of the time and expense associated with the on-site compliance review, only a small fraction of carriers (approximately 12,000) receive a safety fitness determination each year. Since the current safety fitness determination process is based exclusively on the results of an on-site compliance review, the
The great majority of carriers subject to FMCSA jurisdiction do not receive a timely determination of their safety fitness.

The proposed methodology for determining motor carrier safety fitness should correct the deficiencies of the current process. In correcting these deficiencies, FMCSA has made a concerted effort to develop a “transparent” method for the Safety Fitness Determination (SFD) that would allow each motor carrier to understand fully how FMCSA established that carrier's specific SFD.

**Summary of Legal Basis:**

This rule is based primarily on the authority of 49 U.S.C. 31144, which directs the Secretary of Transportation to “determine whether an owner or operator is fit to operate a commercial motor vehicle” and to “maintain by regulation a procedure for determining the safety fitness of an owner or operator.” This statute was first enacted as part of the Motor Carrier Safety Act of 1984, section 215, Public Law 98-554, 98 Stat. 2844 (Oct. 30, 1984).

The proposed rule also relies on the provisions of 49 U.S.C. 31133, which gives the Secretary “broad administrative powers to assist in the implementation” of the provisions of the Motor Carrier Safety Act now found in chapter 311 of title 49, U.S.C. These powers include, among others, authority to conduct inspections and investigations, compile statistics, require production of records and property, prescribe recordkeeping and reporting requirements and to perform other acts considered appropriate. These powers are used to obtain the data used by the Safety Management System and by the proposed new methodology for safety fitness determinations.

Under 49 CFR 1.73(g), the Secretary has delegated the authority to carry out the functions in subchapters I, III, and IV of chapter 311, title 49, U.S.C., to the FMCSA Administrator. Sections 31133 and 31144 are part of subchapter III of chapter 311.

**Alternatives:**

The Agency has been considering only two alternatives: The no-action alternative and the proposal.

**Anticipated Cost and Benefits:**
The Agency has estimated the crash-reduction benefit from the change to the proposed safety fitness determination process to be about $441 million annually. The total cost is estimated at $13 million annually. Net benefits are about $428 million annually.

**Risks:**
A risk of incorrectly identifying a compliant carrier as non-compliant — and consequently subjecting the carrier to unnecessary expenses — has been analyzed and has been found to be negligible under the process being proposed.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Undetermined

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
Undetermined

**Federalism:**
Undetermined

**URL For More Information:**
www.regulations.gov

**URL For Public Comments:**
www.regulations.gov

**Agency Contact:**
David Miller
Regulatory Development Division
Department of Transportation
Federal Motor Carrier Safety Administration
1200 New Jersey Avenue SE
111. NATIONAL REGISTRY OF CERTIFIED MEDICAL EXAMINERS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
PL 109–59 (2005), sec 4116

CFR Citation:
49 CFR 390; 49 CFR 391

Legal Deadline:
Final, Statutory, August 10, 2006.

Abstract:
This rulemaking would establish training, testing, and certification standards for medical examiners responsible for certifying that interstate commercial motor vehicle (CMV) drivers meet established physical qualifications standards; provide a database (or National Registry) of medical examiners that meet the prescribed standards for use by motor carriers, drivers, and Federal and State enforcement personnel in determining whether a medical examiner is qualified to conduct examinations of interstate truck and bus drivers; and require medical examiners to transmit electronically to FMCSA the name of the driver and a numerical identifier for each driver that is examined. The rulemaking would also establish the process by which medical examiners that fail to meet or maintain the minimum standards would be
removed from the National Registry. This action is in response to section 4116 of Safe, Accountable, Flexible, Efficient, Transportation Equity Act: A Legacy for Users (SAFETEA-LU).

**Statement of Need:**

In enacting the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) (Pub. L. 109-59, Aug. 10, 2005), Congress recognized the need to improve the quality of the medical certification of drivers. SAFETEA-LU addresses the requirement for medical examiners to receive training in physical examination standards and be listed on a national registry of medical examiners as one step toward improving the quality of the commercial motor vehicle (CMV) driver physical examination process and the medical fitness of CMV drivers to operate CMVs. The safety impact will result from ensuring that medical examiners have completed training and testing to demonstrate that they fully understand FMCSA's physical qualifications standards and are capable of applying those standards consistently, thereby decreasing the likelihood that a medically unqualified driver may obtain a medical certificate.

**Summary of Legal Basis:**

The fundamental legal basis for the National Registry program comes from 49 U.S.C. 31149(d), which requires FMCSA to establish and maintain a current national registry of medical examiners that are qualified to perform examinations of CMV drivers and to issue medical certificates. FMCSA is required to remove from the registry any medical examiner who fails to meet or maintain qualifications established by FMCSA. In addition, in developing its regulations, FMCSA must consider both the effect of driver health on the safety of CMV operations and the effect of such operations on driver health, 49 U.S.C. 31136(a).

**Alternatives:**

The rulemaking is statutorily mandated. Thus, the Agency must establish the National Registry.

**Anticipated Cost and Benefits:**

We estimated 10-year costs (discounted at 7 percent) at $700,783 million, total benefits at $1,144,961 million, and net benefits over 10 years at $444,177 million.

**Risks:**

FMCSA has not yet fully assessed the risks that might be associated with this activity.

**Timetable:**
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**Regulatory Flexibility Analysis Required:**
No

**Small Entities Affected:**
No

**Government Levels Affected:**
None

**URL For More Information:**
www.regulations.gov

**URL For Public Comments:**
www.regulations.gov

**Agency Contact:**
Dr. Mary D. Gunnels
Director, Office of Medical Programs
Department of Transportation
Federal Motor Carrier Safety Administration
1200 New Jersey Avenue SE
Washington, DC 20590
Phone: 202 366–4001
Email: maggi.gunnels@dot.gov

**RIN:** 2126–AA97

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**DOT—National Highway Traffic Safety Administration (NHTSA)**

| PROPOSED RULE STAGE |
112. +PASSENGER CAR AND LIGHT TRUCK CORPORATE AVERAGE FUEL ECONOMY
STANDARDS MYS 2017 AND BEYOND

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
49 USC 32902; Delegation of Authority at 49 CFR 1.50

CFR Citation:
49 CFR 533

Legal Deadline:
Final, Statutory, April 1, 2015.

Abstract:
This rulemaking would establish Corporate Average Fuel Economy (CAFE) standards for light trucks and passenger cars for model years 2017 and beyond. This rulemaking would respond to requirements of the Energy Policy and Conservation Act, as amended by the Energy Independence and Security Act of 2007. The statute requires that CAFE standards be prescribed separately for passenger automobiles and non-passenger automobiles to achieve a combined fleet fuel economy of at least 35 mpg by model year 2020. For model years 2021 and beyond, the statute requires that the average fuel economy required to be attained by each fleet of passenger and non-passenger automobiles be the maximum feasible for each model year. The law requires the standards be set at least 18 months prior to the start of the model year. On May 21, 2010, President Obama issued a memorandum directing NHTSA and EPA to conduct a joint rulemaking (NHTSA regulating fuel economy and EPA regulating greenhouse gas emissions), and to issue a Notice of Intent to Issue a Proposed Rule (NOI) by September 30, 2010.

Statement of Need:
This rulemaking would respond to requirements of the Energy Policy and Conservation Act, as amended by the Energy Independence and Security Act of 2007. The statute requires that corporate average fuel economy standards be prescribed separately for passenger automobiles and non-passenger automobiles
to achieve a combined fleet fuel economy of at least 35 mpg by model year 2020. For model years 2021 and beyond, the statute requires that the average fuel economy required to be attained by each fleet of passenger and non-passenger automobiles be the maximum feasible for each model year. The law requires the standards be set at least 18 months prior to the start of the model year, and for model year 2017, standards must be set by April 1, 2015. On May 21, 2010, President Obama issued a memorandum directing NHTSA and EPA to conduct joint rulemaking, with NHTSA regulating fuel economy and EPA regulating greenhouse gas emissions.

**Summary of Legal Basis:**

Section 32910(d) of title 49 of the United States Code provides that the Administrator may prescribe regulations necessary to carry out his duties under chapter 329, Automobile Fuel Economy.

**Alternatives:**

The Agency is not pursuing any alternatives.

**Anticipated Cost and Benefits:**

The costs and benefits of the potential changes addressed in this action have not yet been assessed.

**Risks:**

Depending upon how manufacturers use weight reduction to meet the fuel economy standards, there is a potential impact on motor vehicle safety. The 2010 NHTSA analysis shows that a 100-pound reduction in weight, while keeping footprint constant, decreases the fatality rate for light trucks over 3,870 pounds but increases the fatality rate for light trucks less than 3,870 pounds and for all passenger cars. An interagency team from DOT, EPA, and DOE are further examining this issue.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Government Levels Affected:
None

Energy Effects:
Statement of Energy Effects planned as required by Executive Order 13211.

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

URL For More Information:
www.regulations.gov

URL For Public Comments:
www.regulations.gov

Agency Contact:
James Tamm
Fuel Economy Division Chief
Department of Transportation
National Highway Traffic Safety Administration
1200 New Jersey Avenue SE
Washington, DC 20590
Phone: 202 493–0515
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Related RIN: Duplicate of 2060–AQ54
RIN: 2127–AK79

DOT—NHTSA

113. • +SOUND FOR HYBRID AND ELECTRIC VEHICLES

Priority:
Other Significant Legal Authority:

49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166; 49 USC 322; Delegation of Authority at 49 CFR 1.50

CFR Citation:

Not Yet Determined

Legal Deadline:

NPRM, Statutory, July 5, 2012, Initiate rulemaking.

Final, Statutory, January 3, 2014.

Legislation requires the Secretary of Transportation to initiate rulemaking by July 2012 and issue a final rule not later than January 2014.

Abstract:

This rulemaking would respond to The Pedestrian Safety Enhancement Act of 2010, which directs the Secretary of Transportation to study and establish a motor vehicle safety standard that provides for a means of alerting blind and other pedestrians of motor vehicle operation. NHTSA is conducting research in this area and has not yet developed an estimate for the potential costs and benefits associated with this rulemaking action.

Statement of Need:

The Pedestrian Safety Enhancement Act of 2010, signed into law on January 4, 2011, directs the Secretary to study and establish a motor vehicle safety standard that provides for a means of alerting blind and other pedestrians of motor vehicle operation. Prior to that, in June 2008, NHTSA held a public meeting to provide a forum for interested parties to discuss the issue of quieter cars and established a docket (Docket No. NHTSA-2008-0108) to collect information on the issue. Subsequently, the Agency developed and initiated a research plan to identify the critical safety scenarios in which quieter vehicles may pose a hazard to blind and other pedestrians; identify and evaluate various countermeasures to address the safety problem; and support the development of a specification for an artificial vehicle sound.

Summary of Legal Basis:
Section 30111, title 49 of the U.S.C. states that the Secretary shall prescribe motor vehicle safety standards.

**Alternatives:**

The Agency is not pursuing any alternatives.

**Anticipated Cost and Benefits:**

The costs and benefits of the potential changes addressed in this action have not yet been assessed.

**Risks:**

The Agency believes that there are no significant risks associated with this rulemaking and that only beneficial outcomes will occur.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**International Impacts:**

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**URL For More Information:**

www.regulations.gov

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Marisol Medri

Safety Engineer
114. • +MOTORCOACH ROLLOVER STRUCTURAL INTEGRITY

Priority:
Other Significant

Legal Authority:
49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166; 49 USC 322; Delegation of Authority at 49 CFR 1.50

CFR Citation:
49 CFR 571

Legal Deadline:
None

Abstract:
This rulemaking would promulgate a new FMVSS for rollover structural integrity requirements for motorcoaches. In August 2007, NHTSA published a motorcoach safety plan identifying four specific priority items: Seat belts on motorcoaches, rollover structural integrity, emergency evacuation, and fire safety. The DOT published a comprehensive motorcoach safety action plan in November 2009 that reiterated NHTSA’s motorcoach safety priorities. This rulemaking also addresses six recommendations issued by the NTSB on motorcoach roof strength and structural integrity.

Statement of Need:
Over the 10-year period between 1999 and 2008, there were 54 fatal motorcoach crashes resulting in 186 fatalities. During this period, on average, 16 fatalities have occurred annually to occupants of motorcoaches in crash and rollover events, with about 2 of these fatalities being drivers and 14 being passengers. However, while motorcoach transportation overall is safe, when serious crashes of this vehicle type do occur, they can cause a significant number of fatal or serious injuries during a single event, particularly when occupants are ejected. This action is consistent with our detailed plans for improving motorcoach passenger protection, laid out in NHTSA's Approach to Motorcoach Safety 2007 and the Department of Transportation 2009 Motorcoach Action Plan (Docket No. NHTSA-2007-28793), as well as the Agency’s Vehicle Safety and Fuel Economy Rulemaking and Research Priority Plan 2011 to 2013 (Docket No. NHTSA-2009-0108), and is responsive to six recommendations issued by the National Transportation Safety Board.

**Summary of Legal Basis:**

Section 30111, title 49 of the U.S.C. states that the Secretary shall prescribe motor vehicle safety standards.

**Alternatives:**

The Agency is not pursuing any alternatives.

**Anticipated Cost and Benefits:**

The costs and benefits of the potential changes addressed in this action have not yet been assessed.

**Risks:**

The Agency believes that there are no significant risks associated with this rulemaking and that only beneficial outcomes will occur.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No
Government Levels Affected:
None

URL For More Information:
www.regulations.gov

URL For Public Comments:
www.regulations.gov

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RIN: 2127–AK96

DOT—NHTSA

115. • +ELECTRONIC STABILITY CONTROL SYSTEMS FOR HEAVY VEHICLES

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
49 USC 30111; 49 USC 30115; 49 USC 30117; 49 USC 30166; 49 USC 322; Delegation of Authority at
49 CFR 1.50

CFR Citation:
49 CFR 571
Abstract:
This rulemaking would promulgate a new Federal standard that would require stability control systems on truck tractors and motorcoaches that address both rollover and loss of control crashes, after an extensive research program to evaluate the available technologies, an evaluation of the costs and benefits, and a review of manufacturer’s product plans. Rollover and loss of control crashes involving heavy vehicles is a serious safety issue that is responsible for 304 fatalities and 2,738 injuries annually. They are also a major cause of traffic tie-ups, resulting in millions of dollars of lost productivity and excess energy consumption each year. Suppliers and truck and motorcoach manufacturers have developed stability control technology for heavy vehicles to mitigate these types of crashes. Our preliminary estimate produces an effectiveness range of 37 to 56 percent against single-vehicle tractor-trailer rollover crashes and 3 to 14 percent against loss of control crashes that result from skidding on the road surface. With these effectiveness estimates, annually, we estimate 29 to 66 lives would be saved, 517 to 979 MAIS 1 to 5 injuries would be reduced, and 810 to 1,693 crashes that involved property damage only would be eliminated. Additionally, it would save $10 to $26 million in property damage and travel delays. Based on the technology unit costs and affected vehicles, we estimate technology costs would be $55 to $107 million, annually. However, the costs savings from reducing travel delay and property damage would produce net benefits of $128 to $372 million.

Statement of Need:
Rollover and loss of control crashes involving heavy vehicles is a serious safety issue that is responsible for 304 fatalities and 2,738 injuries annually. They are also a major cause of traffic tie-ups, resulting in millions of dollars of lost productivity and excess energy consumption each year. This action is consistent with our detailed plans for improving motorcoach passenger protection, laid out in NHTSA's Approach to Motorcoach Safety 2007 and the Department of Transportation 2009 Motorcoach Action Plan (Docket No. NHTSA-2007-28793), as well as the Agency's Vehicle Safety and Fuel Economy Rulemaking and Research Priority Plan 2011 to 2013 (Docket No. NHTSA-2009-0108), and is responsive to two recommendations issued by the National Transportation Safety Board.
Summary of Legal Basis:

Section 30111, title 49 of the U.S.C. states that the Secretary shall prescribe motor vehicle safety standards.

Alternatives:

The Agency is not pursuing any alternatives.

Anticipated Cost and Benefits:

The costs and benefits of the potential changes addressed in this action have not yet been assessed.

Risks:

The Agency believes that there are no significant risks associated with this rulemaking and that only beneficial outcomes will occur.

Timetable:

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Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

None

URL For More Information:

www.regulations.gov

URL For Public Comments:

www.regulations.gov

Agency Contact:

George Soodoo

Chief, Vehicle Safety Dynamics Division (NVS–122)

Department of Transportation

National Highway Traffic Safety Administration
This rulemaking would require the installation of lap/shoulder belts in newly manufactured motorcoaches. Specifically, this rulemaking would establish a new definition for motorcoaches in 49 CFR part 571.3. It would also amend Federal Motor Vehicle Safety Standard No. 208 “Occupant Crash Protection” to require the installation of lap/shoulder belts at all driver and passenger seating positions. It would also require the installation of lap/shoulder belts at driver seating positions of large school buses in FMVSS no. 208. This rulemaking responds, in part, to recommendations made by the National Transportation Safety Board for improving bus safety.
Over the 10-year period between 1999 and 2008, there were 54 fatal motorcoach crashes resulting in 186 fatalities. During this period, on average, 16 fatalities have occurred annually to occupants of motorcoaches in crash and rollover events, with about 2 of these fatalities being drivers and 14 being passengers. However, while motorcoach transportation overall is safe, when serious crashes of this vehicle type do occur, they can cause a significant number of fatal or serious injuries during a single event, particularly when occupants are ejected.

**Summary of Legal Basis:**
Section 30111, title 49 of the U.S.C., states that the Secretary shall prescribe motor vehicle safety standards.

**Alternatives:**
In addition to the proposed installation of lap/shoulder belts in all passenger seating positions on motorcoaches, the Agency is also pursuing improvements to motorcoach rollover structural integrity, fire safety, electronic stability control, and emergency egress to improve occupant protection. Our detailed plans for improving motorcoach passenger protection can be found in NHTSA's Approach to Motorcoach Safety 2007 and the Department of Transportation 2009 Motorcoach Action Plan (Docket No. NHTSA-2007-28793), as well as the Agency's Vehicle Safety and Fuel Economy Rulemaking and Research Priority Plan 2011 to 2013 (Docket No. NHTSA-2009-0108).

The Agency also alternatively evaluated proposing the installation of lap belts in all passenger seating positions on motorcoaches and is seeking comments on the issue of retrofitting older motorcoaches with seat belts.

**Anticipated Cost and Benefits:**
The anticipated total costs are expected to be $25.8 million for the 2,000 new motorcoaches produced each year, plus added fuel costs. The Agency estimates the proposal has the potential to save 1 to 8 fatalities and 144 to 794 non-fatal injuries annually assuming a range of seat belt use between 15 and 83 percent. The cost per equivalent life saved at a 7 percent discount rate is estimated to range from $1.8 to $9.9 million, based on an assumed seat belt use rate between 83 percent and 15 percent, respectively.

**Risks:**
The Agency believes there are no substantial risks to this rulemaking, and that only beneficial outcomes will occur as the industry moves to reduce injuries of motorcoach occupants.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**International Impacts:**

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**URL For More Information:**

www.regulations.gov

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

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Phone: 202 366–3273
117. +MAJOR CAPITAL INVESTMENT PROJECTS (RRR)

Priority:
Economically Significant. Major under 5 USC 801.

Legal Authority:
49 USC 5309

CFR Citation:
49 CFR 611

Legal Deadline:
Final, Statutory, April 7, 2006.

Abstract:
This rulemaking would make changes to the regulations that govern the New Starts discretionary funding program authorized by 49 U.S.C. 5309. FTA’s initial rulemaking on this subject (RIN 2132-AA81), initiated to meet the statutory deadline, was terminated as the result of subsequent congressional action prohibiting FTA from issuing a rule.

Statement of Need:
Section 3011 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA-LU) made a number of changes to 49 U.S.C. 5309, which authorizes the Federal Transit Administration's (FTA) fixed guideway capital investment grant program known as “New Starts.” SAFETEA-LU also created a new category of major capital investments that have a total project cost of less than $250 million, and that are seeking less than $75 million in section 5309 major capital investment funds. This rulemaking proposes to implement those changes and a number of other changes that FTA believes will improve the process for evaluating major capital investment projects.
Summary of Legal Basis:
Section 5309, title 49 of the United States Code, requires the Secretary to promulgate regulations for the evaluation and selection of major capital investment projects that have a total project cost of less than $250 million, and that are seeking less than $75 million in section 5309 major capital investment funds.

Alternatives:
This rulemaking is mandated by section 3011 of SAFETEA-LU, so there is not an alternative to pursuing rulemaking. Within the rulemaking process, FTA has already issued and has received comments on an Advance Notice of Proposed Rulemaking that will inform the various options FTA might pursue in the Notice of Proposed Rulemaking.

Anticipated Cost and Benefits:
The single largest change in the New Starts program is the creation in SAFETEA-LU of the "Small Starts" program. Over the first 10 years of the Small Starts program, the cumulative impact of transfer from New Starts to Small Starts will likely be $1.9 Billion, with a Net Present Value of $1.311 Billion using a discount rate of 7 percent. This effect is difficult to characterize in terms of cost or benefit, as it simply represents a “transfer of a transfer” from one governmental entity to another.

Risks:
The proposed rulemaking provides a framework for a discretionary grant program; it does not propose to regulate other than for applicants for Federal funds. As such, the rulemaking poses no risks for the regulated community, other than for the risks inherent in pursuing Federal funds that might not be awarded if a project fails to satisfy the eligibility and evaluation criteria in the proposed regulatory structure.

Timetable:

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No

Small Entities Affected:
No

Government Levels Affected:
None

Additional Information:
Includes Retrospective Review under E.O. 13563.

URL For More Information:
www.regulations.gov

URL For Public Comments:
www.regulations.gov

Agency Contact:
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RIN: 2132–AB02

<table>
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<th>DOT—Maritime Administration (MARAD)</th>
<th>PROPOSED RULE STAGE</th>
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<td>118. +REGULATIONS TO BE FOLLOWED BY ALL DEPARTMENTS, AGENCIES, AND SHIPPERS HAVING RESPONSIBILITY TO PROVIDE A PREFERENCE FOR U.S.–FLAG VESSELS IN THE SHIPMENT OF CARGOES ON OCEAN VESSELS</td>
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Other Significant

**Legal Authority:**

49 CFR 1.66; 46 app USC 1101; 46 app USC 1241; 46 USC 2302 (e)(1); PL 91–469

**CFR Citation:**

46 CFR 381

**Legal Deadline:**

None

**Abstract:**

This rulemaking would revise and clarify the Cargo Preference rules that have not been revised substantially since 1971. Revisions would include an updated purpose and definitions section along with the removal of obsolete provisions. This rulemaking also would establish a new part 383 of the Cargo Preference regulations. This rulemaking would cover Public Law 110-417, section 3511, National Defense Authorization Act for FY 2009 changes to the cargo preference rules, which have not been substantially revised since 1971. The rulemaking also would include compromise, assessment, mitigation, settlement, and collection of civil penalties. Originally the agency had two separate rulemakings in process under RIN 2133-AB74 and 2133-AB75. RIN 2133-AB74 would have revised existing regulations and RIN 2133-AB75 would have established a new part 383: Guidance and Civil Penalties and implement Public Law 110-417, section 3511, National Defense Authorization Act for FY 2009. MARAD has decided it would be more efficient to merge both efforts under one; RIN 2133-AB75 has been merged with this action.

**Statement of Need:**

On September 4, 2009, the USDA, MARAD, and USAID entered into a MOU regarding the proper implementation of the Cargo Preference Act. The MOU establishes procedures and standards by which owners and operators of oceangoing cargo ships may seek to designate each of their vessels as either a dry bulk carrier or a dry cargo liner, according to specified service-based criteria. With the help of OMB, these agencies are in the process of negotiating updates to the comprehensive cargo preference rule, which has not been significantly changed since 1971.

**Summary of Legal Basis:**
The Cargo Preference Act requires that Federal agencies take necessary and practicable steps to ensure that privately owned U.S.-flag vessels transport at least 50 percent of the gross tonnage of cargo sponsored under Federal programs to the extent such vessels are available at fair and reasonable rates for commercial vessels of the U.S., in a manner that will ensure a fair and reasonable participation of commercial vessels of the U.S. in those cargoes by geographic areas. 46 U.S.C. 55305(b). An additional 25 percent of gross tonnage of certain food assistance programs is to be transported in accordance with the requirements of 46 U.S.C. 55314.

**Alternatives:**

TBD

**Anticipated Cost and Benefits:**

TBD

**Risks:**

TBD

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**URL For More Information:**

www.regulations.gov

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Christine Gurland
Department of Transportation  
Maritime Administration  
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Washington, DC 20590  
Phone: 202 366–5157  
Email: christine.gurland@dot.gov  

Related RIN: Related to 2133–AB75  
RIN: 2133–AB74  
BILLING CODE 4910–9X–S  
DEPARTMENT OF THE TREASURY

Statement of Regulatory Priorities

The primary missions of the Department of the Treasury are:

- To promote prosperous and stable American and world economies, including promoting domestic economic growth and maintaining our Nation’s leadership in global economic issues, supervising national banks and thrift institutions, and helping to bring residents of distressed communities into the economic mainstream.

- To manage the Government’s finances by protecting the revenue and collecting the correct amount of revenue under the Internal Revenue Code, overseeing customs revenue functions, financing the Federal Government and managing its fiscal operations, and producing our Nation’s coins and currency.

- To safeguard the U.S. and international financial systems from those who would use these systems for illegal purposes or to compromise U.S. national security interests, while keeping them free and open to legitimate users.
Consistent with these missions, most regulations of the Department and its constituent bureaus are promulgated to interpret and implement the laws as enacted by the Congress and signed by the President. It is the policy of the Department to comply with applicable requirements to issue a notice of proposed rulemaking and carefully consider public comments before adopting a final rule. Also, in particular cases, the Department invites interested parties to submit views on rulemaking projects while a proposed rule is being developed.

In response to the events of September 11, 2001, the President signed the USA PATRIOT Act of 2001 into law on October 26, 2001. Since then, the Department has accorded the highest priority to developing and issuing regulations to implement the provisions in this historic legislation that target money laundering and terrorist financing. These efforts, which will continue during the coming year, are reflected in the regulatory priorities of the Financial Crimes Enforcement Network (FinCEN).

To the extent permitted by law, it is the policy of the Department to adhere to the regulatory philosophy and principles set forth in Executive Orders 12866 and 13563 and to develop regulations that maximize aggregate net benefits to society while minimizing the economic and paperwork burdens imposed on persons and businesses subject to those regulations.

Office of Financial Stability

On October 3, 2008, the President signed the Emergency Economic Stabilization Act of 2008 (EESA) (Pub. L. 110-334). Section 101(a) of EESA authorizes the Secretary of the Treasury to establish a Troubled Asset Relief Program (TARP) to “purchase, and to make and fund commitments to purchase, troubled assets from any financial institution, on such terms and conditions as are determined by the Secretary, and in accordance with this Act and policies and procedures developed and published by the Secretary.”
EESA provides authority to issue regulations and guidance to implement the program. Regulations and guidance required by EESA include conflicts of interest, executive compensation, and tax guidance. The Secretary is also charged with establishing a program that will guarantee principal of, and interest on, troubled assets originated or issued prior to March 14, 2008.

The Department has issued guidance and regulations and will continue to provide program information through the next year. Regulatory actions taken to date include:

**Executive compensation.** In October 2008, the Department issued an interim final rule that set forth executive compensation guidelines for the TARP Capital Purchase Program (73 FR 62205). Related tax guidance on executive compensation was announced in IRS Notice 2008-94. In addition, among other EESA tax guidance, the IRS issued interim guidance regarding loss corporation and ownership changes in Notice 2008-100, providing that any shares of stock owned by the Department of the Treasury under the Capital Purchase Program will not be considered to cause Treasury’s ownership in such corporation to increase. On June 15, 2009, the Department issued a revised interim final rule that sets forth executive compensation guidelines for all TARP program participants (74 FR 28394), implementing amendments to the executive compensation provisions of EESA made by the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5). Public comments on the revised interim final rule regarding executive compensation were due by August 14, 2009, and will be considered as part of the process of issuing a final rule on this subject.

**Conflicts of interest.** On January 21, 2009, the Department issued an interim final rule providing guidance on conflicts of interest pursuant to section 108 of EESA (74 FR 3431). Comments on the interim final rule, which were due by March 23, 2009, will be considered as part of the process of issuing a final rule. A final rule was published on October 3, 2011.

The Department will continue implementing the EESA authorities to restore capital flows to the consumers and businesses that form the core of the Nation’s economy.
The Terrorism Risk Insurance Act of 2002 (TRIA) was signed into law on November 26, 2002. The law, which was enacted as a consequence of the events of September 11, 2001, established a temporary Federal reinsurance program under which the Federal Government shares the risk of losses associated with certain types of terrorist acts with commercial property and casualty insurers. The Act, originally scheduled to expire on December 31, 2005, was extended to December 31, 2007, by the Terrorism Risk Insurance Extension Act of 2005 (TRIEA). The Act has since been extended to December 31, 2014, by the Terrorism Risk Insurance Program Reauthorization Act of 2007 (TRIPRA).

The Office of the Assistant Secretary for Financial Institutions is responsible for developing and promulgating regulations implementing TRIA, as extended and amended by TRIEA and TRIPRA. The Terrorism Risk Insurance Program Office, which is part of the Office of the Assistant Secretary for Financial Institutions, is responsible for operational implementation of TRIA. The purposes of this legislation are to address market disruptions, ensure the continued widespread availability and affordability of commercial property and casualty insurance for terrorism risk, and to allow for a transition period for the private markets to stabilize and build capacity while preserving State insurance regulation and consumer protections.

Over the past year, the Office of the Assistant Secretary has issued proposed rules implementing changes authorized by TRIA as revised by TRIPRA. The following regulations should be published by December 31, 2011:

*Final Netting.* This final rule would establish procedures by which, after the Secretary has determined that claims for the Federal share of insured losses arising from a particular Program Year shall be considered final, a final netting of payments to or from insurers will be accomplished.
Affiliates. This proposed rule would make changes to the definition of “affiliate” to conform to the language in the statute.

Civil Penalty. This proposed rule would establish procedures by which the Secretary may assess civil penalties against any insurer that the Secretary determines, on the record after an opportunity for a hearing, has violated provisions of the Act.

Treasury will continue the ongoing work of implementing TRIA and carrying out revised operations as a result of the TRIPRA-related regulation changes.

Customs Revenue Functions

The Homeland Security Act of 2002 (the Act) provides that the Secretary of the Treasury retains sole legal authority over the customs revenue functions. The Act also authorizes the Secretary of the Treasury to delegate any of the retained authority over customs revenue functions to the Secretary of Homeland Security. By Treasury Department Order No. 100-16, the Secretary of the Treasury delegated to the Secretary of Homeland Security authority to prescribe regulations pertaining to the customs revenue functions subject to certain exceptions. This Order further provided that the Secretary of the Treasury retained the sole authority to approve such regulations.

During the past fiscal year, among the customs-revenue function regulations issued was an interim rule (76 FR 692) on January 6, 2011, which implemented the preferential tariff treatment and other customs-related provisions of the United States-Oman Free Trade Agreement Implementation Act. CBP plans to finalize this rulemaking in the first half of FY 2012.

On March 17, 2011, CBP also issued a final rule (76 FR 14575) that adopted, with some changes, the interim amendments to the CBP regulations relating to the country of origin of textile and apparel products. These amendments were necessitated, in part, by the expiration of the Agreement on Textile
and Clothing and the resulting elimination of quotas on the entry of textile and apparel products from World Trade Organizations (WTO) members. The primary regulatory change consisted of the elimination of the requirement that a textile declaration be submitted for every importation of textile and apparel products.

This past fiscal year, consistent with the practice of continuing to move forward with Customs Modernization provisions of the North American Free Trade Implementation Act to improve its regulatory procedures and consistent with the goals of Executive Orders 12866 and 13563, Treasury and CBP finalized on August 17, 2011 (76 FR 50883), the March 2010 proposal and pertaining to how CBP issues courtesy notices of liquidation to importers of record whose entry summaries are filed in the Automated Broker Interface (ABI). In an effort to streamline the notification process and reduce CBP’s printing and mailing costs, the final rule provides that all ABI filers (importers of record and brokers who file as the agent of an importer of record) will receive electronic courtesy notices beginning September 30, 2011. Importers of record whose entries are not filed through the ABI will continue to receive paper courtesy notices of liquidation. In addition, every importer of record with an Automated Commercial Environment (ACE) Account can now monitor the liquidation of its entries by using the reporting tool in the ACE Secure Data Portal Account.

On August 19, 2011, Treasury and CBP published a proposal (76 FR 51914) to amend the CBP regulations to extend the time period after the date of entry for an applicant to file the certification documentation required for duty-free treatment of certain visual and auditory material of an educational, scientific, or cultural character under chapter 98 of the Harmonized Tariff Schedule of the United States.

On September 2, 2011, Treasury and CBP adopted as a final rule (76 FR 54691) only the portion of its July 25, 2008, proposal for amending the country of origin rules codified in part 102 of the CBP regulations applicable to five specific product areas; namely, pipe fittings and flanges, greeting cards, glass optical fiber, rice preparations, and certain textile and apparel products, but, in the light of the public
comments received, it did not adopt the proposal to establish uniform rules governing CBP
determinations of the country of origin of imported merchandise.

During fiscal year 2012, CBP and Treasury plan to give priority to the following regulatory matters
involving the customs revenue functions:

*Trade Act of 2002's preferential trade benefit provisions.* Treasury and CBP plan to make permanent
several interim regulations that implement the trade benefit provisions of the Trade Act of 2002.

*Free Trade Agreements.* Treasury and CBP also plan to issue interim regulations this fiscal year to
implement the preferential trade benefit provisions of the United States-Singapore Free Trade Agreement
Implementation Act. Treasury and CBP also expect to issue interim regulations implementing the
preferential trade benefit provisions of the United States-Australia Free Trade Agreement Implementation
Act and the United States-Peru Free Trade Agreement Implementation Act.

*Customs and Border Protection’s Bond Program.* Treasury and CBP plan to publish a final rule
amending the regulations to reflect the centralization of the continuous bond program at CBP’s Revenue
Division. The changes proposed would support CBP’s bond program by ensuring an efficient and uniform
approach to the approval, maintenance, and periodic review of continuous bonds, as well as
accommodating the use of information technology and modern business practices.

*Use of Sampling Methods and Offsetting of Overpayments and Over-Declarations in CBP Audits.*
Treasury and CBP plan to publish a final rule amending the regulations to add provisions for using
sampling methods in CBP audits and for the offsetting of overpayments and over-declarations when an
audit involves a calculation of lost duties, taxes, or fees or monetary penalties under 19 U.S.C. 1592.

Financial Crimes Enforcement Network
As chief administrator of the Bank Secrecy Act (BSA), the Financial Crimes Enforcement Network (FinCEN) is responsible for developing and implementing regulations that are the core of the Department’s anti-money laundering and counter-terrorism financing efforts. FinCEN’s responsibilities and objectives are linked to, and flow from, that role. In fulfilling this role, FinCEN seeks to enhance U.S. national security by making the financial system increasingly resistant to abuse by money launderers, terrorists and their financial supporters, and other perpetrators of crime.

The Secretary of the Treasury, through FinCEN, is authorized by the BSA to issue regulations requiring financial institutions to file reports and keep records that are determined to have a high degree of usefulness in criminal, tax, or regulatory matters or in the conduct of intelligence or counter-intelligence activities to protect against international terrorism. The BSA also authorizes requiring designated financial institutions to establish anti-money laundering programs and compliance procedures. To implement and realize its mission, FinCEN has established regulatory objectives and priorities to safeguard the financial system from the abuses of financial crime, including terrorist financing, money laundering, and other illicit activity. These objectives and priorities include: (1) Issuing, interpreting, and enforcing compliance with regulations implementing the BSA; (2) supporting, working with, and as appropriate, overseeing compliance examination functions delegated to other Federal regulators; (3) managing the collection, processing, storage, and dissemination of data related to the BSA; (4) maintaining a Governmentwide access service to that same data and for network users with overlapping interests; (5) conducting analysis in support of policymakers, law enforcement, regulatory and intelligence agencies, and the financial sector; and (6) coordinating with and collaborating on anti-terrorism and anti-money laundering initiatives with domestic law enforcement and intelligence agencies, as well as foreign financial intelligence units.

During fiscal year 2011, FinCEN issued the following regulatory actions:

Reorganization of BSA Rules. On October 26, 2010, FinCEN issued a final rule re-designating and reorganizing the BSA regulations in a new chapter, chapter X, within the Code of Federal Regulations.
The regulations are now organized in a more consistent and intuitive structure that more easily allows financial institutions to identify their specific regulatory requirements under the BSA. In reorganizing the regulations, FinCEN has made BSA rules more accessible, easier to research, and easier to understand. The change promotes the goals of the BSA to protect the financial system from criminal abuse by facilitating compliance by regulated financial institutions.

Confidentiality of Suspicious Activity Reports. On November 23, 2010, FinCEN issued a final rule clarifying the non-disclosure provisions with respect to the regulations pertaining to the confidentiality of suspicious activity reports (SARs). In conjunction with this notice, FinCEN finalized two pieces of guidance (SAR Sharing with Affiliates for depository institutions and SAR Sharing with Affiliates for securities and futures industry entities), which permit certain financial institutions to share SARs with their U.S. affiliates that are also subject to SAR reporting requirements. The regulations and the guidance pieces promote the protection of SAR information while seeking to ensure that all appropriate parties have access to SARs. Allowing information sharing among affiliates also will help financial institutions protect themselves from abuses of financial crime, support overarching industry efforts to strengthen enterprise-wide risk management, and promote the reporting of even more useful information to FinCEN and law enforcement investigators.

Non-Bank Residential Mortgage Lenders and Originators. On December 9, 2010, FinCEN issued a Notice of Proposed Rulemaking (NPRM) to solicit public comment on the application of anti-money laundering (AML) program and SAR regulations to a specific sub-set of loan and finance companies; i.e., non-bank residential mortgage lenders and originators. The proposed regulations would close a regulatory gap that allows other originators, such as mortgage brokers and mortgage lenders not affiliated with banks, to avoid having AML and SAR obligations. Based on its ongoing work supporting criminal investigators and prosecutors in combating mortgage fraud, FinCEN believes that this regulatory measure will help mitigate some of the vulnerabilities that criminals have exploited. This NPRM was informed by comments received following an Advance Notice of Proposed Rulemaking issued in July 2009. FinCEN
has a final rule to implement the proposed regulations in clearance and hopes to issue it prior to the end of FY 2011.

**Imposition of Special Measure Against Lebanese Canadian Bank SAL as a Financial Institution of Primary Money Laundering Concern.** On February 10, 2011, FinCEN issued a finding that the Lebanese Canadian Bank SAL is a financial institution of primary money laundering concern under section 311 of the USA PATRIOT Act for the bank’s role in facilitating the money laundering activities of an international narcotics trafficking and money laundering network. Concurrently, FinCEN issued a Notice of Proposed Rulemaking to impose the fifth special measure against the bank. The fifth special measure prohibits or conditions the opening or maintaining of correspondent or payable-through accounts for the designated institution by U.S. financial institutions. These actions are intended to protect the U.S. financial system from the illicit proceeds flowing through the bank and to deprive this international narcotics trafficking and money laundering network of its preferred access point into the formal financial system.

**FBAR Requirements.** On February 24, 2011, working with the Department of Treasury, Office of Tax Policy, and the Internal Revenue Service, FinCEN, issued a final rule that amended the BSA implementing regulations regarding the filing of Reports of Foreign Bank and Financial Accounts (FBARs). The FBAR form is used to report a financial interest in, or signature or other authority over, one or more financial accounts in foreign countries. With slight modifications, the final rule adopted the proposed changes contained in the February 26, 2010, NPRM. FBARs are used in conjunction with SARs, CTRs, and other BSA reports to provide law enforcement and regulatory investigators with valuable information to fight fraud, money laundering, tax evasion, and other financial crime.

**Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 Reporting Requirements Under Section 104(e).** As a result of a congressional mandate to prescribe regulations under the Comprehensive Iran Sanctions, Accountability, and Divestment Act of 2010 (CISADA), on May 2, 2011, FinCEN issued an NPRM to impose a reporting requirement that would be invoked, as necessary, to elicit information valuable in the implementation of CISADA and would work in tandem with other financial
provisions of CISADA to isolate Iran’s Islamic Revolutionary Guard Corps and financial institutions designated by the U.S. Government in connection with Iran’s proliferation of weapons of mass destruction (WMD) or WMD delivery systems or in connection with its support for international terrorism. FinCEN published a final rule to implement the proposed regulations on October 11, 2011.

Money Services Businesses-Definitions and Other Regulations. On July 21, 2011, FinCEN issued a final rule revising the definitions for money services businesses (MSBs) to delineate more clearly the scope of entities regulated as MSBs, incorporating previously issued administrative rulings and guidance with regard to MSBs, and ensuring that certain foreign-located persons engaging in MSB activities within the United States are subject to BSA rules. The rule enables entities to determine in a more predictable and straightforward way whether they are operating as MSBs subject to BSA regulations. In clarifying that foreign entities conducting MSB activities in the United State are required to register, FinCEN recognizes that the Internet and other technological advances make it increasingly possible for persons to offer MSB services in the United States from foreign locations and seeks to ensure that the BSA rules apply to all persons engaging in MSB activities within the United States, regardless of their physical location.

Withdrawal of the Finding of Primary Money Laundering Concern and the Final Rule Against VEF Banka. On July 26, 2011, FinCEN withdrew its April 2005 final rule and finding under section 311 of the USA PATRIOT Act. FinCEN withdrew its finding that VEF Banka was a financial institution of primary money laundering concern. FinCEN also withdrew the final rule against VEF Banka that imposed a special measure prohibiting U.S. financial institutions from, directly or indirectly, opening or maintaining correspondent accounts in the United States for VEF Banks.

Prepaid Access—Regulatory Framework for Activity Previously Referred to as Stored Value. On July 29, 2011, FinCEN issued a final rule establishing a more comprehensive regulatory framework for non-bank prepaid access. The rule puts in place suspicious activity reporting, and customer and transactional information collection requirements on providers and sellers of certain types of prepaid access similar to other categories of MSBs. It addresses regulatory gaps that have resulted from the proliferation of
prepaid access innovations over the last 12 years and their increasing use as an accepted payment method. The regulations also provide a balance to provide law enforcement with the information needed to attack money laundering, terrorist financing, and other illicit transactions through the financial system, without hindering innovation and the many legitimate uses and societal benefits prepaid access offers.

Renewal of Existing Rules. FinCEN renewed without change a number of information collections associated with the following existing requirements: Additional records to be made and retained by banks (31 CFR 1020.410 and 1010.430); records to be made and retained by financial institutions (31 CFR 1010.410 and 1010.430); purchases of bank checks and drafts, cashier’s checks, money orders and traveler’s checks (31 CFR 1010.415 and 1010.430); reports of certain domestic coin and currency transactions (31 CFR 1010.370 and 1010.410(d)); reports of transactions with foreign financial agencies (31 CFR 1010.360); additional records to be made and retained by casinos (31 CFR 1021.410 and 1010.430); additional records to be made and retained by brokers or dealers in securities (31 CFR 1023.410 and 1010.430); additional records to be made and retained by currency dealers or exchangers (31 CFR 1022.410 and 1010.430); special rules for casinos (31 CFR 1021.210, 1021.410(b) and 1010.430); and correspondent accounts for foreign shell banks and recordkeeping and termination of correspondent accounts (31 CFR 1010.630 and 1010.670).

Administrative Rulings and Written Guidance. FinCEN published 6 administrative rulings and written guidance pieces, and provided 39 responses to written inquiries/correspondence (as of August 2011) interpreting the BSA and providing clarity to regulated industries. FinCEN anticipates issuing an additional 10 pieces by the end of FY 2011.

FinCEN’s regulatory priorities for fiscal year 2012 include finalizing any initiatives mentioned above that are not finalized by fiscal year end, as well as the following projects:

Amendment to the BSA Regulations—Definition of Monetary Instrument. On October 17, 2011, FinCEN published an NPRM to address the mandate in the Credit Card Accountability, Responsibility,
and Disclosure Act of 2009, which authorizes regulations regarding international transport of prepaid access devices because of the potential to substitute prepaid access for cash and other monetary instruments as a means to smuggle the proceeds of illegal activity into and out of the United States.

**Anti-Money Laundering Program and SAR Requirements for Housing Government-Sponsored Enterprises.** FinCEN plans to issue an NPRM that would define certain housing government-sponsored enterprises as financial institutions for the purpose of requiring them to establish anti-money laundering programs and report suspicious activity to FinCEN pursuant to the BSA.

**Anti-Money Laundering Program and SAR Requirements for Investment Advisers.** FinCEN is researching and developing an NPRM that would prescribe minimum standards for anti-money laundering programs to be established by certain investment advisers and to require such investment advisers to report suspicious activity to FinCEN.

**Customer Due Diligence Requirements.** FinCEN is developing an advance notice of proposed rulemaking to solicit public comment on a wide range of questions pertaining to the development of a customer due diligence (CDD) regulation that would clarify, consolidate, and strengthen existing CDD obligations for financial institutions and also incorporate the collection of beneficial ownership information into the CDD framework.

**Anti-Money Laundering Program for State-Chartered Credit Unions and Other Depository Institutions without a Federal Functional Regulator.** Pursuant to section 352 of the USA PATRIOT Act, certain financial institutions are required to establish AML programs. Continued from prior fiscal years, FinCEN is researching and developing rulemaking to require State-chartered credit unions and other depository institutions without a Federal functional regulator to implement AML programs.

**Cross Border Electronic Transmittal of Funds.** On September 27, 2010, FinCEN issued a Notice of Proposed Rulemaking (NPRM) in conjunction with the feasibility study prepared pursuant to the
Intelligence Reform and Terrorism Prevention Act of 2004 concerning the issue of obtaining information about certain cross-border funds transfers and transmittals of funds. As FinCEN continues to develop the system to receive, store, and use this data, FinCEN may publish another NPRM prior to issuing a final rule.

Other Requirements. FinCEN also will continue to issue proposed and final rules pursuant to section 311 of the USA PATRIOT Act, as appropriate. Finally, FinCEN expects to propose various technical and other regulatory amendments in conjunction with its ongoing, comprehensive review of existing regulations to enhance regulatory efficiency.

Internal Revenue Service

The Internal Revenue Service (IRS), working with the Office of Tax Policy, promulgates regulations that interpret and implement the Internal Revenue Code and related tax statutes. The purpose of these regulations is to carry out the tax policy determined by Congress in a fair, impartial, and reasonable manner, taking into account the intent of Congress, the realities of relevant transactions, the need for the Government to administer the rules and monitor compliance, and the overall integrity of the Federal tax system. The goal is to make the regulations practical and as clear and simple as possible.

Most IRS regulations interpret tax statutes to resolve ambiguities or fill gaps in the tax statutes. This includes interpreting particular words, applying rules to broad classes of circumstances, and resolving apparent and potential conflicts between various statutory provisions.

During fiscal year 2012, the IRS will accord priority to the following regulatory projects:

Deduction and Capitalization of Costs for Tangible Assets. Section 162 of the Internal Revenue Code allows a current deduction for ordinary and necessary expenses paid or incurred in carrying on any trade or business. Under section 263(a) of the Code, no immediate deduction is allowed for amounts paid out
for new buildings or for permanent improvements or betterments made to increase the value of any property or estate. Those expenditures are capital expenditures that generally may be recovered only in future taxable years, as the property is used in the taxpayer’s trade or business. It often is not clear whether an amount paid to acquire, produce, or improve property is a deductible expense or a capital expenditure. Although existing regulations provide that a deductible repair expense is an expenditure that does not materially add to the value of the property or appreciably prolong its life, the IRS and Treasury believe that additional clarification is needed to reduce uncertainty and controversy in this area. In August 2006, the IRS and Treasury issued proposed regulations in this area and received numerous comments. In March 2008, the IRS and Treasury withdrew the 2006 proposed regulations and issued new proposed regulations, which have generated relatively few comments. The IRS and Treasury intend to finalize those regulations.

Arbitrage Investment Restrictions on Tax-Exempt Bonds. The arbitrage investment restrictions on tax-exempt bonds under section 148 generally limit issuers from investing bond proceeds in higher-yielding investments. Treasury and the IRS plan to issue proposed regulations to address selected current issues involving the arbitrage restrictions, including guidance on the issue price definition used in the computation of bond yield, working capital financings, grants, investment valuation, modifications and terminations of qualified hedging transactions, and selected other issues.

Guidance on the Tax Treatment of Distressed Debt. A number of tax issues relating to the amount, character, and timing of income, expense, gain, or loss on distressed debt remain unresolved. In addition, the tax treatment of distressed debt, including distressed debt that has been modified, may affect the qualification of certain entities for tax purposes or result in additional taxes on the investors in such entities, such as regulated investment companies, real estate investment trusts (REITs), and real estate mortgage investment conduits. During fiscal year 2011, Treasury and the IRS have addressed some of these issues through published guidance, including (1) a revenue procedure providing relief for certain modifications of distressed mortgage loans held by a REIT and (2) final regulations clarifying that the deterioration in the financial condition of the issuer of a modified debt instrument is not taken into
account to determine whether the instrument is debt or equity. Treasury and the IRS plan to address more of these issues in published guidance.

Elective Deferral of Certain Business Discharge of Indebtedness Income. In the recent economic downturn, many business taxpayers realized income as a result of modifying the terms of their outstanding indebtedness or refinancing on terms subjecting them to less risk of default. The American Recovery and Reinvestment Act of 2009 includes a special relief provision allowing for the elective deferral of certain discharge of indebtedness income realized in 2009 and 2010. The provision, section 108(i) of the Code, is complicated and many of the details will have to be supplied through regulatory guidance. On August 9, 2009, Treasury and the IRS issued Revenue Procedure 2009-37 that prescribes the procedure for making the election. On August 13, 2010, Treasury and the IRS published temporary and proposed regulations (TD 9497 and TD 9498) in the Federal Register. These regulations provide additional guidance on such issues as the types of indebtedness eligible for the relief, acceleration of deferred amounts, the operation of the provision in the context of flow-through entities, the treatment of the discharge for the purpose of computing earnings and profits, and the operation of a provision of the statute deferring original issue discount deductions with respect to related refincings. Treasury and the IRS intend to finalize those regulations.

Regulation of Tax Return Preparers. In June 2009, the IRS launched a comprehensive review of the tax return preparer program with the intent to propose a set of recommendations to ensure uniform and high ethical standards of conduct for all tax return preparers and to increase taxpayer compliance. The IRS published findings and recommendations in Publication 4832, Return Preparer Review. In the report, the IRS recommended increased oversight of the tax return preparer industry, including but not limited to, mandatory preparer tax identification number (PTIN) registration and usage, competency testing, continuing education requirements, and ethical standards for all tax return preparers. As part of a multi-step effort to increase oversight of Federal tax return preparers, Treasury and the IRS published in 2010 final regulations: 1) Authorizing the IRS to require tax return preparers who prepare all or substantially all of a tax return for compensation after December 31, 2010, to use PTINs as the preparer’s identifying
number on all tax returns and refund claims that they prepare and 2) setting the user fee for obtaining a PTIN at $50 plus a third-party vendor’s fee. On June 3, 2011, Treasury and IRS published final regulations amending Circular 230, which established registered tax return preparers as a new category of tax practitioner and extended the ethical rules for tax practitioners to any individual who is a tax return preparer. Treasury and the IRS intend to publish additional guidance in 2011 and 2012 to specifically support the tax return preparer program and operations, including regulations that establish user fees for the return preparer competency examination and regulations that provide additional rules with respect to the PTIN. Treasury and the IRS also intend to publish regulations under Circular 230, which will include amendments to the opinion requirements.

**Penalties.** Congress amended several penalty provisions in the Internal Revenue Code in the past several years and Treasury and the IRS intend to publish a number of guidance projects in 2011 addressing these new or amended penalty provisions. Specifically, Treasury and the IRS intend to publish in 2011 proposed regulations under sections 6662, 6662A, and 6664, to provide further guidance on the circumstances under which a taxpayer could be subject to the accuracy-related penalty on underpayments or reportable transaction understatements and the reasonable cause exception, including clarifying that a taxpayer may not rely upon written advice to establish a reasonable cause and good faith defense if the advice states that it cannot be used for the purpose of avoiding penalties. Treasury and the IRS also intend to publish: 1) Proposed regulations under section 6676 regarding the penalty related to an erroneous claim for refund or credit; 2) final regulations under section 6707A addressing whether the penalty for failure to disclose reportable transactions applies, before the temporary regulations expire in September 2011; and 3) temporary and proposed regulations under section 6707A addressing statutory changes to the method of computing the section 6707A penalty, which occurred after existing temporary regulations were published.

**Basis Reporting.** Section 403 of the Energy Improvement and Extension Act of 2008 (Pub. L. No. 110-343), enacted on October 3, 2008, added sections 6045(g), 6045h, 6045A, and 6045B to the Internal Revenue Code. Section 6045(g) provides that every broker required to file a return with the Service
under section 6045(a) showing the gross proceeds from the sale of a covered security must include in the
return the customer’s adjusted basis in the security and whether any gain or loss with respect to the
security is long-term or short-term. Section 6045(h) extends the basis reporting requirement in section
6045(g) and the gross proceeds reporting requirement in section 6045(a) to options that are granted or
acquired on or after January 1, 2013. Section 6045A provides that a broker and any other specified
person (transferor) that transfers custody of a covered security to a receiving broker must furnish to the
receiving broker a written statement that allows the receiving broker to satisfy the basis reporting
requirements of section 6045(g). The transferor must furnish the statement to the receiving broker within
15 days after the date of the transfer or at a later time provided by the Secretary. Section 6045B requires
issuers of specified securities to make a return relating to organizational actions that affect the basis of
the security. Final regulations implementing these provisions for sales of stock were published on
October 18, 2010. Treasury and the IRS plan to issue proposed regulations implementing these
provisions for options and sales or exchanges of debt instruments.

Information Reporting for Foreign Accounts of U.S. Persons. In March 2010, chapter 4 (sections 1471
to 1474) was added to subtitle A of the Internal Revenue Code as part of the Hiring Incentives to Restore
Employment Act (HIRE Act) (Pub. L. 111-147). Chapter 4 was enacted to address concerns with offshore
tax evasion and generally requires foreign financial institutions (FFIs) to enter into an agreement (FFI
Agreement) with the IRS to report information regarding certain financial accounts of U.S. persons and
foreign entities with significant U.S. ownership. An FFI that does not enter into an FFI Agreement
generally will be subject to a withholding tax on the gross amount of certain payments from U.S. sources,
as well as the proceeds from disposing of certain U.S. investments. Treasury and the IRS published
Notice 2010-60, Notice 2011-34, and Notice 2011-53, which provides preliminary guidance and requests
comments on the most important and time-sensitive issues under chapter 4. Treasury and the IRS
expect to follow up on these notices with regulations and a model FFI Agreement in this fiscal year.
These regulations will address numerous issues, notably the definition of FFI, the due diligence required
of withholding agents and FFIs in identifying U.S. accountholders, and the requirements for reporting U.S.
accounts.
Withholding on Certain Dividend Equivalent Payments Under Notional Principal Contracts. The HIRE act also added section 871(l) to the Code (now sec. 871(m)), which designates certain substitute dividend payments in security lending and sale-repurchase transactions and dividend-referenced payments made under certain notional principal contracts as U.S.-source dividends for Federal tax purposes. In response to this legislation, on May 20, 2010, the IRS issued Notice 2010-46, addressing the requirements for determining the proper withholding in connection with substitute dividends paid in foreign-to-foreign security lending and sale-repurchase transactions. The IRS and Treasury intend to issue regulations to implement the provisions of this Notice, as well as regulations addressing cases where dividend equivalents should be found to arise in connection with notional principal contracts and other financial derivatives.

New International Tax Provisions of the Education, Jobs, and Medicaid Assistance Act. On August 10, 2010, the Education, Jobs, and Medicaid Assistance Act of 2010 (Pub. L. 111-226) was signed into law. The new law includes a significant package of international tax provisions, including limitations on the availability of foreign tax credits in certain cases where U.S. tax law and foreign tax law provide different rules for recognizing income and gain, and in cases where income items treated as foreign source under certain tax treaties would otherwise be sourced in the United States. The legislation also limits the ability of multinationals to reduce their U.S. tax burdens by using a provision intended to prevent corporations from avoiding U.S. income tax on repatriated corporate earnings. Other new provisions under this legislation limit the ability of multinational corporations to use acquisitions of related party stock to avoid U.S. tax on what would otherwise be taxable distributions of dividends. The statute also includes a new provision intended to tighten the rules under which interest expense is allocated between U.S.- and foreign-source incomes within multinational groups of related corporations when a foreign corporation has significant amounts of U.S.-source income that is effectively connected with a U.S. business. Treasury and the IRS expect to issue guidance on most of these provisions.
Guidance on Tax-Related Health Care Provisions. On March 23, 2010, the President signed the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111-148) and on March 30, 2010, the President signed the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152) (referred to collectively as the Affordable Care Act (ACA)). The ACA’s comprehensive reform of the health insurance system affects individuals, families, employers, health care providers, and health insurance providers. The ACA provides authority for Treasury and the IRS to issue regulations and other guidance to implement tax provisions in the ACA, some of which are effective immediately and some of which will become effective over the next several years. Since enactment of the ACA, Treasury and the IRS, together with the Department of Health and Human Services and the Department of Labor, have issued a series of temporary and proposed regulations implementing various provisions of the ACA related to individual and group market reforms. In the past year, Treasury and IRS also have issued temporary and proposed regulations addressing the fee on branded prescription drug sales under section 9008 of the ACA and proposed regulations on the premium assistance tax credit under section 36B of the Code. In addition, Treasury and the IRS have issued guidance on specific ACA provisions, including guidance on the treatment of certain nonprofit health insurers (section 833 of the Code), the credit for small employers that provide health insurance coverage (section 45R of the Code), the adoption credit (section 36C of the Code), information reporting to employees of the cost of employer sponsored health coverage (section 6051(a)(14) of the Code), and additional requirements for tax-exempt hospitals (section 501(r) of the Code). Providing additional guidance to implement tax provisions of the ACA is a priority for Treasury and the IRS.

Office of the Comptroller of the Currency (including former Office of Thrift Supervision)

The Office of the Comptroller of the Currency (OCC) was created by Congress to charter national banks, to oversee a nationwide system of banking institutions, and to assure that national banks are safe and sound,
competitive and profitable, and capable of serving in the best possible manner the banking needs of their customers.

Pursuant to title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act, all functions of the Office of Thrift Supervision (OTS) relating to Federal savings associations, including rulemaking authority, were transferred to the OCC on July 21, 2011.

The OCC seeks to assure a banking system in which national banks and Federal savings associations soundly manage their risks, maintain the ability to compete effectively with other providers of financial services, meet the needs of their communities for credit and financial services, comply with laws and regulations, and provide fair access to financial services and fair treatment of their customers.

Significant rules issued during fiscal year 2011 include:

Incentive-Based Compensation Arrangements: Section 956 of the Dodd-Frank Act requires the banking agencies, the National Credit Union Administration (NCUA), the Securities and Exchange Commission (SEC), and the Federal Housing Finance Agency (FHFA), to jointly prescribe regulations or guidance prohibiting any types of incentive-based payment arrangement, or any feature of any such arrangement, that the regulators determine encourages inappropriate risks by covered financial institutions by providing an executive officer, employee, director, or principal shareholder with excessive compensation, fees or benefits, or that could lead to material financial loss to the covered financial institution. The Act also requires such agencies to jointly prescribe regulations or guidance requiring each covered financial institution to disclose to its regulator the structure of all incentive-based compensation arrangements offered by such institution sufficient to determine whether the compensation structure provides any officer, employee, director, or principal shareholder with excessive compensation or could lead to material financial loss to the institution. The agencies issued an NPRM on April 14, 2011. 76 FR 21170. Work on a final rule is underway.
Retail Foreign Exchange Transactions: The OCC adopted a final rule authorizing national banks, Federal branches and agencies of foreign banks, and their operating subsidiaries to engage in off-exchange transactions in foreign currency with retail customers. It describes various requirements with which national banks, Federal branches and agencies of foreign banks, and their operating subsidiaries must comply to conduct such transactions. It is necessary pursuant to amendments by the Dodd–Frank Act to the Commodity Exchange Act (CEA) that provide that a United States financial institution for which there is a Federal regulatory agency shall not enter into, or offer to enter into, a transaction described in section 2(c)(2)(B)(i)(I) of the CEA with a retail customer except pursuant to a rule or regulation of a Federal regulatory agency allowing the transaction under such terms and conditions as the Federal regulatory agency shall prescribe a retail forex rule. This final rule was issued on July 14, 2011. 76 FR 41375. Work on an interim final rule to cover savings associations is underway.

Credit Risk Retention. The banking agencies, Securities and Exchange Commission, Federal Housing Finance Agency, and the Department of Housing and Urban Development proposed rules to implement the credit risk retention requirements of section 15G of the Securities Exchange Act of 1934 (15. U.S.C. section 78o-11), as added by section 941 of the Dodd-Frank Wall Street Reform and Consumer Protection Act. Section 15G generally requires the securitizer of asset-backed securities to retain not less than 5 percent of the credit risk of the assets collateralizing the asset-backed securities. Section 15G includes a variety of exemptions from these requirements, including an exemption for asset-backed securities that are collateralized exclusively by residential mortgages that qualify as “qualified residential mortgages,” as such term is defined by the Agencies by rule. This NPRM was published on April 29, 2011. 76 FR 24090. Work on a final rule is underway.

Margin and Capital Requirements for Covered Swap Entities. The banking agencies, Farm Credit Administration, and the Federal Housing Finance Agency issued a proposed rule to establish minimum margin and capital requirements for registered swap dealers, major swap participants, security-based swap dealers, and major security-based swap participants for which one of the Agencies is the prudential regulator. This proposed rule implements sections 731 and 764 of the Dodd-Frank Wall Street Reform and Consumer Protection Act, which require the Agencies to adopt rules jointly to establish capital requirements and initial and variation margin requirements for such entities on all non-cleared swaps and
non-cleared security-based swaps in order to offset the greater risk to such entities and the financial system arising from the use of swaps and security-based swaps that are not cleared. This NPRM was published on May 11, 2011. 76 FR 27564. Work on a final rule is underway.

**OTS Integration; Dodd-Frank Implementation.** The OCC adopted amendments to its regulations governing organization and functions, availability and release of information, post-employment restrictions for senior examiners, and assessment of fees to incorporate the transfer of certain functions of the Office of Thrift Supervision (OTS) to the OCC pursuant to title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act. The OCC also amended its rules pertaining to preemption and visitorial powers to implement various sections of the Act; change in control of credit card banks and trust banks to implement section 603 of the Act; and deposit-taking by uninsured Federal branches to implement section 335 of the Act. This final rule was effective and published on July 21, 2011. 76 FR 43549.

**Republication of Regulations in Connection with OTS Integration Pursuant to Dodd-Frank.** Pursuant to title III of the Dodd-Frank Wall Street Reform and Consumer Protection Act, all functions of the Office of Thrift Supervision relating to Federal savings associations and rulemaking authority of the OTS relating to all savings associations were transferred to the OCC on July 21, 2011 (transfer date). In order to facilitate the OCC’s enforcement and administration of former OTS rules and to make appropriate changes to these rules to reflect OCC supervision of Federal savings associations as of the transfer date, the OCC republished, with nomenclature and other technical changes, those OTS regulations currently found at 12 CFR chapter V for which the OCC has authority to promulgate and will enforce as of the transfer date. The republished regulations are recodified with the OCC’s regulations in chapter I at 12 CFR 100 et seq., effective on the transfer date. The republished regulations will supersede the OTS regulations in chapter V for purposes of OCC supervision and regulation of Federal savings associations, and for certain rules for purposes of the FDIC’s supervision of State savings associations. This interim final rule was published on August 9, 2011. 76 FR 48950.

**Prohibition and Restrictions on Proprietary Trading and Certain Interests In, and Relationships with, Hedge Funds and Private Equity Funds.** The banking agencies, the Securities and Exchange Commission, and the Commodity Futures Trading Commission, issued a proposed rule that would implement section 619 of Dodd-Frank, which contains certain prohibitions and restrictions on the ability of
banking entities and nonbank financial companies supervised by the Federal Reserve Board to engage in proprietary trading and have certain investments in, or relationships with, hedge funds or private equity funds. Section 619 is commonly referred to as the “Volcker Rule.”

Community Reinvestment Act Regulations (12 CFR part 25). The banking agencies issued final regulations to revise provisions of their rules implementing the Community Reinvestment Act. The agencies proposed revising the term “community development” to include loans, investments, and services by financial institutions that support, enable, or facilitate projects or activities that meet the criteria described in section 2301(c)(3) of the Housing and Economic Recovery Act of 2008 (HERA) and are conducted in designated target areas identified in plans approved by the U.S. Department of Housing and Urban Development under the Neighborhood Stabilization Program (NSP), established by HERA. This final rule was published on December 20, 2010 (75 FR 79278).

Community Reinvestment Act Regulations (12 CFR part 25). On August 14, 2008, the Higher Education Opportunity Act (HEOA) was enacted into law (Pub. L. 110-315, 122 Stat. 3078). Section 1031 of the HEOA revised the Community Reinvestment Act (CRA) to require the banking agencies, when evaluating a bank’s record of meeting community credit needs, to consider, as a factor, low-cost education loans provided by the bank to low-income borrowers. The banking agencies issued a final rule to implement section 1031 of the HEOA. In addition, the rule incorporates into the banking agencies’ rules statutory language that allows them to consider as a factor when evaluating a bank's record of meeting community credit needs capital investment, loan participation, and other ventures undertaken by nonminority- and nonwomen-owned financial institutions in cooperation with minority- and women-owned
financial institutions and low-income credit unions. A final rule was published on October 10, 2010 (75 FR 61035).

Standards Governing the Release of a Suspicious Activity Report (12 CFR part 4). Confidentiality of Suspicious Activity Reports (12 CFR part 21). The OCC and OTS separately issued final regulations governing the release of non-public OCC or OTS information set forth in 12 CFR part 4, subpart C, and section 510.5. These final rules clarify that the decision to release a suspicious activity report (SAR) will be governed by the standards set forth in amendments to the SAR regulations, that are part of separate, but simultaneously issued, final rulemakings discussed below. These final rules were published on December 3, 2010. 75 FR 75574, 75583. The OCC’s and OTS’s final regulations implementing the Bank Secrecy Act governing the confidentiality of a suspicious activity report (SAR): Clarify the scope of the statutory prohibition on the disclosure by an institution of a SAR; address the statutory prohibition on the disclosure by the government of a SAR as that prohibition applies to the OCC’s or OTS’s standards governing the disclosure of SARs; clarify that the exclusive standard applicable to the disclosure of a SAR, or any information that would reveal the existence of a SAR, by the OCC or OTS, is to fulfill official duties consistent with the purposes of the BSA; and modify the safe harbor provision in its rules to include changes made by the USA PATRIOT Act. These final rules are based upon a similar rule prepared by the Financial Crimes Enforcement Network (FinCEN). These final rules were issued on December 3, 2010. 75 FR 75576, 75586.

Risk-Based Capital Guidelines; Revising Transitional Floors for Advanced Approaches Rule (12 CFR part 3). The Federal banking agencies issued a
notice of proposed rulemaking and final rule to revise the transitional floors in the advanced approaches risk-based capital rule to preclude a decline in a banking organization’s risk-based capital requirements during the transition period. Under the revisions, the capital floors used by a banking organization subject to the advanced approaches during its first, second, and third transitional floor periods are 100 percent of the bank’s tier 1 and total risk-based capital requirements computed under the agencies’ general risk-based capital rules. The NPRM was published on December 30, 2010. 75 FR 82317. The final rule was issued on June 28, 2011. 76 FR 37620. OTS issued a parallel proposal on March 8, 2011, but did not issue a final rule. 76 FR 12611.

Regulatory priorities for fiscal year 2012 include, in addition to those listed above that have not yet been finalized, the following:

Strengthening Tier 1 Capital Other Capital Enhancements, Standardized Approach (Basel III). (12 CFR part 3). The banking agencies currently are working jointly on rules to implement provisions in the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank) and to update capital standards to maintain and improve consistency in agency rules. These rules include revisions to implement the International Convergence of Capital Management and Capital Standards: A Revised Framework (Basel II Framework). The Federal banking agencies plan to amend their current capital rules, including revisions to the definition of Tier 1 capital and the leverage capital ratio. This rule would implement a comprehensive set of revisions issued by the Basel Committee in December 2010 to amend the Basel II Capital Framework. Key components of the rule include: Revisions to the definition of Tier 1, the addition of a capital conservation buffer, the addition of a countercyclical buffer, revisions to counterparty credit risk requirements (includes central counterparties), a new international leverage ratio, and new liquidity ratio requirements. In addition, this rule includes the rule entitled Alternatives to the Use of Credit Ratings in the Risk-Based Capital Guidelines of the Federal Banking Agencies (12 CFR part 3).
Section 939A of the Dodd-Frank Act directs all Federal agencies to review, no later than 1 year after enactment, any regulation that requires the use of an assessment of credit-worthiness of a security or money market instrument and any references to or requirements in regulations regarding credit ratings. The agencies are also required to remove references or requirements of reliance on credit ratings and to substitute an alternative standard of credit-worthiness. The agencies issued an ANPRM describing the areas in their risk-based capital standards where the agencies rely on credit ratings, as well as the Basel Committee on Banking Supervision’s recent amendments to the Basel Accord, which could affect those standards and requested comment on potential alternatives to the use of credit ratings. The ANPRM was published on August 25, 2010 (75 FR 52283).

**Risk-Based Capital Standards: Market Risk:** The banking agencies issued a notice of proposed rulemaking to revise their market risk capital rules to modify their scope to better capture positions for which the market risk capital rules are appropriate; reduce procyclicality in market risk capital requirements, enhance the rules' sensitivity to risks that are not adequately captured under current regulatory measurement methodologies; and increase transparency through enhanced disclosures. This NPRM was published on January 11, 2011. 76 FR 1890. Work on a final rule is underway.

**Alternatives to the Use of External Credit Ratings in the Regulations of the OCC (12 CFR parts 1, 16, and 28).** Section 939A of the Dodd-Frank Wall Street Reform and Consumer Protection Act directs all Federal agencies to review, no later than 1 year after enactment, any regulation that requires the use of an assessment of credit-worthiness of a security or money market instrument and any references to or requirements in regulations regarding credit ratings. The agencies are also required to remove references or requirements of reliance on credit ratings and to substitute an alternative standard of credit-worthiness. Through an advanced notice of proposed rulemaking (ANPRM), the OCC sought to gather information as it begins to review its regulations pursuant to the Dodd-Frank Act. It described the areas where the OCC’s regulations, other than those that establish regulatory capital requirements, currently rely on credit ratings; sets forth the considerations underlying such reliance; and requests comment on potential alternatives to the use of credit ratings. Work on an NPRM is underway. The ANPRM was
Recordkeeping Requirements for Securities Activities: The Gramm-Leach-Bliley Act requires the banking agencies to adopt recordkeeping requirements sufficient to facilitate and demonstrate compliance with the exceptions to the definitions of “broker” or “dealer” for banks in the Securities Exchange Act of 1934. Work on an NPRM is underway.

Integration of Savings Association Supervision. Pursuant to the transfer of OTS functions relating to Federal savings associations to the OCC, the OCC plans to issue one or more rulemakings resulting from our review of OCC rules applicable to banks and/or savings associations that will consolidate our rules and establish, to the extent practicable, consistent regulations for national banks and federal savings associations.

Lending Limits for Derivative Transactions. Section 610 of the Dodd-Frank Act amends the lending limit, 12 U.S.C. section 84, to apply it to any credit exposure to a person arising from a derivative transaction and certain other transactions between the bank and the person. The amendment is effective 1 year after the transfer date, July 21, 2012. The OCC plans to issue a rule that will amend our lending limit regulation set forth at 12 CFR part 32 to conform to this new requirement.

Annual Stress Test (12 CFR part 46). This regulation will implement 12 U.S.C. 5365(i) that requires annual stress testing to be conducted by financial companies with total consolidated assets of more than $10 billion and establishes a definition of stress test, methodologies for conducting stress tests, and reporting and disclosure requirements.

Collective Investment Funds. This notice of proposed rulemaking will update the regulation of short-term investment funds (STIFs), a type of collective investment fund permissible under OCC regulations,
through the addition of STIF eligibility requirements to ensure the safety of STIFs and to mitigate financial systemic risks.

**Alcohol and Tobacco Tax and Trade Bureau**

The Alcohol and Tobacco Tax and Trade Bureau (TTB) issues regulations to enforce Federal laws relating to alcohol, tobacco, firearms, and ammunition taxes and relating to commerce involving alcohol beverages and industrial alcohol. TTB's mission and regulations are designed to:

1) Regulate with regard to the issuance of permits and authorizations to operate in the alcohol and tobacco industries;

2) Assure the collection of all alcohol, tobacco, and firearms and ammunition taxes, and obtain a high level of voluntary compliance with all laws governing those industries; and

3) Suppress commercial bribery, consumer deception, and other prohibited practices in the alcohol beverage industry.

The Federal Alcohol Administration Act and the Internal Revenue Code authorize regulations for the labeling of wine, distilled spirits, and malt beverages, which should, among other things, ensure that labels provide the consumer with adequate information as to the identity and quality of the product. In July 2007, in response to a petition for rulemaking from a consumer advocacy group and comments received in response to a 2005 advance notice of proposed rulemaking, TTB published a proposed rule concerning the inclusion of a statement of calories, carbohydrates, fat, and protein per serving in a serving facts panel on wine, beer, and distilled spirits labels. The proposed rule also invited public comments on the extension of alcohol content labeling requirements to all alcohol beverages, which currently apply only to some alcohol beverages. TTB is continuing to evaluate the cost burden to industry and benefits to consumers.
In addition to the regulatory action described above, in FY 2012, TTB plans to give priority to the following regulatory matters:

As described in greater detail below, in FY 2012 TTB plans to continue its Regulations Modernization Project concerning its Specially Denatured and Completely Denatured Alcohol regulations, Labeling Requirement regulations, Export regulations, and Beer regulations.

Revision to Specially Denatured and Completely Denatured Alcohol Regulations: TTB plans to propose changes to regulations for specially denatured alcohol (SDA) and completely denatured alcohol (CDA) that would result in cost savings for both TTB and regulated industry members. Under the authority of the Internal Revenue Code of 1986, TTB regulates denatured alcohol that is unfit for beverage use, and which may be removed from a regulated distilled spirits plant without payment of tax. SDA and CDA are widely used in the American fuel, medical, and manufacturing sectors. The industrial alcohol industry far exceeds the beverage alcohol industry in size and scope, and it is a rapidly growing industry in the United States. Some concerns have been raised that the current regulations may create significant roadblocks for industry members in getting products to the marketplace quickly and efficiently. TTB is proposing to reclassify certain SDA formulas as CDA and to issue new general-use formulas for articles made with SDA so that industry members would less frequently need to seek formula approval from TTB and fewer TTB resources would need to be devoted to formula review. TTB estimates that these proposed changes would result in an 80 percent reduction in the formula approval submissions currently required from industry members and would reduce total annual paperwork burden hours on affected industry members from 2,415 to 517 hours. The reduction in formula submissions will enable TTB to redirect its resources to address backlogs that exist in other areas of TTB’s mission activities, such as analyzing compliance samples for industrial/fuel alcohol to protect the revenue and working with industry to test and approve new and more environmentally friendly denaturants. Other proposed changes would remove unnecessary regulatory burdens and update the regulations to align them with current industry practice.
**CHIPRA Final Rule:** TTB will make final a temporary rule to amend regulations promulgated under the Children’s Health Insurance Program Reauthorization Act of 2009 (CHIPRA). The Act provides enforcement mechanisms to assist in preventing the diversion of tobacco materials to illegal manufacturers, and the regulations implement these enforcement mechanisms. A 3-year temporary rule was published in June of 2009 to continue the implementation of these CHIPRA provisions, a final rule must be published by June 2012 to meet the requirements of 26 U.S.C. 7805 regarding the expiration of temporary rules.

**Revisions to the Labeling Requirements (parts 4 (Wine), 5 (Distilled Spirits), and 7 (Malt Beverages)):** The Federal Alcohol Administration Act requires that alcohol beverages introduced in interstate or foreign commerce have a label issued and approved under regulations prescribed by the Secretary of the Treasury. In connection with E.O. 13563, TTB has near-term plans to revise the regulations concerning the approval of labels for distilled spirits, wine, and malt beverages to reduce the cost to TTB of reviewing and approving an ever increasing number of applications for label approval (well over 130,000 per year). Currently, the review and approval process requires a staff of at least 13 people for the pre-approval of labels in addition to management review. These regulatory changes, to be developed with industry input, also are intended to accelerate the approval process, which shall result in the regulated industries being able to bring products to market faster.

**Selected Revisions of Export Regulations (part 28):** TTB has identified selected sections of its export regulations (part 28) that should be amended to assist industry members in complying with the regulations. Current regulations require industry members to obtain documents and follow procedures that are outdated and not entirely consistent with current industry practices regarding exportation. Under its regulatory authority, TTB routinely provides exceptions to these regulatory provisions. Revising these regulations will provide industry members with clear and up-to-date procedures for removal of alcohol for exportation without having to pay excise taxes (under the Internal Revenue Code, beverage alcohol may be removed from the premises of a distilled spirits plant for exportation without payment of tax), thus increasing their willingness and ability to export their products.
Revisions to the Alcohol Fuel Plant Regulations: TTB’s alcohol fuel plant regulations (within part 19) need to be revised to reflect the current state of the alcohol fuel industry. Alcohol produced at a TTB-approved alcohol fuel plant may be removed from the plant without payment of tax if properly denatured and used only for fuel. Primarily focused on the development of smaller capacity plants, the alcohol fuel plant regulations were initially drafted to promote growth in the industry and to provide minimal permitting, recordkeeping, reporting, and bonding requirements. In the United States, there are currently over 1,400 permitted ethanol fuel plants that produced over 9 billion gallons of ethanol for fuel use in 2010. Fewer than 200 of the largest fuel ethanol plants produce 8 billion gallons of fuel ethanol. The significant growth of the industry, especially the largest capacity plants, since the previous issuance of the applicable regulations has resulted in potential risks to the revenue not currently addressed in the regulations. If just 1 percent of this alcohol were diverted for beverage use, the tax loss would approximate $2.4 billion. Current reporting requirements for certain plants are not sufficient to provide adequate information to TTB to monitor industry compliance and to identify removals of alcohol that should be subject to tax; alcohol removed for beverage purposes or without proper denaturation may go unnoticed. TTB is also considering other changes, such as the addition of provisions regarding the disposition of by-products of the production process, which would update the regulations to reflect current industry practice.

Revision of the Part 17 Regulations, “Drawback on Taxpaid Distilled Spirits Used in Manufacturing Nonbeverage Products,” To Allow Self-Certification of Nonbeverage Product Formulas: TTB is considering revisions to the part 17 regulations governing nonbeverage products made with taxpaid distilled spirits. These nonbeverage products include foods, medicines, and flavors. The revisions would practically eliminate the need for TTB to formally approve nonbeverage product formulas by proposing to allow for self-certification of such formulas. The changes would result in significant cost savings for an important industry which currently must obtain formula approval from TTB, and some savings for TTB, which must review and take action to approve or disapprove each formula. Estimating the specific savings to TTB is premature as this rulemaking project is in the early stages of internal deliberation.
Revisions to the Beer Regulations (part 25): Under the Internal Revenue Code, TTB regulates activities at breweries. The regulations of title 27 of the Code of Federal Regulations, part 25, address the qualification of breweries, bonds and taxation, removals without payment of tax, and records and reporting. The brewery regulations were last revised in 1986 and need to be updated to reflect changes to the industry, including the increased number of small (“craft”) brewers. TTB plans to issue an advance notice of proposed rulemaking soliciting comments regarding potential ways to decrease the regulatory burden on industry members (e.g., streamlining and/or reducing the reporting and recordkeeping requirements for the industry, which includes many small businesses.) and increase efficiency for both the industry and TTB. TTB intends to develop and propose specific regulatory changes after consideration of comments received.

Revisions to Distilled Spirits Plant Reporting Requirements: TTB will propose to revise regulations in part 19 and replace the current four report forms used by distilled spirits plants to report their operations on a monthly basis with two new report forms that would be submitted on a monthly basis (plants that qualify to file taxes on a quarterly basis would submit the new reports on a quarterly basis). This project, which was included in the President’s FY 2012 budget for TTB as a cost saving item, would address numerous concerns and desires for improved reporting by the distilled spirits industry and result in cost savings to the industry and TTB by significantly reducing the number of monthly plant operations reports that must be completed and filed by industry members and processed by TTB. TTB preliminarily estimates that this project would result in an annual savings of approximately 23,218 paperwork burden hours (or 11.6 staff years) for industry members and 629 processing hours (or 0.3 staff years) and $12,442 per year for TTB in contractor time. In addition, TTB estimates that this project would save staff time (approximately 3 staff years costing $300, as a result of more efficient and effective processing of reports and the use of report data to reconcile industry member tax accounts.

Bureau of the Public Debt
The Bureau of the Public Debt (BPD) has responsibility for borrowing the money needed to operate the Federal Government and accounting for the resulting debt, regulating the primary and secondary Treasury securities markets, and ensuring that reliable systems and processes are in place for buying and transferring Treasury securities.

BPD administers regulations: (1) Governing transactions in Government securities by Government securities brokers and dealers under the Government Securities Act of 1986 (GSA), as amended; (2) Implementing Treasury's borrowing authority, including rules governing the sale and issue of savings bonds, marketable Treasury securities, and State and local government securities; (3) Setting out the terms and conditions by which Treasury may buy back and redeem outstanding, unmatured marketable Treasury securities through debt buyback operations; (4) Governing securities held in Treasury's retail systems; and (5) Governing the acceptability and valuation of collateral pledged to secure deposits of public monies and other financial interests of the Federal Government.

During fiscal year 2012, BPD will accord priority to the following regulatory projects:

*Over-the-Counter Savings Bonds.* In December 2011, BPD anticipates issuing a rule ending the sale of definitive (paper) savings bonds.

*Savings Bond Paying Agent Regulations.* BPD plans to issue a final rule amending the savings bond paying agent regulations (31 CFR parts 321, 330) to provide for the conversion from use of the EZ Clear system to Check 21 in processing savings bonds redeemed at financial institutions.

*Eliminating Credit Rating References.* In compliance with the Dodd-Frank Wall Street Reform and Consumer Protection Act, BPD, on behalf of Treasury (Financial Markets), plans to amend the Government Securities Act regulations (17 CFR chapter IV) to eliminate references to credit ratings from Treasury's liquid capital rule.
Financial Management Service

The Financial Management Service (FMS) issues regulations to improve the quality of Government financial management and to administer its payments, collections, debt collection, and Governmentwide accounting programs. For fiscal year 2012, FMS's regulatory plan includes the following priorities:

**Debt Collection Authorities Under the Debt Collection Improvement Act.** The Debt Collection Improvement Act of 1996 authorizes Federal agencies to publish or otherwise publicly disseminate information regarding the identity of persons owing delinquent nontax debts to the United States for the purpose of collecting the debts, provided certain criteria are met. FMS is proposing to amend its regulation to establish the procedures Federal agencies must follow before publishing information about delinquent debtors and the standards for determining when use of this debt collection remedy is appropriate.

**Federal Government Participation in the Automated Clearing House.** FMS recently amended its regulation governing the use of the Automated Clearing House (ACH) system by Federal agencies. The amendments adopt, with some exceptions, the 2009 ACH Rules published by NACHA—The Electronic Payments Association (NACHA), as the rules governing the use of the ACH Network by Federal agencies. FMS issued this rule to address changes that NACHA made to the ACH Rules since the publication of NACHA's 2007 ACH Rules book. These changes include new requirements to identify all international payment transactions using a new Standard Entry Class Code and to include certain information in the ACH record sufficient to allow the receiving financial institution to identify the parties to the transaction and to allow transactions to be screened for compliance with Office of Foreign Assets Control (OFAC) requirements.

In addition, the amendments require financial institutions to provide limited account-related customer information related to the reclamation of post-death benefit payments as permitted under the Payment Transactions Integrity Act of 2008. The amendments also allow Federal payments to be delivered to
pooled or master accounts established by nursing facilities for residents of those facilities or held by religious orders whose members have taken vows of poverty.

*Indorsement and Payment of Checks Drawn on the United States Treasury.* By amending our regulation governing the indorsement and payment of checks drawn on the United States Treasury, Treasury has the authority to direct Federal Reserve Banks to debit a financial institution’s reserve account at the financial institution’s servicing Federal Reserve Bank for all check reclamations that the financial institution has not protested. Financial institutions continue to have the right to file a protest with FMS if they believe a proposed reclamation is in error.

**Domestic Finance—Office of the Fiscal Assistant Secretary (OFAS)**

The Office of the Fiscal Assistant Secretary develops policy for and oversees the operations of the financial infrastructure of the Federal Government, including payments, collections, cash management, financing, central accounting, and delinquent debt collection.

*Anti-Garnishment.* On February 23, 2011, the Treasury published an interim final rule and request for public comment with the Office of Personnel Management, the Railroad Retirement Board, the Social Security Administration, and Veterans Affairs. Treasury plans to promulgate a final rule, with the Federal benefit agencies, in the next several months to give force and effect to various benefit agency statutes that exempt Federal benefits from garnishment. Typically, upon receipt of a garnishment order from a State court, financial institutions will freeze an account as they perform due diligence in complying with the order. The joint final rule will address this practice of account freezes to ensure that benefit recipients have access to a certain amount of lifeline funds while garnishment orders or other legal processes are resolved or adjudicated. The rule will provide financial institutions with specific administrative instructions to carry out upon receipt of a garnishment order. The final rule will apply to financial institutions, but is not expected to have specific provisions for consumers, debt collectors, or banking regulators. However, the
banking regulators would enforce the policy in cases of non-compliance by means of their general authorities.

**Community Development Financial Institutions Fund**

The Community Development Financial Institutions Fund (Fund) was established by the Community Development Banking and Financial Institutions Act of 1994 (12 U.S.C. 4701 et seq.). The primary purpose of the CDFI Fund is to promote economic revitalization and community development through the following programs: The Community Development Financial Institutions (CDFI) Program, the Bank Enterprise Award (BEA) Program, the Native American CDFI Assistance (NACA) Program, and the New Markets Tax Credit (NMTC) Program. In addition, the CDFI Fund administers the Financial Education and Counseling Pilot Program (FEC), the Capital Magnet Fund (CMF), and the CDFI Bond Guarantee Program (BGP).

In fiscal year (FY) 2012, the CDFI Fund will publish Interim regulations implementing the CDFI Bond Guarantee Program (BGP). The BGP was established through the Small Business Jobs Act of 2010 and authorizes the Secretary of the Treasury (through the CDFI Fund) to guarantee the full amount of notes or bonds, including the principal, interest, and call premiums, issued to finance or refinance loans to certified CDFIs for eligible community or economic development purposes for a period not to exceed 30 years. The bonds or notes will support CDFI lending and investment by providing a source of long-term, patient capital to CDFIs. In accordance with Federal credit policy, the Federal Financing Bank (FFB), a body corporate and instrumentality of the United States Government under the general supervision and direction of the Secretary of the Treasury, will finance obligations that are 100 percent guaranteed by the United States, such as the bonds or notes to be issued by Qualified Issuers under the BGP.

In FY 2012, subject to funding availability, the Fund will provide awards through the following programs:
Community Development Financial Institutions (CDFI) Program. Through the CDFI Program, the CDFI Fund will provide technical assistance grants and financial assistance awards to financial institutions serving distressed communities.

Native American CDFI Assistance (NACA) Program. Through the NACA Program, the CDFI Fund will provide technical assistance grants and financial assistance awards to promote the development of CDFIs that serve Native American, Alaska Native, and Native Hawaiian communities.

Bank Enterprise Award (BEA) Program. Through the BEA Program, the CDFI Fund will provide financial incentives to encourage insured depository institutions to engage in eligible development activities and to make equity investments in CDFIs.

New Markets Tax Credit (NMTC) Program. Through the NMTC Program, the CDFI Fund will provide allocations of tax credits to qualified community development entities (CDEs). The CDEs in turn provide tax credits to private sector investors in exchange for their investment dollars; investment proceeds received by the CDEs are to be used to make loans and equity investments in low-income communities. The CDFI Fund administers the NMTC Program in coordination with the Office of Tax Policy and the Internal Revenue Service.

CDFI Bond Guarantee Program (BGP). Through the BGP, the CDFI Fund will select Qualified Issuers of federally guaranteed bonds, the bond proceeds will be used to make or refinance loans to certified CDFIs. The bonds must be a minimum of $100 million and may have terms of up to 30 years. The CDFI Fund is authorized to award up to $1 billion in guarantees per fiscal year through FY 2014.

Retrospective Review of Existing Regulations
Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in “The Regulatory Plan.” However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. Treasury’s final plan can be found at: [www.treasury.gov/open](http://www.treasury.gov/open).

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<td>1545-BF40</td>
<td>Definitions and Special Rules Regarding Accuracy-Related Penalties on Underpayments and Reportable Transaction Understatements and the Reasonable Cause Exception</td>
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<td>1513-AB07</td>
<td>Labeling and Advertising of Wines, Distilled Spirits, and Malt Beverages</td>
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<tr>
<td>1513-AB39</td>
<td>Revision of American Viticultural Area Regulations</td>
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<td>1513-AA23</td>
<td>Revision of Distilled Spirits Plant Regulations</td>
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<td>1513-AB59</td>
<td>Proposed Revisions to SDA and CDA Formulas Regulations</td>
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<tr>
<td>1513-AB72</td>
<td>Implementation of Statutory Amendments Requiring the Qualification of Manufacturers and Importers of Processed Tobacco and Other Amendments</td>
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<tr>
<td>1513-AA00</td>
<td>Exportation of Alcohol</td>
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<tr>
<td>1513-AB62</td>
<td>Proposed Revisions to Distilled Spirits for Fuel Use and Alcohol Fuel Plant Regulations</td>
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<td>1513-AB35</td>
<td>Self-Certification of Nonbeverage Product Formulas</td>
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<td>1513-AB05</td>
<td>Proposed Revisions to Beer Regulations</td>
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<td>1513-AB89</td>
<td>Revisions to Distilled Spirits Plant Operations Reports and Regulations</td>
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<td>1515–AD67</td>
<td>Courtesy Notice of Liquidation</td>
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<td>TARP Conflicts of Interest</td>
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**DEPARTMENT OF VETERANS AFFAIRS (VA)**

**Statement of Regulatory Priorities**

The Department of Veterans Affairs (VA) administers benefit programs that recognize the important public obligations to those who served this Nation. VA’s regulatory responsibility is almost solely confined to carrying out mandates of the laws enacted by Congress relating to programs for veterans and their beneficiaries. VA’s major regulatory objective is to implement these laws with fairness, justice, and efficiency.

Most of the regulations issued by VA involve at least one of three VA components: The Veterans Benefits Administration, the Veterans Health Administration, and the National Cemetery Administration. The primary mission of the Veterans Benefits Administration is to provide high-quality and timely nonmedical benefits to eligible veterans and their beneficiaries. The primary mission of the Veterans Health Administration is to provide high-quality health care on a timely basis to eligible veterans through its system of medical centers, nursing homes, domiciliaries, and outpatient medical and dental facilities. The primary mission of the National Cemetery Administration is to bury eligible veterans, members of the Reserve components, and their dependents in VA National Cemeteries and to maintain those cemeteries as national shrines in perpetuity as a final tribute of a grateful Nation to honor the memory and service of those who served in the Armed Forces.
VA Regulatory Priorities

VA’s regulatory priorities include a special project to undertake a comprehensive review and improvement of its existing regulations. The first portion of this project is devoted to reviewing, reorganizing, and rewriting the VA’s compensation and pension regulations found in 38 CFR part 3. The goal of the Regulation Rewrite Project is to improve the clarity and logical consistency of these regulations in order to better inform veterans and their family members of their entitlements.

A second VA regulatory priority includes a new caregiver benefits program provided by VA. This rule implements title I of the Caregivers and Veterans Omnibus Health Services Act of 2010, which was signed into law on May 5, 2010. The purpose of the new caregiver benefits program is to provide certain medical, travel, training, and financial benefits to caregivers of certain veterans and servicemembers who were seriously injured in the line of duty on or after September 11, 2001.

Retrospective Review of Existing Regulations

Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review" (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final agency plans can be found at:


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<td>Significantly reduce burdens on small businesses</td>
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VA Compensation and Pension Regulation Rewrite Project

Priority:
Other Significant. Major under 5 USC 801.

Legal Authority:
38 USC 501

CFR Citation:
38 CFR 3; 38 CFR 5

Legal Deadline:
None

Abstract:
Since 2004, the Department of Veterans Affairs (V) has published 20 Notices of Proposed Rulemaking to reorganize and rewrite its compensation and pension regulations in a logical, claimant-focused, and user-friendly format. The intended effect of the proposed revisions was to assist claimants, beneficiaries, and VA personnel in locating and understanding these regulations. Several veterans service organizations have requested that VA republish all these regulations together to allow the public another opportunity to comment. This proposed rule would provide that opportunity.

Statement of Need:
Many current VA regulations on compensation and pension benefits are disorganized and confusing. This rulemaking will make these regulations much easier to find, read, understand, and apply.

Summary of Legal Basis:
38 CFR 501(a).

**Alternatives:**
The only alternative would be for VA to amend the regulations in part 3 on a piecemeal basis.

**Anticipated Cost and Benefits:**
The cost of publishing the new regulations in the Federal Register as a proposed and then as a final rule, plus the cost of publishing the regulations in the Code of Federal Regulations, is anticipated to be $281,316. There will be administrative costs to update VA publications with the new regulation citations, and the cost of a short training program for VA adjudication employees regarding the new regulations. These costs should be more than offset by improved efficiency resulting from the use of part 5 and by the benefits inherent in providing both VA employees and veterans with regulations they can more readily understand.

**Risks:**
Not applicable.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
No

**Small Entities Affected:**
No

**Government Levels Affected:**
None

**URL For Public Comments:**
www.regulations.gov

**Agency Contact:**
William F. Russo
Office of Regulation Policy and Management
Department of Veterans Affairs
120. CAREGIVERS PROGRAM

Priority:

Economically Significant. Major under 5 USC 801.

Legal Authority:

38 USC 501; 38 USC 1720G

CFR Citation:

38 CFR 17.38; 38 CFR 71

Legal Deadline:

None

Abstract:

This document promulgates Department of Veterans Affairs (VA) interim final regulations concerning a new caregivers benefits program provided by VA. This rule implements title I of the Caregivers and Veterans Omnibus Health Services Act of 2010, Public Law 111-163, which was signed into law on May 5, 2010. The purpose of the caregivers benefits program is to provide certain medical, travel, training, and
financial benefits to caregivers of veterans and certain servicemembers who were seriously injured in the line of duty on or after September 11, 2001.

**Statement of Need:**

This document adopts as final Department of Veterans Affairs (VA) interim final regulations concerning Caregiver benefits provided by VA. The rule implements title I of the Caregivers and Veterans Omnibus Health Services Act of 2010 (Caregivers Act), which was signed into law on May 5, 2010. The purpose of the Caregiver benefits program is to provide certain medical, travel, training, and financial benefits to Caregivers of certain Veterans and Servicemembers who were seriously injured during service on or after September 11, 2001.

**Summary of Legal Basis:**

38 U.S.C. 111(e) and 1720G.

**Alternatives:**

There is no alternative; VA is required to implement the Caregivers Act.

**Anticipated Cost and Benefits:**

The costs are described in detail in the Impact Analysis. The estimated costs associated with this regulation are $69,044,469.40 for FY 2011 and $777,060,923.18 over a 5-year period. These include costs associated with the implementation and development of the Caregiver Support Program. The benefit is that by enabling and encouraging family members to serve as Caregivers, we hope to prevent the need to place these Veterans and Servicemembers in higher complexity treatment settings, and instead ensure that those who wish to, may continue to live in their homes with their families and loved ones.

**Risks:**

Not applicable.

**Timetable:**

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<th>Action</th>
<th>Date</th>
<th>FR Cite</th>
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<td>76 FR 26148</td>
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Period End

Final Action 04/00/12

Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

URL For Public Comments:
www.regulations.gov

Agency Contact:
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RIN: 2900–AN94

BILLING CODE:  8320-01-S

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Statement of Regulatory and Deregulatory Priorities

The Architectural and Transportation Barriers Compliance Board (Access Board) is an Independent
Federal agency established by section 502 of the Rehabilitation Act (29 U.S.C. 792). The Access Board is responsible for developing accessibility guidelines and standards under various laws to ensure that individuals with disabilities have access to and use of buildings and facilities, transportation vehicles, and information and communication technology. Other Federal agencies adopt the accessibility guidelines and standards issued by the Access Board as mandatory requirements for entities under their jurisdiction.

The item in this regulatory plan is entitled “Accessibility Standards for Medical Diagnostic Equipment.” Section 4203 of the Patient Protection and Affordable Care Act (Pub. L. 111-148, 124 Stat. 570) amended title V of the Rehabilitation Act, which establishes rights and protections for individuals with disabilities, by adding section 510. Section 510 of the Rehabilitation Act (29 U.S.C. 794f) requires the Access Board, in consultation with the Commissioner of the Food and Drug Administration, to issue standards that contain minimum technical criteria to ensure that medical diagnostic equipment, used in or in conjunction with medical settings such as physicians’ offices, clinics, emergency rooms, and hospitals, are accessible to and usable by individuals with disabilities. The statute provides that the standards must allow for independent access to and use of the equipment by individuals with disabilities to the maximum extent possible. The statute lists examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment as examples of equipment to which the standards will apply. However, this list is not exclusive and the statute covers any equipment commonly used by health professionals for diagnostic purposes. The statute does not cover medical devices used for monitoring or treating medical conditions such as glucometers and infusion pumps.

Section 510 of the Rehabilitation Act requires the standards to be issued not later than 24 months after the enactment of the Patient Protection and Affordable Care Act. The Patient Protection and Affordable Care Act was enacted on March 23, 2010. Accordingly, the statutory deadline for issuing the standards is March 23, 2012.
The Access Board has considered alternatives proposed by stakeholders at public hearings and identified in research. In addition, the Access Board has consulted closely with the Department of Justice and the Food and Drug Administration in the development of these draft standards. The Access Board has also considered approaches contained in the Association for the Advancement of Medical Instrumentation’s ANSI/AAMI HE 75:2009, “Human factors engineering—Design of medical devices” in developing the proposed standards. ANSI/AAMI HE 75 is a recommended practice that provides guidance on human factors design principles for medical devices. Chapter 16 of ANSI/AAMI HE 75 provides guidance on accessibility for patients and health care professionals with disabilities. Chapter 16 of ANSI/AAMI HE 75 is available at: http://www.aami.org/he75/. The proposed standards do not reference the guidance in chapter 16 of ANSI/AAMI HE 75 because the guidance is not mandatory. The Access Board seeks to promote harmonization of its standards and guidelines with voluntary consensus standards and plans to participate in future revisions to ANSI/AAMI HE 75.

The Access Board is seeking input from the public on costs and benefits associated with these standards. Section 510 of the Rehabilitation Act does not address who is required to comply with the standards. Compliance with the standards is not mandatory unless other agencies adopt the standards as mandatory requirements for entities under their jurisdiction. In July 2010, the Department of Justice issued an advance notice of proposed rulemaking (ANPRM) announcing that it was considering amending its Americans With Disabilities Act (ADA) regulations to ensure that equipment and furniture are accessible to individuals with disabilities. See 75 FR 43452 (July 26, 2010). The ANPRM noted that the ADA has always required the provision of accessible equipment and furniture, and that the Department has entered into settlement agreements with medical care providers requiring them to provide accessible medical equipment. The ANPRM stated that when the Access Board has issued accessibility standards for medical diagnostic equipment, the Department would consider adopting the standards in its ADA regulations. The ANPRM also stated that if the Department adopts the Access Board’s accessibility standards for medical diagnostic equipment, it would develop scoping requirements that specify the minimum number of accessible types of equipment required for different medical settings.
The rule is intended to reduce health and safety risks to individuals with disabilities by making medical
diagnostic equipment accessible.

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<th>ATBCB</th>
<th>PROPOSED RULE STAGE</th>
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121. ACCESSIBILITY STANDARDS FOR MEDICAL DIAGNOSTIC EQUIPMENT

Priority:
Other Significant

Legal Authority:
29 USC 794(f)

CFR Citation:
30 CFR 1197 (New)

Legal Deadline:

Abstract:
This regulation will establish minimum technical criteria to ensure that medical equipment used for
diagnostic purposes by health professionals in (or in conjunction with) physician's offices, clinics,
emergency rooms, hospitals, and other medical settings is accessible to and usable by individuals with
disabilities.

Statement of Need:
The Access Board is required to issue accessibility standards for medical diagnostic equipment by
section 510 of the Rehabilitation Act. The standards will reduce health and safety risks to individuals with
disabilities by making medical diagnostic equipment accessible.

Summary of Legal Basis:
Section 4203 of the Patient Protection and Affordable Care Act (Pub. L. 111-148, 124 Stat. 570) amended
title V of the Rehabilitation Act, which establishes rights and protections for individuals with disabilities by
adding section 510. Section 510 of the Rehabilitation Act (29 U.S.C. 794f) requires the Access Board, in consultation with the Commissioner of the Food and Drug Administration, to issue standards that contain minimum technical criteria to ensure that medical diagnostic equipment used in or in conjunction with medical settings such as physicians' offices, clinics, emergency rooms, and hospitals are accessible to and usable by individuals with disabilities. The statute provides that the standards must allow for independent access to and use of the equipment by individuals with disabilities to the maximum extent possible. The statute lists examination tables, examination chairs, weight scales, mammography equipment, and other imaging equipment as examples of equipment to which the standards will apply. However, this list is not exclusive and the statute covers any equipment commonly used by health professionals for diagnostic purposes. The statute does not cover medical devices used for monitoring or treating medical conditions such as glucometers and infusion pumps.

**Alternatives:**

The Access Board has considered alternatives proposed by stakeholders at public hearings and identified in research. In addition, the Access Board has consulted closely with the Department of Justice and the Food and Drug Administration in the development of these draft standards. The Access Board has also considered approaches contained in the Association for the Advancement of Medical Instrumentation's ANSI/AAMI HE 75:2009, “Human factors engineering—Design of medical devices” in developing the proposed standards. ANSI/AAMI HE 75 is a recommended practice that provides guidance on human factors design principles for medical devices. Chapter 16 of ANSI/AAMI HE 75 provides guidance on accessibility for patients and health care professionals with disabilities. Chapter 16 of ANSI/AAMI HE 75 is available at: http://www.aami.org/he75/. The proposed standards do not reference the guidance in chapter 16 of ANSI/AAMI HE 75 because the guidance is not mandatory. The Access Board seeks to promote harmonization of its standards and guidelines with voluntary consensus standards and plans to participate in future revisions to ANSI/AAMI HE 75.

**Anticipated Cost and Benefits:**

The Access Board is seeking input from the public on costs and benefits associated with these standards. Section 510 of the Rehabilitation Act does not address who is required to comply with the standards. Compliance with the standards is not mandatory unless other agencies adopt the standards as
mandatory requirements for entities under their jurisdiction. In July 2010, the Department of Justice issued an advance notice of proposed rulemaking (ANPRM) announcing that it was considering amending its ADA regulations to ensure that equipment and furniture are accessible to individuals with disabilities. See 75 FR 43452 (Jul. 26, 2010). The ANPRM noted that the ADA has always required the provision of accessible equipment and furniture, and that the Department has entered into settlement agreements with medical care providers requiring them to provide accessible medical equipment. The ANPRM stated that when the Access Board has issued accessibility standards for medical diagnostic equipment, the Department would consider adopting the standards in its ADA regulations. The ANPRM also stated that, if the Department adopts the Access Board's accessibility standards for medical diagnostic equipment, it would develop scoping requirements that specify the minimum number of accessible types of equipment required for different medical settings.

**Risks:**

The rule is intended to reduce health and safety risks to individuals with disabilities by making medical diagnostic equipment accessible.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:**

Undetermined

**URL For More Information:**

www.access-board.gov/medical-equipment.htm
ENVIRONMENTAL PROTECTION AGENCY (EPA)

Statement of Priorities

Overview

The U.S. Environmental Protection Agency (EPA) was created on December 2, 1970, when Americans across the Nation took up a call for cleaner air, safer water, and unpolluted land. For the past 4 decades, EPA has confronted health and environmental challenges, fostered innovations, and cleaned up pollution in the places where people live, work, play, and learn.

The EPA remains strongly committed to protecting health and the environment through:

- Taking action on climate change;
- Improving air quality;
- Assuring the safety of chemicals;
• Cleaning up our communities;
• Protecting America’s waters;
• Expanding the conversation on environmentalism and working for environmental justice; and
• Building strong State and tribal partnerships.

EPA and its Federal, State, local, and community partners have made enormous progress in protecting the Nation’s health and environment. From reducing mercury and other toxic air pollution from power plants to doubling the fuel economy of our cars and trucks, the Agency is working to save tens of thousands of lives each year. Further, EPA has removed over a billion tons of pollution from the air and produced hundreds of billions of dollars in benefits for the American people. For example:
• The number of Americans receiving water that meets health standards has gone from 79 percent in 1993 to 92 percent in 2008.
• EPA has also helped realize a 60 percent reduction in the dangerous air pollutants that cause smog, acid rain, lead poisoning, and more since the passage of the Clean Air Act in 1970. Innovations like smokestack scrubbers and catalytic converters in automobiles have helped this process.
• Today, new cars are 98 percent cleaner in terms of smog-forming pollutants than they were in 1970.
• Meanwhile, American families and businesses have gone from recycling about 10 percent of trash in 1980 to more than 33 percent in 2008. Eighty-three million tons of trash are recycled annually—the equivalent of cutting greenhouse gas emissions from more than 33 million automobiles.

Highlights of EPA’s Regulatory Plan

EPA’s 40 years of environmental and health protection demonstrate our Nation’s ability to create jobs while we clean our air, water, and land. Clean air, clean water, and healthy workers are all essential to American businesses. Moreover, innovations in clean technology are creating new jobs right now. Addressing climate change calls for coordinated national and global efforts to research alternative fuels and other emission reduction technologies and requires strong partnerships across economic sectors and around the world. Similarly, energy consumption and higher costs underscore the need to promote alternative energy sources and invest in new technologies.
Seven Guiding Priorities

The EPA’s success depends on supporting innovation and creativity in both what we do and how we do it. To guide the Agency’s efforts, Administrator Lisa P. Jackson has established seven guiding priorities. These priorities are enumerated in the list that follows, along with recent progress and future objectives for each.

1. Taking Action on Climate Change

While the EPA stands ready to help Congress craft strong, science-based climate legislation that addresses the spectrum of issues, the Agency will deploy existing regulatory tools as they are available and warranted. Using the Clean Air Act, EPA will continue to develop greenhouse gas standards for both mobile and stationary sources.

   Greenhouse Gas Emission Standards for Automobiles and Trucks. Last year, EPA issued joint regulations with the National Highway Traffic Safety Administration that will improve fuel economy and reduce GHG emissions from light-duty vehicles for the 2012 to 2016 model years and from heavy-duty engines and vehicles. Building on that success, the two agencies are now developing a rule that will require further improvements in light-duty vehicles for the model years 2017 to 2025.

   Greenhouse Gas Emission Standards for Power Plants. In 2012, EPA will also continue to develop common-sense solutions for reducing greenhouse gas emissions from large stationary sources like power plants.

2. Improving Air Quality

Since passage of the Clean Air Act Amendments in 1990, nationwide air quality has improved significantly for the six criteria air pollutants for which there are national ambient air quality standards. Long-term exposure to air pollution can cause cancer and damage to the immune, neurological, reproductive, cardiovascular, and respiratory systems.

   Reviewing and Implementing Air Quality Standards. Despite progress, millions of Americans still live in areas that exceed one or more of the national standards. Ground-level ozone and particle pollution still present challenges in many areas of the country. This year’s regulatory plan describes efforts to review the primary National Ambient Air Quality Standards (NAAQS) for particulates.
Tier 3 Vehicle and Fuel Standards. EPA plans to propose new vehicle emission and fuel standards to further reduce NOx, PM, and air toxics. These standards will address the Energy Independence and Security Act (EISA) “anti-backsliding” provision, which requires the Agency to assess the air quality impacts of renewable fuel mandates and take steps to mitigate them. These standards will also help states to achieve air quality standards.

Cleaner Air From Improved Technology. EPA continues to address toxic air pollution under authority of the Clean Air Act Amendments of 1990. The centerpiece of this effort is the "Maximum Achievable Control Technology" (MACT) program, which requires that all major sources of a given type use emission controls that better reflect the current state of the art.

3. Assuring the Safety of Chemicals

One of EPA’s highest priorities is to make significant and long-overdue progress in assuring the safety of chemicals. Using sound science as a compass, EPA protects individuals, families, and the environment from potential risks of pesticides and other chemicals.

Enhancing EPA’s Current Chemicals Management Program Under the Toxic Substances Control Act. EPA continues to target priority chemicals for action and to identify both concerns that the chemicals may present and actions the Agency will take to address those concerns. EPA is undertaking a range of actions to address potential risks, including establishing for the first time criteria for the use of TSCA’s section 5(b)(4) authority and proposing actions under TSCA to gather additional information on nanoscale chemical materials.

Enhancing Agricultural Worker Protection and Strengthening Pesticide Applicator Safety. EPA is developing a proposal to strengthen the existing agricultural worker protection regulation, which is designed to protect agricultural farm workers and pesticide handlers by improving pesticide safety training for workers and protections from exposure during work activities. This proposal will also address key environmental justice concerns for a population that is disproportionately affected by pesticide exposure. In addition, EPA expects to propose changes to the existing regulations for certifying the competency of
pesticide applicators to apply pesticides safely. Both of these rules also aim to protect child and adolescent agricultural workers.

4. Cleaning Up Communities

EPA supports urban, suburban, and rural community goals of improving environmental, human health, and quality-of-life outcomes through partnerships that also promote economic opportunities, energy efficiency, and revitalized neighborhoods. Sustainable communities balance their economic and natural assets so that the diverse needs of local residents can be met now and in the future with limited environmental impacts. EPA accomplishes these outcomes by working with communities, other Federal agencies, States, and national experts to develop and encourage development strategies that have better outcomes for air quality, water quality, and land preservation and revitalization.

5. Protecting America’s Waters

We have made considerable progress in cleaning up many of America’s waters, but water quality and enforcement programs face on-going challenges. These challenges demand both traditional and innovative strategies.

Concentrated Animal Feeding Operations. EPA proposed a regulation that would collect information about concentrated animal feeding operations (CAFOs). CAFOs are a significant source of nutrient pollution and pathogens in U.S. watersheds. The information that would be collected under the proposed rule would allow EPA to increase water quality protection through better implementation of the NPDES permitting program for CAFOs. The proposed regulation would apply to all permitted and unpermitted CAFOs. EPA co-proposed a regulation that would only collect information from CAFOs in targeted areas, if EPA determined such collection was necessary based on specified factors, such as water quality concerns.

Streamlining. EPA intends to review the regulations that apply to the issuance of National Pollutant Discharge Elimination System (NPDES) permits, which are the wastewater permits that facility operators must obtain before they discharge pollutants to any water of the United States. EPA plans to update
specific elements of the existing NPDES in order to better harmonize regulations and application forms, improve permit documentation and transparency, and provide clarifications to the existing regulations.


   Environmental Justice in Rulemaking. EPA released “Plan EJ 2014” in September 2011. This Plan, which marks the 20th anniversary of the signing of Executive Order 12898 on environmental justice, is EPA’s overarching strategy for advancing environmental justice. It seeks to protect the environment and health in overburdened communities, empower communities to take action to improve their health and environment, and establish partnerships with local, State, tribal, and Federal governments, and organizations to achieve healthy and sustainable communities. The Plan is an important and positive step toward meeting EPA Administrator Lisa P. Jackson’s priority to work for environmental justice and protect the health and safety of communities that have been disproportionately impacted by pollution.

   Children’s Health. EPA continues to lead efforts to protect children from environmental health risks, in accordance with Executive Order 13045. To accomplish this, EPA intends to use a variety of approaches, including regulation, enforcement, research, outreach, community-based programs, and partnerships to protect pregnant women, infants, children, and adolescents from environmental and human health hazards.

7. Building Strong State and Tribal Partnerships

   EPA’s success depends more than ever on working with increasingly capable and environmentally conscious partners. While the Agency works with the States and tribes on the day-to-day mission of environmental protection, declining tax revenues and fiscal challenges are pressuring State agencies and tribal governments to do more with fewer resources. EPA is supportive of State and tribal capacity to ensure that programs are consistently delivered nationwide. This provides EPA and its intergovernmental partners with an opportunity to further strengthen their working relationship and, thereby, more effectively pursue their shared goal of protecting the Nation’s environment and public health.

   Recognizing the Right of Tribes as Sovereign Nations. In FY 2009, EPA Administrator Jackson reaffirmed the Agency’s Indian Policy, which recognizes that the United States has a unique legal relationship
with tribal governments based on treaties, statutes, Executive orders, and court decisions. EPA recognizes the right of tribes as sovereign governments to self-determination and acknowledges the Federal Government’s trust responsibility to tribes.

* * * * * * * * *

The priorities described above will guide EPA’s work in the years ahead. They are built around the challenges and opportunities inherent in our mission to protect health and the environment for all Americans. This mission is carried out by respecting EPA’s core values of science, transparency, and the rule of law. Within these parameters, EPA carefully considers the impacts its regulatory actions will have on society.

Retrospective Review of Existing Regulations

Just as today’s economy is vastly different from that of 40 years before, EPA’s regulatory program is evolving to recognize the progress that has already been made in environmental protection and to incorporate new technologies and approaches that allow us to accomplish our mission more efficiently and effectively. A central goal, consistent with January’s Executive Order 13563, is to identify methods for reducing unjustified burdens and costs. In August, EPA released a plan for periodically reviewing EPA’s existing regulations. The Agency intends to apply the principles and directives of EO 13563 to both retrospective reviews of existing regulations and the development of new regulations. As called for by Executive Order 13563, EPA intends to seek ways “to determine whether…regulations should be modified, streamlined, expanded, or repealed so as to make the Agency’s regulatory program more effective or less burdensome in achieving the regulatory objectives.”

The EPA’s Final Plan for Retrospective Reviews of Existing Regulations (Retrospective Review Plan) describes a large number of burden-reducing, cost-saving reforms, including 35 priority initiatives. Some of these have recently been completed; others are in process; still others are in their earliest stages. The potential economic savings are significant. For example, a recently proposed rule may eliminate redundant air pollution control requirements now imposed on gas stations; that rule would save $87 million annually. Taken as a whole, recent reforms, already finalized or formally proposed, are anticipated
to save up to $1.5 billion over the next 5 years. Other reforms described in the Retrospective Review Plan, including efforts to streamline requirements and to move to electronic reporting, could save more.

Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review" (Jan. 18, 2011), the following Regulation Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in EPA’s final Retrospective Review Plan. Some of the entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for the Agency. These rulemakings can also be found on Regulations.gov. The final Agency plan can be found at: http://www.epa.gov/regdarrt/retrospective/.

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<td>2060-AQ86</td>
<td>Control of Air Pollution From Motor Vehicles: Tier 3 Motor Vehicle Emission and Fuel Standards</td>
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<td>2060-AQ54</td>
<td>Joint Rulemaking To Establish 2017 and Later Model Year Light Duty Vehicle GHG Emissions and CAFE Standards</td>
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<td>2060-AQ41</td>
<td>Risk and Technology Review for National Emission Standards for Hazardous Air Pollutants From the Pulp and Paper Industry</td>
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<tr>
<td>2060-AO60</td>
<td>New Source Performance Standards (NSPS) Review Under CAA Section 111(b)(1)(B)</td>
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<td>2060-AR00</td>
<td>Uniform Standards for Equipment Leaks and Ancillary Systems, Closed Vent Systems and Control Devices, Storage Vessels and Transfer Operations, and Wastewater Operations</td>
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<tr>
<td>2070-AJ20</td>
<td>Pesticides; Certification of Pesticide Applicators</td>
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<tr>
<td>2070-AJ63</td>
<td>TSCA Reporting Requirements; Minor Revisions</td>
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<tr>
<td>2040-AF25</td>
<td>National Pollutant Discharge Elimination System (NPDES) Application and Program Updates Rule</td>
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<tr>
<td>2050-AG50</td>
<td>Oil Pollution Prevention: Spill Prevention, Control, and Countermeasure Rule</td>
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By better coordinating small business activities, EPA aims to improve its technical assistance and outreach efforts, minimize burdens to small businesses in its regulations, and simplify small businesses' participation in its voluntary programs. Actions that may affect small entities can be tracked on EPA’s Regulatory Development and Retrospective Review Tracker (http://www.epa.gov/regdarrt/) at any time.

This Plan includes a number of rules that may be of particular interest to small entities:

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<td>Industrial, Commercial, and Institutional Boilers and Process Heaters; Proposed</td>
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<td>2060-AP52</td>
<td>National Emission Standards for Hazardous Air Pollutants From Coal- and Oil-fired</td>
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<td>Electric Utility Steam Generating Units and Standards of Performance for Electric</td>
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<td>2060-AQ86</td>
<td>Control of Air Pollution From Motor Vehicles: Tier 3 Motor Vehicle Emission and</td>
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<td>Fuel Standards</td>
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<td>2070-AJ56</td>
<td>Lead; Renovation, Repair, and Painting Program for Public and Commercial</td>
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<td>2070-AJ44</td>
<td>Formaldehyde Emissions From Pressed Wood Products</td>
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<td>2050-AG61</td>
<td>Financial Responsibility Requirements Under CERCLA Section 108(b) for Classes</td>
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<td>of Facilities in the Hard Rock Mining Industry</td>
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<tr>
<td>2040-AF13</td>
<td>Stormwater Regulations Revision To Address Discharges from Developed Sites</td>
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122. RISK AND TECHNOLOGY REVIEW FOR NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FROM THE PULP AND PAPER INDUSTRY

Priority:
Other Significant

Legal Authority:
Clean Air Act sec 112

CFR Citation:
40 CFR 63.440 to 63.459

Legal Deadline:
NPRM, Judicial, December 15, 2011, Consent decree deadline completed.
Final, Judicial, July 31, 2012, Consent decree deadline.

Abstract:
Section 112(f)(2) of the Clean Air Act (CAA) directs EPA to conduct risk assessments on each source category subject to maximum achievable control technology (MACT) standards and to determine if additional standards are needed to reduce residual risks, to be completed 8 years after promulgation. Section 112(d)(6) of the CAA requires EPA to review and revise the MACT standards as necessary, taking into account developments in practices, processes, and control technologies, to be done at least every 8 years. The National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Pulp and Paper Industry (subpart S) was promulgated in 1998 and also has not been reviewed. This action will propose those amendments.

Statement of Need:
The National Emission Standard for Hazardous Air Pollutants (NESHAP) in the Pulp and Paper Category was promulgated April 15, 1998 and codified as subpart S in 40 CFR parts 63.440 to 63.459. Section 112(f)(2) of the Clean Air Act (CAA) directs EPA to conduct risk assessments on each source category subject to maximum achievable control technology (MACT) standards, and to determine if additional standards are needed to reduce residual risks, to be completed 8 years after promulgation. Section 112(d)(6) of the CAA requires EPA to review and revise the MACT standards as necessary, taking into
account developments in practices, processes and control technologies, to be done at least every 8 years.

**Summary of Legal Basis:**

EPA has signed a consent agreement that directs it to propose a Risk and Technology Review rule (RTR) to address the requirements of Sections 112 (f)(2) and (d)(6) by December 15, 2011 and promulgate a final RTR rule for this category by July 31, 2012.

**Alternatives:**

Not yet determined.

**Anticipated Cost and Benefits:**

Not yet determined.

**Risks:**

Not yet determined.

**Timetable:**

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<td>12/27/11</td>
<td>76 FR 81328</td>
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**Regulatory Flexibility Analysis Required:**

No

**Government Levels Affected:**

Local, State, Tribal

**Additional Information:**

Docket number EPA-HQ-OAR-2007-0544

**Agency Contact:**

Bill Schrock

Environmental Protection Agency

Air and Radiation

E143–03
123. JOINT RULEMAKING TO ESTABLISH 2017 AND LATER MODEL YEAR LIGHT DUTY VEHICLE GHG EMISSIONS AND CAFE STANDARDS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
42 USC 7401 to 7671q

CFR Citation:
40 CFR 86 and 600

Legal Deadline:
None

Abstract:
The Environmental Protection Agency (EPA) and the National Highway Traffic Safety Administration (NHTSA), on behalf of the Department of Transportation, have proposed a joint rulemaking on GHG and CAFE standards for model years 2017 to 2025 light-duty vehicles. This action represents a continuation of a coordinated National Program under the Clean Air Act (CAA) and the Energy Policy and Conservation Act (EPCA), as amended by the Energy Independence and Security Act (EISA), to improve fuel efficiency and to reduce greenhouse gas (GHG) emissions of light-duty vehicles. On July 29, 2011, President Obama announced a historic agreement with 13 automakers and the State of California to pursue 2017 to 2025 standards. This announcement was accompanied by a joint Supplemental Notice of Intent, issued by EPA and NHTSA, which outlined the standards and other key program elements the agencies intend to propose in the upcoming rulemaking. EPA and NHTSA intend to propose that automobile manufacturers meet a model year 2025 CO2 standard of 163 grams/mile, which is equivalent to 54.5 miles per gallon if the standard were achieved with fuel economy technologies alone. This latest notice followed a September 30, 2010, joint Notice of Intent that provided an initial assessment of potential levels of stringency for 2017 to 2025 standards, an Interim Joint Technical Assessment Report published jointly by EPA, NHTSA, and the California Resources Board in September 2010, and a November 30, 2010, Supplemental Notice summarizing key stakeholder comments.

**Statement of Need:**

EPA has found that emissions of greenhouse gases (GHGs) from new motor vehicles cause or contribute to pollution that may reasonably be anticipated to endanger public health and welfare. Light-duty vehicles emit four GHGs—carbon dioxide (CO2), methane (CH4), nitrous oxide (NOX), and hydrofluorocarbons (HFCs)—and are responsible for nearly 60 percent of all mobile-source GHGs. On May 21, 2010, the President called on the EPA and NHTSA, in close coordination with California, to begin the next phase of the National Clean Car Program and propose new standards for model years 2017 to 2025, in response to the urgent and closely intertwined challenges faced by our Nation of dependence on oil, energy security, and global climate change. This rulemaking would provide significant additional reductions in GHGs from future light-duty vehicles and fuel efficiency improvements.

**Summary of Legal Basis:**
The Clean Air Act section 202(a)(1) states that “The Administrator shall by regulation prescribe (and from time to time revise) in accordance with the provisions of this section, standards applicable to the emissions of any air pollutant from any class or classes of new motor vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution, which may reasonably be anticipated to endanger public health or welfare.” Section 202(a) covers light-duty vehicles. In April 2007, the Supreme Court found in Massachusetts v. EPA that greenhouse gases fit well within the Act’s capacious definition of “air pollutant” and that EPA has statutory authority to regulate emission of such gases from new motor vehicles. Lastly, in December 2009, EPA published two findings (74 FR 66496) that emissions of GHGs from new motor vehicles and motor vehicle engines contribute to air pollution, and that the air pollution may reasonably be anticipated to endanger public health and welfare.

**Alternatives:**

The rulemaking proposal includes an evaluation of regulatory alternatives that can be considered in addition to the Agency’s primary proposal. In addition, the proposal includes tools such as averaging, banking, and trading of emissions credits and other flexibilities for alternative approaches for compliance with the proposed program.

**Anticipated Cost and Benefits:**

The standards under consideration are projected to reduce GHGs by approximately 2 billion metric tons and save 4 billion barrels of oil over the lifetime of MY 2017 to 2025 vehicles. These standards would have significant benefits to American consumers by reducing the costs they would pay to fuel these more efficient vehicles.

**Risks:**

The failure to set new GHG standards for light-duty vehicles would increase the risk of unacceptable climate change impacts.

**Timetable:**

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Intent

NPRM 12/01/11 76 FR 74854
Final Action 08/00/12

Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal

Federalism:

This action may have federalism implications as defined in EO 13132.

International Impacts:

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Additional Information:

EPA Docket information: EPA-HQ-OAR-2010-0799

Sectors Affected:

811198 All Other Automotive Repair and Maintenance; 336111 Automobile Manufacturing; 423110 Automobile and Other Motor Vehicle Merchant Wholesalers; 811112 Automotive Exhaust System Repair; 811111 General Automotive Repair; 441120 Used Car Dealers

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This action is the Petroleum Refining Sector Rulemaking, which will address our obligation to perform Risk and Technology Reviews (RTR) for Petroleum Refinery MACT 1 and 2 source categories and will address issues related to the reconsideration of Petroleum Refinery New Source Performance Standards (NSPS) subpart Ja.
EPA entered into a settlement agreement with multiple litigants on December 23, 2010. The settlement agreement requires EPA to propose standards of performance for GHGs for affected facilities at refineries that are subject to NSPS subparts J and Ja (Petroleum Refineries, including flares, process heaters, fluid catalytic cracking units, fluid cokers, delayed cokers, and sulfur recovery plants), subpart Db (Industrial-Commercial-Institutional Steam Generating Units [Boilers]), subpart Dc (Small Industrial-Commercial-Institutional Steam Generating Units), subpart GGG (Equipment Leaks of VOC in Petroleum Refineries; e.g., leaking equipment components such as pumps, valves, flanges), and subpart QQQ (VOC Emissions from Petroleum Refinery Wastewater Systems; e.g., drain systems and oil water separators) and to propose emissions guidelines for GHGs from existing affected facilities at refineries in the source categories covered by those NSPS subparts. The settlement also requires EPA to propose to address remaining issues raised in a petition filed in response to the June 24, 2008, promulgation of amendments to the Refinery NSPS subpart J and new standards of performance for subpart Ja, and to propose standards, as necessary, to address the RTR review for the 2002 Refinery MACT II standards. The settlement requires EPA to issue final standards for the NSPS and RTR reviews by November 10, 2012. This settlement agreement is currently under negotiation.

In this action, we will also conduct RTR reviews for the two Petroleum Refinery MACT. We will use information obtained through a comprehensive information collection process to address The MACT and NSPS reviews.

Uniform standards (for heat exchangers, equipment leaks, storage vessels and transfer operations; control devices and closed-vent systems) are being developed in separate actions and will specify work practices, equipment standards, and monitoring, recordkeeping, and reporting requirements. The refinery sector MACT and NSPS are expected to reference the uniform standards. Later, chemical sector MACT and NSPS will also reference the uniform standards, which will ensure that requirements are consistent, to the extent appropriate, across the chemical sectors.

**Statement of Need:**
Under the “technology review” provision of CAA section 112, EPA is required to review maximum achievable control technology (MACT) standards and to revise them “as necessary (taking into account developments in practices, processes, and control technologies)” no less frequently than every 8 years. Under the “residual risk” provision of CAA section 112, EPA must evaluate the MACT standards within 8 years after promulgation and promulgate standards if required to provide an ample margin of safety to protect public health or prevent an adverse environmental effect. Section 111(b)(1)(B) of the CAA mandates that EPA review and, if appropriate, revise existing NSPS every 8 years.

**Summary of Legal Basis:**
CAA sections 111 and 112.

**Alternatives:**
Not yet determined.

**Anticipated Cost and Benefits:**
EPA is currently assessing the costs and benefits associated with this action.

**Risks:**
EPA is currently assessing risks for this action.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Undetermined

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
Federal, Local, State

**Additional Information:**
Action described in RIN 2060-AQ28 (NSPS reconsideration issues) will be included in this action. EPA Docket information: EPA-HQ-OAR-2010-0682
Sectors Affected:
32411 Petroleum Refineries

URL For More Information:
http://www.epa.gov/ttn/atw/petrefine/petrefpg.html

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RIN: 2060–AQ75
Economically Significant. Major under 5 USC 801.

**Unfunded Mandates:**
Undetermined

**Legal Authority:**
CAA 202(a) and 211(v)

**CFR Citation:**
Not Yet Determined

**Legal Deadline:**
None

**Abstract:**
This rule will establish new standards for light-duty vehicles and their fuels in order to reduce emissions of criteria and toxic pollutants and their impact on air quality and health. This action will set forth a comprehensive approach toward regulating motor vehicles for non-greenhouse gas pollutants, as requested by a May 2010 Presidential memorandum.

**Statement of Need:**
States are working to attain National Ambient Air Quality Standards for ozone, PM, and NOx. Light-duty vehicles are responsible for a significant portion of the precursors to these pollutants and are large contributors to ambient air toxic pollution. For example, without future controls, by 2014 light-duty vehicles are projected to contribute 25 percent of nationwide mobile-source NOx, 40 percent of nationwide mobile-source VOC, and 10 percent nationwide mobile-source PM. Importantly, by 2020 mobile sources are expected to be as much as 50 percent of the inventories for some individual urban areas without future controls. Light-duty vehicles also contribute about half of the 2030 mobile source inventory of toxics; the 2002 National-Scale Air Toxics Assessment showed that mobile sources were responsible for over 50 percent of cancer risk and over 80 percent of noncancer hazard. Clearly, there is a need for tighter light-duty vehicle standards and fuel standards as part of a comprehensive approach to reducing pollution from motor vehicles. Renewable fuels are recognized to pose potential air quality concerns, and EPA has a mandate to address them under Clean Air Act section 211(q) and 211(v). Specifically, both EPAct of 2005...
and EISA (2007) amended the CAA to require EPA to determine adverse air quality impacts of renewable fuels and to implement appropriate measures to mitigate these impacts to the greatest extent achievable.

**Summary of Legal Basis:**

The Clean Air Act, section 202(a)(1), states “The Administrator shall by regulation prescribe (and from time to time revise) in accordance with the provisions of this section, standards applicable to the emission of any air pollutant from any class, or class of new motor vehicles or new motor vehicle engines, which in his judgment cause, or contribute to, air pollution which may be reasonably be anticipated to endanger public health or welfare.” Section 202(a) covers all on-highway vehicles, including medium and heavy-duty trucks. EPA is also using its authority under section 211(c) of the Clean Air Act to address gasoline sulfur controls, section 211(h) to address Reid Vapor Pressure, and section 211(v), which requires that the Administrator promulgate fuel regulations to implement appropriate measures to mitigate, to the greatest extent achievable, and considering the results of the anti-backsliding study completed under section 211(v) (1), any adverse impacts on air quality as a results of the renewable volumes or make a determination that no such measures are necessary.

**Alternatives:**

The rulemaking proposal will include an evaluation of regulatory alternatives that can be considered in addition to the Agency's primary proposal.

**Anticipated Cost and Benefits:**

Detailed analysis of economy-wide cost impacts, emissions reductions, and societal benefits will be performed during the rulemaking process.

**Risks:**

The failure to set new Tier 3 vehicle/fuel standards will adversely impact the population living in nonattainment areas, where reductions from the Tier 3 rule are needed to help attain and maintain the ozone and PM NAAQS (and to mitigate adverse effects of renewable fuels). Also, without the new Tier 3 vehicle/fuel standards, the sizeable population living, working, and going to school near roads will continue to be exposed to higher levels of air toxics, which is a current environmental justice and children's health concern.

**Timetable:**
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**Regulatory Flexibility Analysis Required:**

Undetermined

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Additional Information:**


**Sectors Affected:**

811198 All Other Automotive Repair and Maintenance; 336111 Automobile Manufacturing; 811112 Automotive Exhaust System Repair; 336311 Carburetor, Piston, Piston Ring, and Valve Manufacturing; 336312 Gasoline Engine and Engine Parts Manufacturing; 336120 Heavy Duty Truck Manufacturing; 336112 Light Truck and Utility Vehicle Manufacturing; 454312 Liquefied Petroleum Gas (Bottled Gas) Dealers; 541690 Other Scientific and Technical Consulting Services; 324110 Petroleum Refineries; 484220 Specialized Freight (except Used Goods) Trucking, Local; 484230 Specialized Freight (except Used Goods) Trucking, Long-Distance

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EPA

126. GREENHOUSE GAS NEW SOURCE PERFORMANCE STANDARD FOR ELECTRIC GENERATING UNITS FOR NEW SOURCES

Priority:
Economically Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:
Undetermined

Legal Authority:
CAA 111

CFR Citation:
40 CFR 60

Legal Deadline:
NPRM, Judicial, September 30, 2011.

Abstract:
This action will amend the electric generating units (EGUs) New Source Performance Standard and add a section 111(b) greenhouse gas (GHG) standard for new and modified facilities.

Statement of Need:
EPA entered into settlement agreement with multiple State and environmental petitioners on December 21, 2010, to establish standards of performance for GHGs for new EGUs and emissions guidelines for GHGs from existing EGUs.

**Summary of Legal Basis:**
Clean Air Act, section 111

**Alternatives:**
Not yet determined.

**Anticipated Cost and Benefits:**
Not yet determined.

**Risks:**
Not yet determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
No

**Small Entities Affected:**
No

**Government Levels Affected:**
Undetermined

**Federalism:**
Undetermined

**Energy Effects:**
Statement of Energy Effects planned as required by Executive Order 13211.

**Additional Information:**
EPA Docket information: EPA-HQ-OAP-2011-0660

**Sectors Affected:**
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RIN: 2060–AQ91

127. • NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANT EMISSIONS:
GROUP IV POLYMERS AND RESINS, PESTICIDE ACTIVE INGREDIENT PRODUCTION, AND
POLYETHER POLYOLS PRODUCTION RISK AND TECHNOLOGY REVIEW

Priority:
Other Significant

Legal Authority:
Clean Air Act secs 111 and 112

**CFR Citation:**
40 CFR 60 and 63

**Legal Deadline:**
NPRM, Judicial, November 30, 2011.
Final, Judicial, November 30, 2012.

**Abstract:**
In this action, EPA will perform risk and technology reviews for three National Emission Standards for Hazardous Air Pollutants (NESHAP). These NESHAP are under a deadline consent decree for proposal in November 2011 and promulgation in November 2012: Group IV Polymers and Resins, Pesticide Active Ingredient Production, and Polyether Polyols Production. Clean Air Act (CAA) sections 112(f)(2) and 112(d)(6) require EPA to conduct residual risk and technology reviews. Under the “technology review” provision of CAA section 112, EPA is required to review maximum achievable control technology (MACT) standards and to revise them “as necessary (taking into account developments in practices, processes, and control technologies)” no less frequently than every 8 years. Under the “residual risk” provision of CAA section 112, EPA must evaluate the MACT standards within 8 years after promulgation and promulgate standards if required to provide an ample margin of safety to protect public health or prevent an adverse environmental effect. Section 111(b)(1)(B) of the CAA mandates that EPA review and, if appropriate, revise existing NSPS every 8 years. EPA will also remove startup, shutdown, and malfunction exemptions for these source categories, as required by recent court decisions.

**Statement of Need:**
This action addresses EPA's statutory obligations to perform Risk and Technology Reviews (RTR) and NSPS reviews for chemical sector MACT. It will address Clean Air Act (CAA) section 112(f)(2) to conduct residual risk reviews, section 112(d)(6) to conduct technology reviews, and section 111(b)(1)(B) to conduct NSPS reviews for multiple chemical sector source categories. Under the “technology review” provision of CAA section 112, EPA is required to review maximum achievable control technology (MACT) standards and to revise them "as necessary (taking into account developments in practices, processes, and control technologies)” no less frequently than every 8 years. Under the “residual risk” provision of
CAA section 112, EPA must evaluate the MACT standards within 8 years after promulgation and promulgate standards if required to provide an ample margin of safety to protect public health or prevent an adverse environmental effect. Under the CAA section 111, EPA must evaluate NSPS requirements and, if appropriate, revise existing NSPS every 8 years.

Summary of Legal Basis:

CAA sections 111 and 112

Alternatives:

Unavailable.

Anticipated Cost and Benefits:

We are currently estimating the costs and benefits associated with this action.

Risks:

We are currently assessing the risks associated with this action.

Timetable:

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Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Sectors Affected:

325 Chemical Manufacturing

Agency Contact:

Nick Parsons

Environmental Protection Agency
EPA

128. • NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR MAJOR SOURCES: INDUSTRIAL, COMMERCIAL, AND INSTITUTIONAL BOILERS AND PROCESS HEATERS; PROPOSED RECONSIDERATION

Priority:
Other Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect State, local or tribal governments and the private sector.

Legal Authority:
Clean Air Act sec 112

CFR Citation:
Legal Deadline: None

Abstract:
EPA estimates the total national capital cost for the proposed reconsideration rule to be approximately $5.4 billion in the year 2015, with a total national annual cost of $1.5 billion in the year 2015. The annual cost, which considers fuel savings, includes control device operation and maintenance, as well as monitoring, recordkeeping, reporting, and performance testing. EPA estimates that implementation of the rulemaking, as proposed, would reduce nationwide emissions from major source boilers and process heaters by: 1,000 to 3,600 pounds per year of mercury, 2,200 tpy of non-mercury metals, 37,000 tpy of HCl, 41,000 tpy of PM, 560,000 tpy of SO2, and 4,700 tpy of volatile organic compounds. These emissions reductions would lead to the following annual health benefits. In 2015, this rule will protect public health by avoiding 3,100 to 8,000 premature deaths, 2,000 cases of chronic bronchitis, 4,900 nonfatal heart attacks, 5,350 hospital and emergency room visits, 4,600 cases of acute bronchitis, 390,000 days when people miss work, 51,000 cases of aggravated asthma, and 96,000 acute respiratory symptoms. The monetized value of the benefits ranges from $27 billion to $67 billion in 2015—outweighing the costs by at least $25 billion.

Statement of Need:
As a result of the vacatur of the Industrial Boiler MACT, the Agency will develop another rulemaking under CAA section 112, which will reduce hazardous air pollutant (HAP) emissions from this source category. Recent court decisions on other CAA section 112 rules will be considered in developing this regulation.

Summary of Legal Basis:
Clean Air Act, section 112.

Alternatives:
Not yet determined.

Anticipated Cost and Benefits:
EPA estimates the total national capital cost for the final rule to be approximately $9.5 billion in the year 2013, with a total national annual cost of $2.9 billion in the year 2013. The annual cost, which considers fuel savings, includes control device operation and maintenance as well as monitoring, recordkeeping, reporting, and performance testing. EPA estimates that implementation of the rulemaking, as proposed, would reduce nationwide emissions from major source boilers and process heaters by: 15,000 pounds per year of mercury, 3,200 tons per year (tpy) of non-mercury metals, 37,000 tpy of HCl, 50,000 tpy of PM, 340,000 tpy of SO2, 722 grams per year of dioxin, and 1,800 tpy of volatile organic compounds. These emissions reductions would lead to the following annual health benefits. In 2013, this rule will protect public health by avoiding 1,900 to 4,800 premature deaths, 1,300 cases of chronic bronchitis, 3,000 nonfatal heart attacks, 3,200 hospital and emergency room visits, 3,000 cases of acute bronchitis, 250,000 days when people miss work, 33,000 cases of aggravated asthma, and 1,500,000 acute respiratory symptoms. The monetized value of the benefits ranges from $17 billion to $41 billion in 2013—outweighing the costs by at least $14 billion.

**Risks:**

Not yet determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses, Governmental Jurisdictions, Organizations

**Government Levels Affected:**

Federal, Local, State, Tribal

**Federalism:**

This action may have federalism implications as defined in EO 13132.
Additional Information:
Split from RIN 2060-AQ25. Split from RIN 2060-AM44. This rulemaking combines the area source rulemaking for boilers and the rulemaking for reestablishing the vacated NESHAP for boilers and process heaters. EPA Docket information: EPA-HQ-OAR-2002-0058

Sectors Affected:
325 Chemical Manufacturing; 611 Educational Services; 322 Paper Manufacturing; 221 Utilities; 321 Wood Product Manufacturing

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RIN: 2060–AR13
EPA

129. • NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FOR AREA SOURCES: INDUSTRIAL, COMMERCIAL, AND INSTITUTIONAL BOILERS; RECONSIDERATION AND PROPOSED RULE AMENDMENTS

Priority:
Other Significant

Legal Authority:
Clean Air Act sec 112

CFR Citation:
40 CFR 63

Legal Deadline:
Other, Statutory, April 30, 2012, Tentative date for promulgation of amendments to the rule.

Abstract:
On March 21, 2011, EPA issued a final rule establishing standards for emissions of hazardous air pollutants from boilers located at area sources. EPA also issued on March 21, 2011, a Notice of Reconsideration listing four issues for which additional opportunity for public review and comment should be obtained. Subsequently, we received petitions to reconsider and clarify and amend certain applicability and implementation provisions of the final rule. This action will propose the amendments after we analyze the information submitted in the petitions.

Statement of Need:
Section 307(d)(7)(B) of the CAA requires EPA to convene a proceeding for reconsideration of the rule if a person raising an objection to the rule can demonstrate to EPA that it was impracticable to raise such objection within the period for public comment or if the grounds for such objection arose after the period for public comment, and if such objection is of central relevance to the outcome of the rule.

Summary of Legal Basis:
Clean Air Act, section 112.

Alternatives:
Not yet determined.
**Anticipated Cost and Benefits:**

Cost and benefits numbers for the Boiler Area Source Rule (subpart JJJJJJ) are as follows.

Proposal: Total annualized costs = $1.0 billion. Total net monetized benefits = $0.5 billion to $1.9 billion (3% discount rate), $0.4 billion to $1.7 billion (7% discount rate). Non-monetized Benefits = 39,000 tons of carbon monoxide, 130 tons of HCl, 5 tons of HF, 0.75 tons of mercury, 250 tons of other metals, 470 grams of dioxins/furans. Additionally, health effects from NO2 and SO2 exposure diminish, as well as ecosystem effects and visibility impairment.

Final: Total annualized costs = $535 million. Total net monetized benefits = -$280 million to $30 million (3% discount rate), -$300 million to -$20 million (7% discount rate). Non-monetized Benefits = 1,100 tons of carbon monoxide, 340 tons of HCl, 8 tons of HF, 90 pounds of mercury, 320 tons of other metals, <1 gram of dioxins/furans (TEQ), health effects from SO2 exposure, ecosystem effects, visibility impairment.

**Risks:**

Not yet determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**
Sectors Affected:
611 Educational Services; 62 Health Care and Social Assistance; 44-45 Retail Trade; 321 Wood Product Manufacturing

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RIN: 2060–AR14

130. • STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES AND EMISSION GUIDELINES FOR EXISTING SOURCES: COMMERCIAL AND INDUSTRIAL SOLID WASTE INCINERATION UNITS; RECONSIDERATION AND PROPOSED AMENDMENTS
Priority:
Other Significant

Legal Authority:
42 USC 7401 et seq

CFR Citation:
40 CFR 60; 40 CFR 62

Legal Deadline:
None

Abstract:
On March 21, 2011, EPA issued a final rule establishing new source performance standards and emission guidelines for commercial and industrial solid waste incineration units. EPA also issued on March 21, 2011, a Notice of Reconsideration listing issues for which additional opportunity for public review and comment should be obtained. Subsequently, we received more than 15 petitions to reconsider, clarify, and amend certain provisions of the final rule. This action will propose the amendments after we analyze the information submitted in the petitions.

Statement of Need:
As a result of the vacatur of the CISWI definition and the remand of the CISWI rule, the Agency will develop another rulemaking under CAA section 129 that will reduce hazardous air pollutant (HAP) emissions from this source category. Recent court decisions on other rules will be considered in developing this regulation.

Summary of Legal Basis:
Clean Air Act, section 129

Alternatives:
Not yet determined

Anticipated Cost and Benefits:
EPA estimates the total national capital cost for the final rule to be approximately $706 million in the year 2013, with a total national annual cost of $280 million in the year 2013. The annual cost, which considers fuel savings, includes control device operation and maintenance as well as monitoring, recordkeeping,
reporting, and performance testing. EPA estimates that implementation of the rulemaking, as proposed, would reduce nationwide emissions from commercial and industrial solid waste incineration units by: 5,700 tons per year (tpy) of acid gases (i.e., hydrogen chloride and sulfur dioxide), 1,600 tpy of particulate matter, 23,000 tpy of carbon monoxide, 5,700 tpy of nitrogen oxides, and 5.5 tpy of metals (i.e., lead, cadmium, and mercury) and dioxins/furans. These emissions reductions would lead to the following annual health benefits. In 2013, this rule will protect public health by avoiding 40 to 100 premature deaths, 27 cases of chronic bronchitis, 64 nonfatal heart attacks, 68 hospital and emergency room visits, 65 cases of acute bronchitis, 1,350 cases of respiratory symptoms, 5,300 days when people miss work or school, 700 cases of aggravated asthma, and 31,000 days when people must restrict their activities. The monetized value of the benefits ranges from $360 to $870 million in 2013—outweighing the costs by at least $80 million.

**Risks:**

Not yet determined

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Additional Information:**


**Sectors Affected:**
325 Chemical Manufacturing; 334 Computer and Electronic Product Manufacturing; 3254 Pharmaceutical and Medicine Manufacturing; 321 Wood Product Manufacturing

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**RIN:** 2060–AR15

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**EPA**

**131. NPDES ELECTRONIC REPORTING RULE**

**Priority:**

Other Significant

**Legal Authority:**

CWA secs 304(i) and 501(a), 33 USC 1314(i) and 1361(a)
The EPA has responsibility to ensure that the Clean Water Act's (CWA) National Pollutant Discharge Elimination System (NPDES) program is effectively and consistently implemented across the country. This regulation would identify the essential information that EPA needs to receive electronically, primarily from NPDES permittees with some data required from NPDES agencies (NPDES-authorized States, territories, and tribes) to manage the national NPDES permitting and enforcement program. Through this regulation, EPA seeks to ensure that such facility-specific information would be readily available, accurate, timely, and nationally consistent on the facilities that are regulated by the NPDES program.

In the past, EPA primarily obtained this information from the Permit Compliance System (PCS). However, the evolution of the NPDES program since the inception of PCS has created an increasing need to better reflect a more complete picture of the NPDES program and the diverse universe of regulated sources. In addition, information technology has advanced significantly so that PCS no longer meets EPA's national needs to manage the full scope of the NPDES program or the needs of individual States that use PCS to implement and enforce the NPDES program.

**Statement of Need:**
As the NPDES program and information technology have evolved in the past several decades, the Permit Compliance System (PCS)—EPA's NPDES national data system, which has been in use since 1985—has become increasingly ineffective in meeting the full scope of EPA's and individual States' needs to manage, direct, oversee, and report on the implementation and enforcement of the NPDES program. Therefore, a NPDES component of EPA's existing Integrated Compliance Information System (ICIS), ICIS-NPDES, was designed and constructed based upon EPA and State input to manage data for the full breadth of the NPDES program. This rulemaking would identify essential NPDES-specific information EPA needs to receive from NPDES agencies (authorized States and tribes, as well as EPA regions). This
information would be sought in a format compatible with the new NPDES component of the Integrated Compliance Information System (ICIS) in order to better enable EPA to ensure the protection of public health and the environment, effectively manage the national NPDES permitting and enforcement program, identify and address environmental problems, and ultimately replace PCS. This action would be of interest primarily to NPDES permittees, NPDES-authorized States, and to the public at large, which would ultimately have increased access to this NPDES information.

**Summary of Legal Basis:**

In 1972, Congress passed the Clean Water Act to “restore and maintain the chemical, physical, and biological integrity of the Nation's waters.” 33 U.S.C. 1251(a). The Clean Water Act established a comprehensive program for protecting and restoring our Nation’s waters. The Clean Water Act prohibits the discharge of pollutants from a point source to waters of the United States except when authorized by a National Pollutant Discharge Elimination System (NPDES) permit. The Clean Water Act established the NPDES permit program to authorize and regulate the discharges of pollutants to waters of the United States. EPA has issued comprehensive regulations that implement the NPDES program at 40 CFR parts 122 to 125, 129 to 133, 136, and subpart N.

Under the NPDES permit program, point sources subject to regulation may discharge pollutants to waters of the United States subject to the terms and conditions of an NPDES permit. With very few exceptions (40 CFR 122.3), point sources require NPDES permit authorization to discharge, including both municipal and industrial discharges. NPDES permit authorization may be provided under an individual NPDES permit, which is developed after a process initiated by a permit application (40 CFR 122.21), or under a general NPDES permit, which among other things, applies to one or more categories of dischargers (e.g., oil and gas facilities, seafood processors) with the same or substantially similar types of operations and the same effluent limitations, operating conditions, or standards for sewage sludge use or disposal.

The U.S. Environmental Protection Agency has the primary responsibility to ensure that the NPDES program is effectively and consistently implemented across the country, thus ensuring that public health and environmental protection goals of the CWA are met. Many States and some territories have received
authorization to implement and enforce the NPDES program, and EPA works with its State partners to ensure effective program implementation and enforcement. CWA section 304(i)(2) directs EPA to promulgate guidelines establishing the minimum procedural and other elements of a State, territory, or tribal NPDES program, including monitoring requirements; reporting requirements (including procedures to make information available to the public); enforcement provisions; and funding, personnel qualifications, and manpower requirements [CWA sec. 304(i)(2)].

EPA published NPDES State, territory, and tribal program regulations under CWA section 304(i)(2) at 40 CFR part 123. Among other things, the part 123 regulations specify NPDES program requirements for permitting, compliance evaluation programs, enforcement authority, sharing of information, transmission of information to EPA, and noncompliance and program reporting to EPA.

This proposed rulemaking may add some specificity to those particular regulations regarding what NPDES information is required to be submitted to EPA by States and may modify other regulations to require electronic reporting of NPDES information by NPDES permittees to the States and EPA.

**Alternatives:**

For this proposed rulemaking, EPA has determined that the need for EPA's receipt of such NPDES information exists. If, for whatever reason, electronic reporting by permittees is not a feasible option for certain NPDES information, the obvious alternative would be for EPA to require States to provide that information to EPA. The States already receive that information from the permittees, and therefore, they have the information that EPA seeks.

Within the rulemaking process itself, various alternatives are under consideration based on the feasibility of particular electronic reporting options. For example, EPA may consider establishing requirements for electronic reporting of discharge monitoring reports by NPDES permittees. Under this proposed rulemaking, EPA may consider establishing similar requirements for any or all of the following types of NPDES information: Notices of Intent to discharge (for facilities seeking coverage under general permits), permitting information (including permit applications), various program reports (e.g., pretreatment...
compliance reports from approved local pretreatment programs, annual reports from concentrated animal feeding operations, biosolids reports, sewage overflow incident reports, annual reports for pesticide applicators, annual reports for municipal stormwater systems), and annual compliance certifications.

Some States might also raise the possibility of supplying only summary-level information to EPA rather than facility-specific information to EPA. Based upon considerable experience, EPA considers such alternative non-facility-specific data to be insufficient to meet its needs, except in very particular situations or reports.

One alternative that EPA may consider for rule implementation is whether third-party vendors may be better equipped to develop and modify such electronic reporting tools than EPA.**

**Anticipated Cost and Benefits:**
The economic analysis for this proposed rulemaking has not yet been completed; therefore, the dollar values of estimated costs and benefits are not yet known. However, some generalizations can still be made regarding expectations. EPA anticipates that electronic reporting of discharge monitoring reports (DMRs) by NPDES permittees will provide significant data entry cost savings for States and EPA. These discharge monitoring reports are already required to be submitted by NPDES permittees to States and EPA, which in turn currently enter that information into the State NPDES data system or EPA's national NPDES data system. These discharge monitoring reports contain significant amounts of information regarding pollutants discharged, identified concentrations and quantities of pollutants, discharge locations, etc. Through electronic reporting by permittees, States and EPA will no longer have associated data entry costs to enter this information. Electronic reporting by NPDES permittees of other NPDES information (such as notices of intent to discharge or various program reports) may also yield considerable data entry savings to the States and EPA. In addition, some States have been able to quantify savings by the permittees to electronically report their NPDES information using existing electronic reporting tools. Such savings are being examined in the economic analysis process for this rulemaking.
Additional benefits of this rule will likely include improved transparency of information regarding the NPDES program, improved information regarding the national NPDES program, improved targeting of resources and enforcement based on identified program needs and noncompliance problems, and ultimately improved protection of public health and the environment.

Some NPDES information will need to be reported by States to EPA; therefore, there will be some data entry costs associated with that information, but it will likely be far less than the savings that will be realized by States through electronic reporting by NPDES permittees. In addition, EPA will likely have sizable costs to develop tools for electronic reporting by permittees, as well as operation and maintenance costs associated with those tools.

**Risks:**

Given the scope of this proposed rulemaking, the most significant risks associated with this effort may be those if EPA does not proceed with this rulemaking. At this point, EPA does not receive sufficient NPDES information from the States to be able to fully assess the implementation of the national NPDES program nor the smaller subprograms. Such information is not currently required by EPA from the States, and the lack of such reporting requirements perpetuates this problem. Furthermore, EPA does not have facility-specific information regarding most of the facilities regulated under the NPDES program, and therefore, EPA cannot easily identify potential implementation problems or noncompliance problems. This lack of information may adversely impact EPA’s ability to better ensure the protection of public health and the environment, nationally and locally.

A potential risk associated with this rule may involve EPA efforts to develop electronic reporting tools for use by permittees. The costs associated with the internal development of such tools, possibly for multiple types of NPDES information from various types of NPDES permittees, and the future costs of operation and maintenance may be substantial for EPA, possibly impacting the availability of funding for other purposes. Furthermore, EPA would also need to determine the feasibility of ensuring that the electronic tools can be flexible enough to meet state needs and work well with State data systems. Problems in the
development and maintenance of these electronic tools could pose significant risks for the effective implementation of this rule.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
State

Federalism:
This action may have federalism implications as defined in EO 13132.

Additional Information:
SAN No. 5251

URL For More Information:
http://www.regulations.gov/exchange/topic/npdes

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132. PESTICIDES; CERTIFICATION OF PESTICIDE APPLICATORS

Priority:
Other Significant

Legal Authority:
7 USC 136; 7 USC 136i; 7 USC 136w

CFR Citation:
40 CFR 171; 40 CFR 156

Legal Deadline:
None

Abstract:
EPA is proposing change to the Federal regulations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that guide the certified pesticide applicator program (40 CFR 171). Change is sought to strengthen the regulations to better protect pesticide applicators and the public and the environment from harm due to pesticide exposure. The possible need for change arose from EPA discussions with key stakeholders. EPA has been in extensive discussions with stakeholders since 1997 when the Certification and Training Assessment Group (CTAG) was established. CTAG is a forum used by regulatory and academic stakeholders to discuss the current state of, and the need for improvements
in, the national certified pesticide applicator program. Throughout these extensive interactions with stakeholders, EPA has learned of the potential need for changes to the regulation.

Statement of Need:

These regulations have been in place since 1972. Since then, many States have advanced the existing requirements to better protect applicators, the public, and the environment. The Agency is proposing revisions to establish a more protective national standard.

Summary of Legal Basis:


Alternatives:

The Agency has developed mechanisms to improve applicator trainers and make training materials more accessible. The Agency has also developed nationally relevant training and certification materials to preserve State resources.

Anticipated Cost and Benefits:

Costs and benefits from the proposed rule are being prepared.

Risks:

Applicators are at risk from exposure to pesticides they handle for their work. The public and the environment may also be at risk from misapplication by non-competent applicators. Revisions to the regulations are expected to minimize these risks by ensuring the competency of certified applicators.

Timetable:

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Regulatory Flexibility Analysis Required:

Undetermined

Small Entities Affected:

Businesses

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:
Sectors Affected:

9241 Administration of Environmental Quality Programs; 112 Animal Production; 111 Crop Production; 1132 Forest Nurseries and Gathering of Forest Products; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 5617 Services to Buildings and Dwellings; 115 Support Activities for Agriculture and Forestry

URL For More Information:

http://www.epa.gov/pesticides/health/worker.htm

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RIN: 2070–AJ20
133. PESTICIDES; AGRICULTURAL WORKER PROTECTION STANDARD REVISIONS

Priority:
Other Significant

Legal Authority:
7 USC 136; 7 USC 136w

CFR Citation:
40 CFR 170

Legal Deadline:
None

Abstract:
EPA is developing a proposal under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to revise the Federal regulations guiding agricultural worker protection (40 CFR 170). The changes under consideration are intended to improve agricultural workers’ ability to protect themselves from potential exposure to pesticides and pesticide residues. In addition, EPA is proposing to make adjustments to improve and clarify current requirements and facilitate enforcement. Other changes sought are to bring hazard communication requirements more in line with OSHA requirements and make improvements to pesticide safety training, with improved worker safety the intended outcome. The potential need for change arose from EPA discussions with key stakeholders beginning in 1996 and continuing through 2004. EPA held nine public meetings throughout the country, during which the public submitted written and verbal comments on issues of their concern. In 2000 through 2004, EPA held meetings where invited stakeholders identified their issues and concerns with the regulations.

Statement of Need:
Stakeholders have identified gaps in the protections in the current regulation. Revisions to the rule are necessary to better protect agricultural workers and pesticide handlers from unreasonable adverse effects of pesticide exposure.

Summary of Legal Basis:
Alternatives:
Wherever deficiencies in the existing regulation could be adequately addressed through non-regulatory means, EPA has done so. For example, the Agency has developed improved training materials that are sector-specific and in multiple languages; improved capacity for outreach; a train-the-trainer program; health care practitioner (HCP) curricula to train HCPs on pesticide exposure identification and treatment; and a bilingual manual for HCPs to use in identifying pesticide poisonings. The Agency also provides financial support for pesticide safety training.

Anticipated Cost and Benefits:
Incremental costs to agricultural employers are expected to increase as a result of revised requirements for training, notification, and other protections. Incremental costs to commercial pesticide handler employers are expected to decrease. Benefits will accrue to workers’ and handlers’ health, and improved protection of children is expected to be realized from the proposed revisions.

Risks:
Agricultural workers and pesticide handlers are at risk from pesticide exposure through their work activities, and may put their families at risk of secondary exposure. In order to address exposure risks to workers, pesticide handlers, and their families, the Agency is proposing revisions identified by stakeholders and the public.

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
Businesses

Government Levels Affected:
Federal, State, Tribal

Additional Information:
EPA Docket information: EPA-HQ-OPP-2005-0561

**Sectors Affected:**

111 Crop Production; 32532 Pesticide and Other Agricultural Chemical Manufacturing; 115 Support Activities for Agriculture and Forestry

**URL For More Information:**

http://www.epa.gov/pesticides/health/worker.htm

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**RIN:** 2070–AJ22
134. FORMALDEHYDE; THIRD–PARTY CERTIFICATION FRAMEWORK FOR THE FORMALDEHYDE STANDARDS FOR COMPOSITE WOOD PRODUCTS

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:
Undetermined

Legal Authority:
15 USC 2697; TSCA sec 601

CFR Citation:
Not Yet Determined

Legal Deadline:
Final, Statutory, January 1, 2013.

Abstract:
In 2008, EPA initiated a proceeding under Toxics Substance and Control Act (TSCA) to investigate risks posed by formaldehyde emitted from pressed wood products. An advance notice of proposed rulemaking (ANPRM) sought to engage stakeholders to contribute to obtaining a better understanding of the available control technologies and approaches, industry practices, and the implementation of California's formaldehyde emission limits. Subsequently, EPA developed an industry survey to obtain more information on these ANPRM topics and continued to assess the hazards of and exposures to formaldehyde emissions from pressed wood products. On July 7, 2010, the Formaldehyde Standards for Composite Wood Products Act was enacted. This law amends TSCA to establish specific formaldehyde emission limits for hardwood plywood, particleboard, and medium-density fiberboard, which limits are identical to the California emission limits for these products. The law further requires EPA to promulgate implementing regulations by January 1, 2013. This rulemaking covers the mandate for EPA to promulgate regulations to address requirements for accrediting bodies and third-party certifiers. A separate regulatory agenda entry (RIN 2070-tbd) covers the mandate for EPA to promulgate regulations to implement the statutory formaldehyde emission standards for hardwood plywood, medium-density fiberboard, and particleboard sold, supplied, offered for sale, or manufactured (including imported) in the United States.
**Statement of Need:**
EPA is concerned about the human health risks that may be presented by exposure to formaldehyde emissions from composite wood products, because formaldehyde is a probable human carcinogen and an eye, nose, and throat irritant.

**Summary of Legal Basis:**
TSCA title VI

**Alternatives:**
TSCA title VI establishes national formaldehyde emission limits for hardwood plywood, particleboard, and medium-density fiberboard, and EPA has not been given the authority to change the limits. However, EPA will evaluate various implementation alternatives during the course of this rulemaking.

**Anticipated Cost and Benefits:**
EPA is currently evaluating the costs and benefits of this action.

**Risks:**
EPA is currently evaluating the risks presented by exposure to formaldehyde emissions in excess of the statutory limits.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Yes

**Small Entities Affected:**
Businesses

**Government Levels Affected:**
Undetermined
Federalism:
Undetermined

International Impacts:
This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Additional Information:
EPA publication information: ANPRM -

Sectors Affected:
325199 All Other Basic Organic Chemical Manufacturing; 423110 Automobile and Other Motor Vehicle Merchant Wholesalers; 4441 Building Material and Supplies Dealers; 42321 Furniture Merchant Wholesalers; 4421 Furniture Stores; 337 Furniture and Related Product Manufacturing; 42331 Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers; 45393 Manufactured (Mobile) Home Dealers; 321991 Manufactured Home (Mobile Home) Manufacturing; 336213 Motor Home Manufacturing; 423390 Other Construction Material Merchant Wholesalers; 325211 Plastics Material and Resin Manufacturing; 321992 Prefabricated Wood Building Manufacturing; 441210 Recreational Vehicle Dealers; 336214 Travel Trailer and Camper Manufacturing; 3212 Veneer, Plywood, and Engineered Wood Product Manufacturing

URL For More Information:
http://www.epa.gov/opptintr/chemtest/formaldehyde/index.html

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135. MERCURY; REGULATION OF USE IN CERTAIN PRODUCTS

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Unfunded Mandates:
Undetermined

Legal Authority:
15 USC 2605

CFR Citation:
40 CFR 750

Legal Deadline:
None

Abstract:
Elemental mercury is well documented as a toxic, environmentally persistent substance that is atmospherically transported on a local, regional, and global scale. In addition, mercury can be environmentally transformed into methylmercury, which bioaccumulates, biomagnifies, and is highly toxic. EPA conducted a preliminary analysis of the costs, advantages, and disadvantages associated with
mercury-free alternatives to certain mercury-containing products, and made a preliminary judgment that effective and economically feasible alternatives exist. These mercury-containing products include switches, relays/contactors, flame sensors, and button cell batteries. Therefore, EPA is evaluating whether an action (or combination of actions) under Toxic Substances Control Act (TSCA) is appropriate for mercury used in such products. As appropriate, such an action(s) would involve a group(s) of these products. Specifically, EPA will determine whether the continued use of mercury in one or more of these products would pose an unreasonable risk to human health and the environment.

**Statement of Need:**

Elemental mercury is well documented as a toxic, environmentally persistent substance that is atmospherically transported on a local, regional, and global scale. In addition, mercury can be environmentally transformed into methylmercury, which bioaccumulates, biomagnifies, and is highly toxic. Human health risks associated with elemental mercury and methylmercury are well documented. Humans can be exposed to mercury in products directly through inhalation of elemental mercury vapor and indirectly through ingestion of fish contaminated with methylmercury. EPA conducted a preliminary analysis of the costs, advantages, and disadvantages associated with mercury-free alternatives to certain mercury-containing products, and made a preliminary judgment that effective and economically feasible alternatives exist. In its initial analysis of mercury in certain products, EPA considered mercury’s well-documented toxicity, persistence, ability to bioaccumulate, ability to be environmentally transformed into methylmercury, and its demonstrated ability to be transported globally, as well as locally. EPA also considered the availability of effective and economically feasible alternatives for mercury in certain products. EPA believes manufacturing, processing, use, or disposal of elemental mercury in these products may result in significant potential for human and environmental exposures to elemental mercury and methylmercury.

**Summary of Legal Basis:**

EPA is evaluating whether an action (or combination of actions) under Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 et seq., is appropriate for mercury used in certain products. TSCA provides EPA with authority to require reporting, recordkeeping, and testing requirements, and restrictions relating to chemical substances and/or mixtures. Specifically, section 4 authorizes EPA to require testing of
chemicals by manufacturers, importers, and processors where risks or exposures of concern are found. Section 5 authorizes EPA to require prior notice by manufacturers, importers, and processors when it identifies a "significant new use" that could result in exposures to, or releases of, a substance of concern. Section 6 gives EPA the authority to protect against unreasonable risk of injury to health or the environment from chemical substances. If EPA finds that there is a reasonable basis to conclude that the chemical's manufacture, processing, distribution, use or disposal presents an unreasonable risk, EPA may by rule take action to: Prohibit or limit manufacture, processing, or distribution in commerce; prohibit or limit the manufacture, processing, or distribution in commerce of the chemical substance above a specified concentration; require adequate warnings and instructions with respect to use, distribution, or disposal; require manufacturers or processors to make and retain records; prohibit or regulate any manner of commercial use; prohibit or regulate any manner of disposal; and/or require manufacturers or processors to give notice of the unreasonable risk of injury, and to recall products if required. Section 8 authorizes EPA to require reporting and recordkeeping by persons who manufacture, import, process, and/or distribute chemical substances in commerce.

Alternatives:
EPA conducted a preliminary analysis of the costs, advantages, and disadvantages associated with mercury-free alternatives to certain mercury-containing products, and made a preliminary judgment that effective and economically feasible alternatives exist.

Anticipated Cost and Benefits:
As part of the economic, exposure, and risk assessment to support the current action, EPA is conducting a comprehensive use-substitute analysis and industry profile that will consider the costs and benefits of an action (or combination of actions) under Toxic Substances Control Act (TSCA). Those assessments consider the costs of mercury-containing and mercury-free alternatives and the impact that any action would have on potentially affected stakeholders, including economic, human health, and environmental criteria.

Risks:
As part of the economic, exposure, and risk assessment to support the current action, EPA is conducting a comprehensive use-substitute analysis and industry profile that will consider the risks associated with
an action (or combination of actions) under Toxic Substances Control Act (TSCA). Those assessments consider the relative toxicity and other considerations associated with mercury-free alternatives to mercury-containing products and the impact that any action would have on potentially affected stakeholders, including economic, human health, and environmental criteria.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Undetermined

**Government Levels Affected:**

Undetermined

**Federalism:**

Undetermined

**International Impacts:**

This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

**Additional Information:**

SAN No. 5312

**Sectors Affected:**

325188 All Other Basic Inorganic Chemical Manufacturing

**URL For More Information:**

http://www.epa.gov/mercury/

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136. LEAD; RENOVATION, REPAIR, AND PAINTING PROGRAM FOR PUBLIC AND COMMERCIAL BUILDINGS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
15 USC 2682(c)(3)

CFR Citation:
40 CFR 745

Legal Deadline:
Other, Judicial, April 22, 2010, Advance Notice of Proposed Rulemaking, deadline from settlement agreement.
Final, Judicial, February 15, 2014, Deadline from settlement agreement and subsequent renegotiation with litigants.

Abstract:
Section 402(c)(3) of the Toxic Substances Control Act (TSCA) requires EPA to regulate renovation or remodeling activities in target housing (most pre-1978 housing), pre-1978 public buildings, and commercial buildings that create lead-based paint hazards. On April 22, 2008, EPA issued a final rule to address lead-based paint hazards created by these activities in target housing and child-occupied facilities built before 1978 (child-occupied facilities are a subset of public and commercial buildings or facilities where children under age 6 spend a great deal of time). The 2008 rule established requirements for training renovators, other renovation workers, and dust sampling technicians; for certifying renovators, dust sampling technicians, and renovation firms; for accrediting providers of renovation and dust sampling technician training; for renovation work practices; and for recordkeeping. This new rulemaking will address renovation or remodeling activities in the remaining buildings described in TSCA section 402(c)(3): Public buildings built before 1978 and commercial buildings that are not child-occupied facilities. On May 6, 2010, EPA announced the commencement of proceedings to propose lead-safe work practices and other requirements for renovations on the exteriors of public and commercial buildings and to determine whether lead-based paint hazards are created by interior renovation, repair, and painting projects in public and commercial buildings. For those renovations in the interiors of public and commercial buildings that create lead-based paint hazards, EPA will propose regulations to address these hazards.

Statement of Need:
This rulemaking is being undertaken in response to a settlement agreement and is designed to help insure that individuals and firms conducting renovation, repair, and painting activities in and on public and commercial buildings will do so in a way that safeguards the environment and protects the health of building occupants and nearby residents, especially children under 6 years old. Lead is known to cause deleterious health effects on multiple organ systems through diverse mechanisms of action in both adults
and children. This array of health effects includes effects on heme biosynthesis and related functions, neurological development and function, reproduction and physical development, kidney function, cardiovascular function, and immune function. EPA has conducted several studies and reviewed additional information that indicates that the renovation of buildings containing lead-based paint can create health hazards in the form of lead-based paint dust under typical industry work practices.

**Summary of Legal Basis:**

Section 402(c)(3) of the Toxic Substances Control Act (TSCA) requires EPA to regulate renovation or remodeling activities that create lead-based paint hazards in target housing, public buildings built before 1978, and commercial buildings.

**Alternatives:**

For those activities that EPA determines create lead-based paint hazards, EPA will evaluate options to address the hazards. These options are likely to include different combinations of work practices and worker training and certification.

**Anticipated Cost and Benefits:**

Not yet determined.

**Risks:**

Not yet determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses
Government Levels Affected:
Undetermined

Federalism:
Undetermined

Additional Information:
EPA publication information: ANPRM -
http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480ae7eb8; EPA Docket
information: EPA-HQ-OPPT-2010-0173

Sectors Affected:
236 Construction of Buildings; 921 Executive, Legislative, and Other General Government Support;
561210 Facilities Support Services; 531 Real Estate; 238 Specialty Trade Contractors

URL For More Information:
http://www.epa.gov/lead/pubs/renovation.htm

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137. REVISIONS TO THE NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN; SUBPART J PRODUCT SCHEDULE LISTING REQUIREMENTS

Priority:
Other Significant

Legal Authority:
33 USC 1321(d)(2); 33 USC 1321(b)(3); CWA 311(d)(2)

CFR Citation:
40 CFR 300; 40 CFR 110

Legal Deadline:
None

Abstract:
EPA is considering proposing revisions to subpart J of the National Contingency Plan (NCP). The Clean Water Act requires EPA to prepare a schedule of dispersants, other chemicals, and other spill mitigating devices and substances, if any, that may be used in carrying out the NCP. Under subpart J, respondents wishing to add a product to the Product Schedule must submit technical product data to EPA. The Agency is considering revisions to subpart J to clarify and/or change the effectiveness and toxicity testing protocols required for adding a product to the Schedule. These changes, if finalized, will help ensure protection of the environment when these products are used to clean up and mitigate oil spills (1) into or upon navigable waters, adjoining shorelines, or the waters of the contiguous zone, or (2) which may affect natural resources belonging to or under the exclusive management authority of the United States. Further, the Agency is considering proposed changes to 40 CFR 110.4 regarding the use of dispersants.

Statement of Need:
The unprecedented use of dispersants on the surface and in the subsea during the 2010 Deepwater Horizon oil spill in the Gulf of Mexico raised many questions about dispersant efficacy, toxicity,
environmental fate, and monitoring. The public and officials working at local, State, and Federal levels expressed concerns regarding the effects of dispersant use on the ecosystem. These concerns require a review of the product toxicity and efficacy testing and application in the current subpart J regulatory requirements. Additionally, the large-scale submission of oil-mitigating technologies through the Interagency Alternative Technology Assessment Program (IATAP) as a result of this incident also highlights the need to re-evaluate the current subpart J regulations, particularly the technical data requirements.

**Summary of Legal Basis:**
The Federal Water Pollution Control Act (FWPCA) requires the President to prepare and publish a National Contingency Plan (NCP) for the removal of oil and hazardous substances. In turn, the President delegated the authority to implement this section of the FWPCA to EPA through Executive Order 12777 (56 FR 54757; Oct. 22, 1991). Section 311(d)(2)(G)(i) of the FWPCA (a.k.a., Clean Water Act), as amended by the OPA, requires that the NCP include a schedule identifying “dispersants, other chemicals, and other spill mitigating devices and substances, if any, that may be used in carrying out” the NCP.

Currently, the use of dispersants, other chemicals, and other oil spill mitigating devices and substances (e.g., bioremediation agents) to respond to oil spills in U.S. waters is governed by subpart J of the NCP (40 CFR part 300 series 900).

**Alternatives:**
To be determined.

**Anticipated Cost and Benefits:**
To be determined.

**Risks:**
To be determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Undetermined

Small Entities Affected:
Businesses

Government Levels Affected:
Federal, Local, State, Tribal

Additional Information:
Includes Retrospective Review under E.O.13563.

Sectors Affected:
3251 Basic Chemical Manufacturing; 325 Chemical Manufacturing; 3259 Other Chemical Product and Preparation Manufacturing; 54 Professional, Scientific, and Technical Services

URL For More Information:
www.epa.gov/oilspill

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RIN: 2050–AE87

138. STORMWATER REGULATIONS REVISION TO ADDRESS DISCHARGES FROM DEVELOPED SITES

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
33 USC 1251 et seq

CFR Citation:
Not Yet Determined

Legal Deadline:


Abstract:
Stormwater discharge from developed areas is a major cause of degradation of surface waters. This is true for both conveyance of pollutants and the erosive power of increased stormwater flow rates and volumes. Current stormwater regulations were promulgated in 1990 and 1999. In 2006, the Office of Water asked the National Research Council (NRC) to review the stormwater program and recommend ways to strengthen it. The NRC Report, which was finalized in October 2008, found that the current stormwater program “. . .is not likely to adequately control stormwater's contribution to waterbody impairment” and recommended that EPA take action to address the harmful effects of stormwater flow.
This proposed action would establish requirements for, at minimum, managing stormwater discharges from newly developed and re-developed sites, to reduce the amount of pollutants in stormwater discharges entering receiving waters by reducing the discharge of excess stormwater. EPA may take other actions to implement improved control of stormwater pollution and more efficient rainwater use. The Phase I and Phase II MS4 regulations might also be combined and amended, and may include provisions for better managing existing discharges.

**Statement of Need:**

Section 402(p) of the Clean Water Act requires EPA to regulate certain stormwater discharges. Stormwater is a primary contributor of water quality impairment. There is a need to strengthen the stormwater program’s effectiveness by reducing pollutant loading from currently regulated and unregulated stormwater discharges and preserving surface water health and integrity. This action was informed by the 2006 National Research Council report.

**Summary of Legal Basis:**

Section 402(p) of the Clean Water Act requires EPA to regulate certain discharges from stormwater in order to protect water quality.

**Alternatives:**

To be determined.

**Anticipated Cost and Benefits:**

To be determined.

**Risks:**

To be determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**
Businesses, Governmental Jurisdictions

**Government Levels Affected:**
Federal, Local, State

**Federalism:**
Undetermined

**Additional Information:**
EPA Docket information: EPA-HQ-OW-2009-0817

**URL For More Information:**
www.epa.gov/npdes/stormwater/rulemaking

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**RIN:** 2040–AF13
Abstract:
EPA establishes national technology-based regulations, called effluent guidelines, to reduce discharges of pollutants from industries to waters of the U.S. These requirements are incorporated into National Pollutant Discharge Elimination System (NPDES) discharge permits issued by EPA and States, and through the national pretreatment program. The steam electric effluent guidelines apply to steam electric power plants using nuclear or fossil fuels, such as coal, oil, and natural gas. There are about 1,200 nuclear- and fossil-fueled steam electric power plants nationwide; approximately 500 of these power plants are coal fired. In a study completed in 2009, EPA found that the current regulations, which were last updated in 1982, do not adequately address the pollutants being discharged and have not kept pace with changes that have occurred in the electric power industry over the last 3 decades. The rulemaking will address discharges from ash ponds and flue gas desulfurization (FGD) air pollution controls, as well as other power plant waste streams. Power plant discharges can have major impacts on water quality, including reduced organism abundance and species diversity, contamination of drinking water sources,
and other effects. Pollutants of concern include metals (e.g., mercury, arsenic and selenium), nutrients, and total dissolved solids.

**Statement of Need:**

EPA’s decision to proceed with a rulemaking was announced on September 15, 2009. EPA reviewed wastewater discharges from power plants and the treatment technologies available to reduce pollutant discharges, which demonstrated the need to update the current effluent guidelines (40 CFR 423). The current regulations, which were last updated in 1982, do not adequately address the pollutants being discharged and have not kept pace with changes that have occurred in the electric power industry over the last 3 decades. Steam electric power plants are responsible for a significant amount of the toxic pollutant loadings discharged to surface waters by point sources, and coal ash ponds and flue gas desulfurization (FGD) systems are the source of much of these pollutants.

**Summary of Legal Basis:**

Section 301(b)(2) of the Clean Water Act requires EPA to promulgate effluent limitations for categories of point sources, using technology-based standards that govern the sources’ discharge of certain pollutants. 33 U.S.C. section 1311(b). Section 304(b) of the Act directs EPA to develop effluent limitations guidelines (ELGs) that identify certain technologies and control measures available to achieve effluent reductions for each point source category, specifying factors to be taken into account in identifying those technologies and control measures. 33 U.S.C. section 1314(b). Since the 1970s, EPA has formulated effluent limitations and ELGs in tandem through a single administrative process. Am. Frozen Food Inst. v. Train, 539 F.2d 107 (D.C. Cir. 1976). The CWA also requires EPA to perform an annual review of existing ELGs and to revise them, if appropriate. 33 U.S.C. section 1314(b); see also 33 U.S.C. section 1314(m)(1)(A). EPA originally established effluent limitations and guidelines for the steam electric generating industry in 1974 and last updated them in 1982. 47 FR 52290 (Nov. 19, 1982). As described above, EPA determined the existing regulations do not adequately address the pollutants being discharged and that revisions are appropriate.

**Alternatives:**

To be determined.

**Anticipated Cost and Benefits:**
To be determined.

**Risks:**
To be determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Undetermined

**Small Entities Affected:**
Businesses, Governmental Jurisdictions

**Government Levels Affected:**
Undetermined

**Federalism:**
Undetermined

**Additional Information:**
EPA Docket information: EPA-HQ-OW-2009-0819

**Sectors Affected:**
221112 Fossil Fuel Electric Power Generation; 221113 Nuclear Electric Power Generation

**URL For More Information:**
http://water.epa.gov/scitech/wastetech/guide/steam_index.cfm

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140. NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) CONCENTRATED
ANIMAL FEEDING OPERATION (CAFO) REPORTING RULE

Priority:
Other Significant

Legal Authority:
33 USC 1251(a); 33 USC 1311(a); 33 USC 1342; 33 USC 1362(14); 33 USC 1318(a); 33 USC 1319

CFR Citation:
40 CFR 122

Legal Deadline:
None

Abstract:
EPA proposed a regulation that would collect information about concentrated animal feeding operations (CAFOs). CAFOs are a significant source of nutrient pollution and pathogens in U.S. watersheds. The information that would be collected under the proposed rule would allow EPA to increase water quality
protection through better implementation of the NPDES permitting program for CAFOs. The proposed regulation would apply to all permitted and unpermitted CAFOs. EPA co-proposed a regulation that would only collect information from CAFOs in targeted areas, if EPA determined such collection was necessary based on specified factors, such as water quality concerns.

**Statement of Need:**

The proposed rule would collect facility-specific information about CAFOs to help inform watershed management activities. This will enhance EPA's ability to effectively implement the NPDES program.

**Summary of Legal Basis:**

The proposed rule would collect facility-specific information about CAFOs to help inform watershed management activities. This will enhance EPA's ability to effectively implement the NPDES program and reduce pathogens from CAFOs.

**Alternatives:**

EPA proposed a number of alternatives including relying on existing information to collect information from CAFOs.

**Anticipated Cost and Benefits:**

Not yet determined.

**Risks:**

Not yet determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**
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RIN: 2040–AF22

141. NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM (NPDES) APPLICATION AND PROGRAM UPDATES RULE

Priority:
Other Significant

Legal Authority:
33 USC 1251 et seq

CFR Citation:
Not Yet Determined
Legal Deadline:
None

Abstract:
EPA plans to propose regulations that would update specific elements of the existing National Pollutant Discharge Elimination System (NPDES) in order to better harmonize regulations and application forms, improve permit documentation and transparency and provide clarifications to the existing regulations. In this effort, EPA plans to address application, permitting, monitoring, and reporting requirements that have become obsolete or outdated due to programmatic, technical, or other changes that have occurred over the past 35 years. Specifically, EPA plans to focus on revising the NPDES permit application forms to specifically include all final Agency data standards, improving the consistency between the application forms, and updating the applications to better reflect current program practices, and specifically to incorporate new program areas into the forms (e.g., Clean Water Act section 316(b) requirements for cooling water intake structures). EPA also plans to address other program elements, including permit documentation, EPA State permit objection, and public participation procedures to improve the quality and transparency of permit development. As an example of a regulation which could be proposed to change to reduce burden, as well as improve transparency and public access to information, EPA is considering whether to revise the public notice requirements to allow a State to post notices of draft NPDES permits and other permit actions under the Clean Water Act on their State agency Web sites in lieu of traditional newspaper posting.

Statement of Need:
Certain application, permitting, monitoring, and reporting requirements need to be updated to reflect programmatic and technical changes that have occurred over the past 35 years.

Summary of Legal Basis:
33 U.S.C. 1251 et seq.

Alternatives:
Not yet determined.

Anticipated Cost and Benefits:
Not yet determined.
Risks:
Not yet determined.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
Federal, Local, State, Tribal

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RIN: 2040–AF25

EPA FINAL RULE STAGE

142. REVIEW OF THE SECONDARY NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OXIDES OF NITROGEN AND OXIDES OF SULFUR

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
42 USC 7408; 42 USC 7409

CFR Citation:
40 CFR 50

Legal Deadline:
NPRM, Judicial, July 12, 2011.
Final, Judicial, March 20, 2012, The court has approved the amendments to the consent decree incorporating the revised dates.

Abstract:
Under the Clean Air Act, EPA is required to review and, if appropriate, revise the air quality criteria for the primary (health-based) and secondary (welfare-based) national ambient air quality standards (NAAQS) every 5 years. On October 11, 1995, EPA published a final rule not to revise either the primary or secondary NAAQS for nitrogen dioxide (NO2). On May 22, 1996, EPA published a final decision that revisions of the primary and secondary NAAQS for sulfur dioxide (SO2) were not appropriate at that time, aside from several minor technical changes. On December 9, 2005, EPA's Office of Research and Development (ORD) initiated the current periodic review of NO2 air quality criteria with a call for information in the Federal Register (FR). On May 3, 2006, ORD initiated the current periodic review of SO2 air quality criteria with a call for information in the FR. Subsequently, the decision was made to review the oxides of nitrogen and the oxides of sulfur together, rather than individually, with respect to a
secondary welfare standard for NO2 and SO2. This decision derives from the fact that NO2, SO2, and their associated transformation products are linked from an atmospheric chemistry perspective, as well as from an environmental effects perspective, most notably in the case of secondary aerosol formation and acidification in ecosystems. This review includes the preparation of an Integrated Science Assessment (ISA), Risk/Exposure Assessment (REA), and a Policy Assessment Document (PAD) by EPA, with opportunities for review by EPA's Clean Air Scientific Advisory Committee and the public. These documents inform the Administrator's proposed decision as to whether to retain or revise the standards. It should be noted that this review will be limited to only the secondary standards; the primary standards for SO2 and NO2 were reviewed separately. The ISA, REA, and PAD have been completed, and a notice of proposed rulemaking was signed on July 12, 2011. The court ordered date for the final rule to be signed is March 20, 2012.

**Statement of Need:**

As established in the Clean Air Act, the national ambient air quality standards for oxides of nitrogen and oxides of sulfur are to be reviewed every 5 years.

**Summary of Legal Basis:**

Section 109 of the Clean Air Act (42 U.S.C. 7409) directs the Administrator to propose and promulgate “primary” and “secondary” national ambient air quality standards for pollutants identified under section 108 (the “criteria” pollutants). The “primary” standards are established for the protection of public health, while “secondary” standards are to protect against public welfare or ecosystem effects.

**Alternatives:**

The main alternatives for the Administrator's decision on the review of the national ambient air quality standards for oxides of nitrogen and oxides of sulfur are whether to retain or revise the existing standards.

**Anticipated Cost and Benefits:**

The Clean Air Act makes clear that the economic and technical feasibility of attaining standards are not to be considered in setting or revising the NAAQS, although such factors may be considered in the development of State plans to implement the standards. Accordingly, the Agency prepares cost and benefit information in order to provide States information that may be useful in considering different
implementation strategies for meeting proposed or final standards. Cost and benefit information is not
developed to support a NAAQS rulemaking until sufficient policy and scientific information is available to
narrow potential options for the form and level associated with any potential revisions to the standard.
Therefore, work on developing the plan for conducting the cost and benefit analysis will generally start 1
1/2 to 2 years following the start of a NAAQS review.

Risks:
During the course of this review, risk assessments may be conducted to evaluate public welfare risks
associated with retention or revision of the NOx/SOx secondary standards.

Timetable:

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Regulatory Flexibility Analysis Required:

No

Small Entities Affected:

No

Government Levels Affected:

Federal, Local, State, Tribal

Additional Information:

EPA publication information: NPRM -

http://www.regulations.gov/#!documentDetail;D=EPA_FRDOC_0001-10843; EPA Docket information:

EPA-HQ-OAR-2007-1145

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Rich Scheffe

Environmental Protection Agency

Air and Radiation

C304–02
EPA

143. NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS FROM COAL– AND
OIL–FIRED ELECTRIC UTILITY STEAM GENERATING UNITS AND STANDARDS OF
PERFORMANCE FOR ELECTRIC UTILITY STEAM GENERATING UNITS

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect State, local or tribal governments and the private sector.

Legal Authority:
Clean Air Act sec 112(d); Clean Air Act sec 111(b)

CFR Citation:
40 CFR 63; 40 CFR 60, subpart Da

Legal Deadline:
NPRM, Judicial, March 16, 2011, No later than March 16, 2011, EPA shall sign for publication in the

Federal Register a notice of proposed rulemaking.

Final, Judicial, December 16, 2011, No later than December 16, 2011, EPA shall sign for publication in
the Federal Register a notice of final rulemaking.

Abstract:

On May 18, 2005 (70 FR 28606), EPA published a final rule requiring reductions in emissions of mercury
from Electric Utility Steam Generating Units. That rule was vacated on February 8, 2008, by the U.S.
Court of Appeals for the District of Columbia Circuit. As a result of that vacatur, coal- and oil-fired electric
utility steam generating units remain on the list of sources that must be regulated under section 112 of the
Clean Air Act (CAA). The Agency will develop standards under CAA section 112(d), which will reduce
hazardous air pollutant (HAP) emissions from this source category. Recent court decisions on other CAA
section 112(d) rules will be considered in developing this regulation. The rule was proposed on May 3,
2011 (76 FR 24976).

Under this action, EPA also proposed amendments to the criteria pollutant new source performance
standards (NSPS) for utilities. On February 27, 2006, EPA promulgated amendments to the utility NSPS
and was subsequently sued by multiple state attorney general offices and environmental organizations.
On September 2, 2009, EPA was granted a voluntary remand without vacatur of the 2006 amendments.
Combining the two rules in a single action provides interested parties the opportunity to provide
comments on the combined requirements of the two rules. It also avoids double-counting either costs or
environmental benefits of the separate rules.

Statement of Need:

Section 112(n)(1)(A) of the Clean Air Act required EPA to conduct a study of the hazards to public health
resulting from emissions of hazardous air pollutants from electric utility steam generating units and, after
considering the results of that study, determine whether it was appropriate and necessary to regulate
such units under section 112. The study was completed in 1998, and, in December 2000, EPA
determined that it was appropriate and necessary to regulate coal- and oil-fired electric utility steam
generating units and added such units to the list of sources for which standards must be developed under
section 112. The February 8, 2008, vacatur of the May 18, 2005, Clean Air Mercury Rule and March 29, 2005, section 112(n) revision rule (which had removed such sources from the list) resulted in the requirement to regulate under section 112 being reinstated.

Summary of Legal Basis:
Clean Air Act, section 112

Alternatives:
Not yet determined.

Anticipated Cost and Benefits:
EPA estimates that this final rule will yield annual monetized benefits (in 2007$) of between $37 to $90 billion using a 3 percent discount rate and $33 to $81 billion using a 7 percent discount rate. The great majority of the estimates are attributable to co-benefits from 4,200 to 11,000 fewer PM2.5-related premature mortalities. The monetized benefits from reductions in mercury emissions, calculated only for children exposed to recreationally caught freshwater fish, are expected to be $0.004 to $0.006 billion in 2016 using a 3 percent discount rate and $0.0005 to $0.001 billion using a 7 percent discount rate. The annual social costs, approximated by the compliance costs, are $9.6 billion (2007$) and the annual monetized net benefits are $27 to $80 billion using 3 percent discount rate or $24 to $71 billion using a 7 percent discount rate. The benefits outweigh costs by between 3 to 1 or 9 to 1 depending on the benefit estimate and discount rate used.

Risks:
Not yet determined.

Timetable:

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<td>76 FR 23768</td>
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Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Businesses, Governmental Jurisdictions

Government Levels Affected:
Federal, Local, State, Tribal

Federalism:
This action may have federalism implications as defined in EO 13132.

Energy Effects:
Statement of Energy Effects planned as required by Executive Order 13211.

Additional Information:
EPA-HQ-OAR-2005-0031

Sectors Affected:
221112 Fossil Fuel Electric Power Generation

Agency Contact:
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Environmental Protection Agency
Air and Radiation
D243–01
Research Triangle Park, NC 27711
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Robert J Wayland
Environmental Protection Agency
Air and Radiation
D243–01
144. OIL AND NATURAL GAS SECTOR—NEW SOURCE PERFORMANCE STANDARDS AND NATIONAL EMISSION STANDARDS FOR HAZARDOUS AIR POLLUTANTS

Priority:
Economically Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
42 USC 7411; 42 USC 7412

CFR Citation:
40 CFR 60; 40 CFR 63

Legal Deadline:

Abstract:
New Source Performance Standards (NSPS) regulate criteria pollutants from new stationary sources. Two NSPS (subparts KKK and LLL) for the oil and natural gas industry were promulgated in 1985. Section 111 of the Clean Air Act (CAA) requires that NSPS be reviewed every 8 years and revised as appropriate. National Emission Standards for Hazardous Air Pollutants (NESHAP) regulate hazardous air pollutants (HAP) from new and existing stationary sources. Two NESHAP (subparts HH and HHH) for the oil and natural gas industry were promulgated in 1999. Section 112 of the CAA requires that NESHAP be reviewed every 8 years and revised as appropriate. In addition, section 112(f) requires that each category
regulated under section 112(d) be reviewed to ensure that such regulations provide for an ample margin of safety to protect public health (i.e., address “residual risk” for each category). This action will include the required reviews under sections 111 and 112. Because the existing regulations are narrow in scope, the reviews will include consideration of broadening the scope of operations and emission points covered by the NSPS and MACT.

**Statement of Need:**

Not yet determined.

**Summary of Legal Basis:**

Not yet determined.

**Alternatives:**

Not yet determined.

**Anticipated Cost and Benefits:**

For the NSPS, the annual costs are estimated at $738 million. After taking into account the value of the natural gas and condensate recovered, there would be a net savings of $45 million annually. For the NESHAP, the annual costs of compliance will be $16 million. EPA estimates benefits for the VOCs 540,000 tons per year, or about 25 percent reduction overall; for methane, 3.4 million tpy, which is equal to 65 million metric tons of carbon dioxide equivalent (CO2e), which is a reduction of about 26 percent; and for air toxics, 38,000 tons, or a reduction of nearly 30 percent.

**Risks:**

Not yet determined.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**
No

**Government Levels Affected:**

None

**Additional Information:**


**URL For More Information:**

http://epa.gov/airquality/oilandgas/

**Agency Contact:**

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E143–01

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Email: cozzie.david@epa.gov

**RIN:** 2060–AP76
145. CRITERIA AND STANDARDS FOR COOLING WATER INTAKE STRUCTURES

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
This action may affect the private sector under PL 104-4.

Legal Authority:
CWA 101; CWA 301; CWA 304; CWA 308; CWA 316; CWA 401; CWA 402; CWA 501; CWA 510

CFR Citation:
40 CFR 122; 40 CFR 125

Legal Deadline:
NPRM, Judicial, March 28, 2011.

Abstract:
Section 316(b) of the Clean Water Act (CWA) requires EPA to ensure that the location, design, construction, and capacity of cooling water intake structures reflect the best technology available (BTA) for minimizing adverse environmental impacts. Phase II, for existing electric generating plants that use at least 50 MGD of cooling water, was completed in July 2004. Industry and environmental stakeholders challenged the Phase II regulations. On review, the U.S. Court of Appeals for the Second Circuit remanded several key provisions.

In July 2007, EPA suspended the Phase II rule following the decision in the Second Circuit. Several parties petitioned the U.S. Supreme Court to review that decision, and the Supreme Court granted the petitions, limited to the issue of whether the Clean Water Act authorized EPA to consider the relationship of costs and benefits in establishing section 316(b) standards. On April 1, 2009, the Supreme Court reversed the Second Circuit, finding that the Agency may consider cost-benefit analysis in its decisionmaking, but not holding that the Agency must consider costs and benefits in these decisions.
In June 2006, EPA promulgated the Phase III regulation, covering existing electric generating plants using less than 50 MGD of cooling water, new offshore oil and gas facilities, and all existing manufacturing facilities. Petitions to review this rule were filed in the U.S. Court of Appeals for the Fifth Circuit. In July 2010, the U.S. Court of Appeals for the Fifth Circuit issued a decision upholding EPA's rule for new offshore oil and gas extraction facilities. Further, the court granted the request of EPA and environmental petitioners in the case to remand the existing facility portion of the rule back to the Agency for further rulemaking. EPA expects this new rulemaking would apply to the approximately 1,200 existing electric generating and manufacturing plants. The Fifth Circuit also affirmed that EPA may consider costs in relation to benefits but is not required to do so.

EPA entered into a settlement with the plaintiffs in two lawsuits related to section 316(b) rulemakings. Under the settlement agreement, as modified, EPA agreed to sign a notice of a proposed rulemaking implementing section 316(b) of the CWA at existing facilities no later than March 28, 2011, and to sign a notice taking final action on the proposed rule no later than July 27, 2012. Plaintiffs agreed to seek dismissal of both their suits, subject to a request to reopen the Cronin proceeding in the event EPA failed to meet the agreed deadlines.

EPA's proposed regulation includes uniform controls at all existing facilities to prevent fish from being trapped against screens (impingement), site-specific controls for existing facilities other than new units to prevent fish from being drawn through cooling systems (entrainment), and uniform controls equivalent to closed cycle cooling for new units at existing facilities (also entrainment). Other regulatory options analyzed included similar uniform impingement controls and progressively more stringent requirements for entrainment controls. Another option considered would impose the uniform impingement controls only for facilities withdrawing 50 million or more gallons per day of cooling water, with site-specific impingement controls for facilities withdrawing less than 50 million gallons per day.

**Statement of Need:**
In the absence of national regulations, NPDES permit writers have developed requirements to implement section 316(b) on a case-by-case basis. This may result in a range of different requirements, and in some cases, delays in permit issuance or reissuance. This regulation may have substantial ecological benefits.

**Summary of Legal Basis:**

The Clean Water Act requires EPA to establish best technology available standards to minimize adverse environmental impacts from cooling water intake structures. On February 16, 2004, EPA took final action on regulations governing cooling water intake structures at certain existing power producing facilities under section 316(b) of the Clean Water Act (Phase II rule). 69 FR 41576 (Jul. 9, 2004). These regulations were challenged, and the Second Circuit remanded several provisions of the Phase II rule on various grounds. Riverkeeper, Inc., v. EPA, 475F.3d83, (2d Cir., 2007). EPA suspended most of the rule in response to the remand. 72 FR 37107 (Jul. 9, 2007). The remand of Phase III does not change permitting requirements for these facilities. Until the new rule is issued, permit directors continue to issue permits on a case-by-case, Best Professional Judgment basis for Phase II facilities.

**Alternatives:**

This analysis will cover various sizes and types of potentially regulated facilities and control technologies. EPA is considering whether to regulate on a national basis, by subcategory, by broad water body category, or some other basis.

**Anticipated Cost and Benefits:**

The technologies under consideration in this rulemaking are similar to the technologies considered for the original Phase II and Phase III rules, and costs have been updated to 2009. The annual social costs associated with EPA’s proposed regulation are $384 million, plus an additional $15 million in costs associated with the new units provision. The annual social costs of the other options ranged from $327 million to $4.63 billion. EPA monetized only a portion of the expected annual benefits of the rule, amounting to $18 million. The monetized benefits for the other options ranged from $17 to $126 million. EPA is also conducting a stated preference survey to provide a more comprehensive estimate of the monetized benefits and expects to publish a notice of data availability with these results around the end of 2011.

**Risks:**
Cooling water intake structures may pose significant risks for aquatic ecosystems.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal, Local, State

**Additional Information:**


**Sectors Affected:**

336412 Aircraft Engine and Engine Parts Manufacturing; 332999 All Other Miscellaneous Fabricated Metal Product Manufacturing; 321999 All Other Miscellaneous Wood Product Manufacturing; 324199 All Other Petroleum and Coal Products Manufacturing; 326299 All Other Rubber Product Manufacturing; 331521 Aluminum Die-Casting Foundries; 331524 Aluminum Foundries (except Die-Casting); 331315 Aluminum Sheet, Plate, and Foil Manufacturing; 311313 Beet Sugar Manufacturing; 31321 Broadwoven Fabric Mills; 311312 Cane Sugar Refining; 32731 Cement Manufacturing; 61131 Colleges, Universities, and Professional Schools; 33312 Construction Machinery Manufacturing; 333922 Conveyor and Conveying Equipment Manufacturing; 331525 Copper Foundries (except Die-Casting); 339914 Costume
Jewelry and Novelty Manufacturing; 211111 Crude Petroleum and Natural Gas Extraction; 321912 Cut Stock, Resawing Lumber, and Planing; 332211 Cutlery and Flatware (except Precious) Manufacturing; 31214 Distilleries; 221121 Electric Bulk Power Transmission and Control; 221122 Electric Power Distribution; 331112 Electrometallurgical Ferroalloy Product Manufacturing; 31332 Fabric Coating Mills; 333111 Farm Machinery and Equipment Manufacturing; 311225 Fats and Oils Refining and Blending; 221112 Fossil Fuel Electric Power Generation; 332212 Hand and Edge Tool Manufacturing; 33251 Hardware Manufacturing; 221111 Hydroelectric Power Generation; 21221 Iron Ore Mining; 331111 Iron and Steel Mills; 22121 Natural Gas Distribution; 211112 Natural Gas Liquid Extraction; 221113 Nuclear Electric Power Generation; 332323 Ornamental and Architectural Metal Work Manufacturing; 221119 Other Electric Power Generation; 332618 Other Fabricated Wire Product Manufacturing; 332439 Other Metal Container Manufacturing; 332919 Other Metal Valve and Pipe Fitting Manufacturing; 321918 Other Millwork (including Flooring); 312229 Other Tobacco Product Manufacturing; 333923 Overhead Traveling Crane, Hoist, and Monorail System Manufacturing; 3212 Paper Mills; 32213 Paperboard Mills; 32411 Petroleum Refineries; 325992 Photographic Film, Paper, Plate, and Chemical Manufacturing; 333315 Photographic and Photocopying Equipment Manufacturing; 212391 Potash, Soda, and Borate Mineral Mining; 332117 Powder Metallurgy Part Manufacturing; 331312 Primary Aluminum Production; 331419 Primary Smelting and Refining of Nonferrous Metal (except Copper and Aluminum); 3221 Pulp, Paper, and Paperboard Mills; 333911 Pump and Pumping Equipment Manufacturing; 33651 Railroad Rolling Stock Manufacturing; 321219 Reconstituted Wood Product Manufacturing; 54171 Research and Development in the Physical, Engineering, and Life Sciences; 326192 Resilient Floor Covering Manufacturing; 331221 Rolled Steel Shape Manufacturing; 322291 Sanitary Paper Product Manufacturing; 321113 Sawmills; 331492 Secondary Smelting, Refining, and Alloying of Nonferrous Metal (except Copper and Aluminum); 337215 Showcase, Partition, Shelving, and Locker Manufacturing; 321212 Softwood Veneer and Plywood Manufacturing; 311222 Soybean Processing; 22133 Steam and Air-Conditioning Supply; 331222 Steel Wire Drawing; 111991 Sugar Beet Farming; 11193 Sugarcane Farming; 311311 Sugarcane Mills; 326211 Tire Manufacturing (except Retreading); 31221 Tobacco Stemming and Redrying; 311221 Wet Corn Milling

URL For More Information:
EQUAL EMPLOYMENT OPPORTUNITY COMMISSION (EEOC)

Statement of Regulatory and Deregulatory Priorities

The mission of the Equal Employment Opportunity Commission (EEOC, Commission, or agency) is to ensure equality of opportunity in employment by vigorously enforcing seven Federal statutes. These
statutes are: Title VII of the Civil Rights Act of 1964, as amended (prohibits employment discrimination on
the basis of race, color, sex, religion, or national origin); the Equal Pay Act of 1963, as amended (makes it
illegal to pay unequal wages to men and women performing substantially equal work at the same
establishment, unless the difference is attributable to a bona fide seniority, merit, or incentive system, or
to a factor other than sex); the Age Discrimination in Employment Act of 1967 (ADEA) as amended
(prohibits employment discrimination based on age of 40 or older); titles I and V of the Americans with
Disabilities Act, as amended, and sections 501 and 505 of the Rehabilitation Act, as amended (prohibits
employment discrimination based on disability); title II of the Genetic Information Nondiscrimination Act
(GINA) (prohibits employment discrimination based on genetic information and limits acquisition and
disclosure of genetic information); and section 304 of the Government Employee Rights Act of 1991
(protects certain previously exempt State and local government employees from employment
discrimination on the basis of race, color, religion, sex, national origin, age, disability, or genetic
information).

The item in this Regulatory Plan is entitled “Disparate Impact and Reasonable Factors Other Than
Age Under the Age Discrimination in Employment Act.” This item previously appeared as two separate
items titled “Disparate Impact Burden of Proof Under the Age Discrimination in Employment Act” (RIN
3046-AA76) and “Reasonable Factors Other Than Age Under the Age Discrimination in Employment Act”
(RIN 3046-AA87). These two items have been merged, and a final rule will be issued addressing the
issues covered in both (appearing under RIN 3046-AA76).

Prior to the Supreme Court’s decision in Smith v. City of Jackson, 544 U.S. 228 (2005), Commission
regulations interpreted the ADEA to require employers to prove that actions that had an age-based
disparate impact were justified as a business necessity. Although the Court, in Smith, agreed with the
EEOC that disparate impact claims were recognizable under the ADEA, it held that the defense was not
business necessity but reasonable factors other than age (RFOA). The Smith Court did not specify
whether the employer or employee bore the burden of proof on the RFOA defense.
On March 31, 2008, the Commission issued a Notice of Proposed Rulemaking (NPRM) to conform Commission ADEA regulations to Smith, also taking the position that the employer bore the burden of proving the defense. Because current EEOC regulations do not define the meaning of “RFOA,” the NPRM asked whether regulations should provide more information on the meaning of “reasonable factors other than age” and, if so, what the regulations should say. 73 FR 16807 (March 31, 2008).

Subsequently, the Supreme Court held in Meacham v. Knolls Atomic Laboratory, 554 U.S. 84, 128 S. Ct. 2395 (2008), that employers have the RFOA burdens of production and persuasion. After consideration of the public comments, and in light of the Supreme Court decisions, the Commission issued a second NPRM on February 18, 2010, to address the scope of the RFOA defense. A final rule will be issued addressing the topics covered in both NPRMs and conforming to both Smith and Meacham. The rule will not have a significant impact on small businesses because, among other reasons, their employment actions generally will not affect individuals in numbers sufficient to raise questions of disparate impact.

This item is highlighted in EEOC’s Plan for Retrospective Review of Significant Regulations, developed pursuant to Executive Order 13563.

Consistent with section 4(c) of Executive Order 12866, this statement was reviewed and approved by the Chair of the Agency. The statement has not been reviewed or approved by the other members of the Commission.

**Retrospective Review of Existing Regulations**

Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the EEOC’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan.
However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov. These rulemakings can also be found on Regulations.gov. The final agency plans can be found at: http://www.eeoc.gov/laws/regulations/retro_review_plan_final.cfm.

RIN: 3046-AA76

DISPARATE IMPACT AND REASONABLE FACTORS OTHER THAN AGE UNDER THE AGE DISCRIMINATION IN EMPLOYMENT ACT

This rulemaking is not expected to alter burdens on small businesses.

RIN: 3046-AA73

FEDERAL SECTOR EQUAL EMPLOYMENT OPPORTUNITY COMPLAINT PROCESSING

This rulemaking does not apply to small businesses. It applies only to the Federal Government.

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<th>FINAL RULE STAGE</th>
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Priority:
Other Significant

Legal Authority:
29 USC 628

CFR Citation:
29 CFR 1625.7(d)

Legal Deadline:
Abstract:

Prior to the Supreme Court's decision in Smith v. City of Jackson, 544 U.S. 228 (2005), Commission regulations interpreted the ADEA to require employers to prove that actions that had an age-based disparate impact were justified as a business necessity. Although the Court, in Smith, agreed with the EEOC that disparate impact claims were cognizable under the ADEA, it held that the defense was not business necessity but reasonable factors other than age (RFOA). The Smith Court did not specify whether the employer or employee bore the burden of proof on the RFOA defense.

On March 31, 2008, the Commission issued a Notice of Proposed Rulemaking (NPRM) to conform Commission ADEA regulations to Smith, also taking the position that the employer bore the burden of proving the defense. Because current EEOC regulations do not define the meaning of “RFOA,” the NPRM also asked whether regulations should provide more information on the meaning of “reasonable factors other than age” and, if so, what the regulations should say. 73 FR 16807 (March 31, 2008).

Subsequently, the Supreme Court held in Meacham v. Knolls Atomic Laboratory, 554 U.S. 84, 128 S. Ct. 2395 (2008), that employers have the RFOA burdens of production and persuasion. After consideration of the public comments, and in light of the Supreme Court decisions, the Commission issued a second NPRM on February 18, 2010 to address the scope of the RFOA defense. A final rule will be issued addressing the issues covered in both NPRMs and conforming to both Smith and Meacham.

The RIN associated with the NPRM titled “Reasonable Factors Other Than Age Under the Age Discrimination in Employment Act" (RIN 3046-AA87) has been merged with this item (RIN 3046-AA76), which will be the RIN used to identify the final rule.

Statement of Need:

Current EEOC regulations interpret the ADEA as prohibiting an employment practice that has a disparate impact on individuals within the protected age group unless it is justified as a business necessity. The Supreme Court's holding in Smith v. City of Jackson validated the Commission's position that disparate impact analysis applies in ADEA cases. The holding, however, differed from the Commission's position
that the business necessity test was the appropriate standard for determining the lawfulness of a practice
that had an age-based disparate impact. The EEOC is revising its regulation to reflect the Smith decision.
Moreover, as noted above, a related item (RIN #3046-AA87) entitled "Reasonable Factors Other Than
Age Under the Age Discrimination in Employment Act" has been merged with this item. In this final rule,
the EEOC is also revising its regulations to address the scope of the RFOA defense.

Summary of Legal Basis:

The ADEA authorizes the EEOC “to issue such rules and regulations it may consider necessary or
appropriate for carrying out this chapter . . . .” 29 U.S.C. section 628.

Alternatives:

The Commission has considered all alternatives proposed by the public comments.

Anticipated Cost and Benefits:

Based on the information currently available, the EEOC does not anticipate that the rule will have
significant economic effects. The purpose of the rule is to help explain the implications of recent Supreme
Court decisions and the type of conduct that would support an RFOA defense in court. It therefore does
not directly require any action on the part of covered entities.

The regulation makes clear that the employer's burden is to prove the RFOA, rather than the more
stringent business necessity, defense. Further, the rule instructs covered entities what to do if they want
to ensure that their practices are based on reasonable factors other than age. The rule does not expand
the coverage of the ADEA to additional employers or employees, and does not include reporting,
recordkeeping, or other requirements for compliance. Costs would result primarily from voluntary
modifications to covered entities' business practices made to protect against disparate-impact liability.
Modifications may include performing disparate impact analyses of business practices before they are
adopted, providing guidance to decisionmakers on how to implement the practice, and evaluating other
options to mitigate harm. The costs will be minimal, because these actions are required, for purposes of
establishing the RFOA defense, only to the extent that a reasonable employer would perform them under
the circumstances. Many covered entities already routinely perform them. To the extent that the
regulation motivates employers to take additional actions, free resources minimize the cost of doing so.
This revision, informed by the comments of stakeholders, will be beneficial to courts, employers, and employees seeking to interpret, understand, and comply with the ADEA.

**Risks:**

The rule does not affect risks to public health, safety, or the environment.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

Businesses, Governmental Jurisdictions, Organizations

**Government Levels Affected:**

Federal, Local, State, Tribal

**Additional Information:**

Includes Retrospective Review under E.O. 13563.

**Agency Contact:**

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Senior Attorney Advisor, Office of Legal Counsel  
Equal Employment Opportunity Commission  
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Lyn McDermott
Statement of Regulatory Priorities

Title I, subtitle A, of the Dodd-Frank Wall Street Reform and Consumer Protection Act ("Dodd-Frank" or "Act") established the Financial Stability Oversight Council (FSOC or Council). The purpose of the FSOC is to identify risks to the financial stability of the United States that could arise from the material financial distress or failure, or ongoing activities, of large, interconnected bank holding companies or nonbank financial companies. In addition, the Council is responsible for promoting market discipline and responding to emerging risks to the stability of the United States financial system. The duties of the FSOC are set forth in section 112(a)(2) of the Act. The FSOC consists of 10 voting members and 5 non-voting members, who serve in an advisory capacity. The Secretary of the Treasury serves as Chairperson.

Dodd-Frank provides the FSOC with authority to issue certain regulations to carry out the business of the Council and for certain other purposes. In October 2011, the FSOC issued a revised notice of
proposed rulemaking with guidance on the framework that the Council will apply when considering the designation of nonbank financial companies that will be subject to consolidated supervision by the Federal Reserve and enhanced prudential standards. In fiscal year 2012, the Council will approve a rule, which will be issued by the Secretary of the Treasury, outlining an assessment schedule to collect assessments from bank holding companies with greater than $50bn in total assets and non-bank financial companies supervised by the FRB, to provide for the total expenses of the Office of Financial Research and the Council. Additionally, the Council will issue a final rule to implement the Freedom of Information Act that will set forth procedures for requesting access to FSOC records.

Over the next several months, the FSOC and its members will continue efforts to issue regulations, policies, and guidance mandated by the Act and to take other actions necessary to effectively carry out the Act.

BILLING CODE: 4810-25-S

GENERAL SERVICES ADMINISTRATION (GSA)

I. Mission and Overview

GSA oversees the business of the Federal Government. GSA’s acquisition solutions supplies Federal purchasers with cost-effective, high-quality products and services from commercial vendors. GSA provides workplaces for Federal employees and oversees the preservation of historic Federal properties. GSA helps keep the Nation safe by providing tools, equipment, and non-tactical vehicles to the U.S. military, and providing State and local governments with law enforcement equipment, firefighting and rescue equipment, and disaster recovery products and services.
GSA serves the public by delivering services directly to its Federal customers through the Federal Acquisition Service (FAS), the Public Buildings Service (PBS), and the Office of Governmentwide Policy (OGP). GSA has a continuing commitment to its Federal customers and the U.S. taxpayers by providing those services in the most cost-effective manner possible.

Federal Acquisition Service (FAS)

FAS is the lead organization for procurement of products and services (other than real property) for the Federal Government. The FAS organization leverages the buying power of the Government by consolidating Federal agencies requirements for common goods and services. FAS provides a range of high-quality and flexible acquisition services that increase overall Government effectiveness and efficiency. FAS business operations are organized into four business portfolios based on the product or service provided to customer agencies: Integrated Technology Services (ITS); Assisted Acquisition Services (AAS); General Supplies and Services (GSS); and Travel, Motor Vehicles and Card Services (TMVCS). The FAS portfolio structure enables GSA and FAS to provide best value services, products, and solutions to its customers by aligning resources around key functions.

Public Buildings Service (PBS)

PBS is the largest public real estate organization in the United States, providing facilities and workspace solutions to more than 60 Federal agencies. PBS aims to provide a superior workplace for the Federal worker and superior value for the U.S. taxpayer. Balancing these two objectives is PBS’ greatest management challenge. PBS’ activities fall into two broad areas. The first is space acquisition through both leases and construction. PBS translates general needs into specific requirements, marshals the necessary resources, and delivers the space necessary to meet the respective missions of its Federal
clients. The second area is management of space. This involves making decisions on maintenance, servicing tenants, and ultimately, deciding when and how to dispose of a property at the end of its useful life.

Office of Governmentwide Policy (OGP)

OGP sets Governmentwide policy in the areas of personal and real property, travel and transportation, information technology, regulatory information, and use of Federal advisory committees. OGP also helps direct how all Federal supplies and services are acquired as well as GSA’s own acquisition programs. OGP’s regulatory function fully incorporates the provisions of the President’s priorities and objectives under Executive Order 12866 and 13563 with policies covering acquisition, travel, and property and management practices to promote efficient Government operations. OGP’s strategic direction is to ensure that Governmentwide policies encourage agencies to develop and utilize the best, most cost effective management practices for the conduct of their specific programs. To reach the goal of improving Governmentwide management of property, technology, and administrative services, OGP builds and maintains a policy framework by (1) incorporating the requirements of Federal laws, Executive orders, and other regulatory material into policies and guidelines; (2) facilitating Governmentwide reform to provide Federal managers with business-like incentives and tools and flexibility to prudently manage their assets; (3) identifying, evaluating, and promoting best practices to improve efficiency of management processes; and (4) performing ongoing analysis if existing rules that may be obsolete, unnecessary, unjustified, excessively burdensome, or counterproductive. In regard to the retrospective analysis of existing rules, GSA’s plan (dated Aug. 18, 2011) has been approved by OMB.

OGP’s policy regulations are described in the following subsections:
Office of Travel, Transportation, and Asset Management (Federal Travel Regulation)


The FTR is the regulation contained in 41 Code of Federal Regulations (CFR), chapters 300 through 304, that implements statutory requirements and executive branch policies for travel by Federal civilian employees and others authorized to travel at Government expense.

The Administrator of General Services promulgates the FTR to: (a) Interpret statutory and other policy requirements in a manner that balances the need to ensure that official travel is conducted in a responsible manner with the need to minimize administrative costs and (b) communicate the resulting policies in a clear manner to Federal agencies and employees.

Office of Travel, Transportation, and Asset Management (Federal Management Regulation)

Federal Management Regulation (FMR) establishes policy for aircraft, transportation, personal property, and mail management. The FMR is the successor regulation to the Federal Property Management Regulation (FPMR), and it contains updated regulatory policies originally found in the FPMR. However, it does not contain FPMR material that describes how to do business with the GSA.

Office of Acquisition Policy (Federal Acquisition Regulation and GSA Acquisition Regulation Manual)
GSA helps provide to the public and the Federal buying community the updating and maintaining of the rule book for all Federal agency procurements, the Federal Acquisition Regulation (FAR). This is achieved through its extensive involvement with the Federal Acquisition Regulatory (FAR) Council. The FAR Council is comprised of senior representation from the Office of Federal Procurement Policy (OFPP), National Aeronautics and Space Administration (NASA), the Department of Defense (DoD), and GSA.

The FAR Council directs the writing of the FAR cases, which is accomplished, in part, by teams of expert FAR analysts. All changes to the FAR are accompanied by review and analysis of public comment. Public comments play an important role in clarifying and enhancing this rulemaking process. The regulatory agenda pertaining to changes to the FAR are outside the scope of this discussion as GSA cannot speak on behalf of the FAR Council.

GSA’s internal rules and practices on how it buys goods and services from its business partners are covered by the General Services Administration Acquisition Manual (GSAM) and the General Services Administration Acquisition Regulation (GSAR). The GSAM is closely related to the FAR as it supplements areas of the FAR where GSA has additional and unique regulatory requirements. Office of Acquisition Policy writes and revises the GSAM and the GSAR. The size and scope of the FAR are substantially larger than the GSAR. In effect, the GSAR and the GSAM adds to the FAR by providing additional guidance to GSA officials and its business partners.

Federal Acquisition Regulation (FAR): The FAR was established to codify uniform policies for acquisition of supplies and services by executive agencies. It is issued and maintained jointly, pursuant to the Office of Federal Procurement Policy (OFPP) Reauthorization Act, under the statutory
authorities granted to the Secretary of Defense, Administrator of General Services, and the Administrator, National Aeronautics and Space Administration. Statutory authorities to issue and revise the FAR have been delegated to the procurement executives in Department of Defense (DoD), GSA, and National Aeronautics and Space Administration (NASA).

GSA Acquisition Regulation Manual (GSAM) along with Acquisition Letters: The GSAM incorporates the GSAR, as well as internal agency acquisition policy. The rules that require publication fall into two major categories:

- Those that affect GSA’s business partners (e.g., prospective offerors and contractors).
- Those that apply to acquisition of leasehold interests in real property. The FAR does not apply to leasing actions. GSA establishes regulations for lease of real property under the authority of 40 U.S.C. 490 note.

GSA Acquisition Regulation (GSAR): The GSAR establishes agency acquisition rules and guidance, which contains agency acquisition policies and practices, contract clauses, solicitation provisions, and forms that control the relationship between GSA and contractors and prospective contractors.

II. Statement of Regulatory and Deregulatory Priorities

FTR Regulatory Priorities

In fiscal year 2012, GSA plans to amend the FTR by:
• Revising the Relocation Income Tax (RIT) Allowance; amending coverage on family relocation;

• Amending the calculations regarding the commuted rate for employee-managed household goods shipments; and

• Removing the Privately Owned Vehicle (POV) rates from the FTR; amending reimbursement for employees staying in their privately owned homes/condos while on TDY.

FMR Regulatory Priorities

In fiscal year 2012, GSA plans to amend the FMR by:

• Revising rules regarding management of government aircraft;

• Revising rules regarding mail management;

• Amending coverage in motor vehicle management by revising the definition of “motor vehicle rental”;

• Migrating the provisions of the Federal Property Management Regulations (FPMR) regarding purchase of new motor vehicles to the FMR;
• Migrating the provisions of the Interagency Fleet Management Systems from the Federal Property Management Regulations (FPMR) into the FMR;

• Incorporating the requirements of the Presidential Memorandum on Federal Fleet Performance of May 24, 2011, that all agencies develop annual vehicle allocation methodologies to rightsize their fleets and that by fiscal year 2015 all light duty vehicles acquired be alternatively fueled;

• Amending transportation management regulations by revising coverage on open skies agreements, obligation authority, and training for civilian transportation officers, and transportation data collection;

• Amending Transportation Management and Audit by revising the requirements regarding the refund of unused and expired tickets;

• Publishing procedures for handling the transfer of title for vehicles to donees via State Agencies for Surplus Property; removing activities related to the Federal Asset Sales program, which initiated the program (policies began rulemaking process in fiscal year 2011);

• Removing aircraft, aircraft-related parts, fire control equipment, and guided missiles from the exchange/sale prohibited list; and

• Migrating supply and procurement policy from the FPMR to the FMR.

GSAR Regulatory Priorities
GSA plans, in fiscal year 2012, to finalize the rewrite of the GSAR to maintain consistency with the Federal Acquisition Regulation (FAR) and to implement streamlined and innovative acquisition procedures that contractors, offerors, and GSA contracting personnel can utilize when entering into and administering contractual relationships. Currently, there are only a few parts of the GSAR rewrite effort still outstanding.

GSA is clarifying the GSAR by—

- Providing consistency with the FAR;

- Eliminating coverage that duplicates the FAR or creates inconsistencies within the GSAR;

- Correcting inappropriate references listed to indicate the basis for the regulation;

- Rewriting sections that have become irrelevant because of changes in technology or business processes or that place unnecessary administrative burdens on contractors and the Government;

- Streamlining or simplifying the regulation;

- Rolling up coverage from the services and regions/zones that should be in the GSAR;

- Providing new and/or augmented coverage; and

- Deleting unnecessary burdens on small businesses.

Specific GSAR cases that the agency plans to address in FY 2012 and 2013 include:
- The rewrite of GSAM part 515, Contracting by Negotiation.

- The rewrite of GSAM part 538, Federal Supply Schedule Contracting.

- The rewrite of GSAM part 536, Construction and A/E Contracts.

These cases are more fully described in the Agency's approved Final Plan for Retrospective Analysis of Existing Rules (Aug. 18, 2011), created in response to Executive Order 13563.

**Regulations of Concern to Small Businesses**

FAR and GSAR rules are relevant to small businesses who do or wish to do business with the Federal Government. Approximately 18,000 businesses, most of whom are small, have GSA schedule contracts. GSA assists its small businesses by providing assistance through its Office of Small Business Utilization. In addition, GSA extensively utilizes its regional resources, within FAS and PBS, to provide grass-roots outreach to small business concerns, through hosting such outreach events, or participating in a vast array of other similar presentations hosted by others.

**Regulations Which Promote Open Government and Disclosure**

While there are currently no regulations which promote open Government and disclosure, all Government contract spend transactions are available online through Federal Procurement Data System-Next Generation (FPDS-NG).

**Regulations Required by Statute or Court Order**

GSA plans to publish FTR Case 2011-308; Payment of Expenses Connected with the Death of Certain Employees in FY 2012. Presidential Memorandum “Delegation Under Section 2(a) of the Special Agent Samuel Hicks Families of Fallen Heroes Act”, dated September 12, 2011, delegates to the Administrator of General Services the authority to issues regulations under Public Law 111-178, the Special Agent Samuel Hicks Families of Fallen Heroes Act, codified at 5 U.S.C. 5724d, relating to the
payment of certain expenses when a covered employee dies as a result of injuries sustained in the performance of his or her official duties. GSA is amending the FTR to establish policy for the transportation of the immediate family, household goods, personal effects, and one privately owned vehicle of a covered employee whose death occurred as a result of personal injury sustained while in the performance of the employee’s duty as defined by the agency.

Regulation Required by Office of Federal Procurement Policy (OFPP)

A FAR case will be necessary to implement OFPP Policy Letter 11-01; Performance of Inherently Governmental and Critical Functions.” Updates will be provided in the Spring Regulatory Agenda.

III Retrospective Review of Existing Regulations

Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (January 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final agency plans can be found at: www.gsa.gov/improvingregulations.

FAR Rules:

- 9000-AL93 FAR Case 2007-012; Requirements for Acquisitions Pursuant to Multiple-Award Contracts; yes, this rule increases competition which will benefit small businesses.
• 9000-AL46  FAR Case 2008-025; Preventing Personal Conflicts of Interest for Contractor Employees Performing Acquisition Functions; no specific impact on small businesses.

• 9000-AL82  FAR Case 2011-001; Organizational Conflicts of Interest; no specific impact on small businesses.

• 9000-AL88  FAR Case 2011-004; Socioeconomic Program Parity; this rule, implementing Section 1347 of the Small Business Jobs Act of 2010, specifically impacts small businesses; however, no overall negative impact is expected.

• 9000-AM12  FAR Case 2011-024; Set-Asides for Small Business; yes, this rule, implementing Section 1331 of the Small Business Jobs Act of 2010, will increase opportunities for small business contractors authorizing agencies to set aside more work for small businesses under multiple award contracts.

GSAR Rules:

• 3090-A177  GSAR Case 2006-G507; Rewrite of GSAR Part 538, Federal Supply Schedule Contracting.

• 3090-A176  GSAR Case 2008-G506; Rewrite of GSAR Part 515, Contracting by Negotiation.

• 3090-A181  GSAR Case 2008-G509; Rewrite of GSAR Part 536, Construction and A/E Contracts.

Note: The GSAR cases do not specifically provide relief to small businesses or additional administrative flexibility to state, local or tribal governments. However, we do believe that updating and clarifying the regulation will benefit all contractors (and Schedule users).
Statement of Regulatory Priorities

NASA continues to implement programs according to its 2011 Strategic Plan, released in February 2011. NASA’s mission is to “Drive advances in science, technology, and exploration to enhance knowledge, education, innovation, economic vitality, and stewardship of the Earth.” The 2011 Strategic Plan guides NASA’s program activities through a framework of the following six strategic goals:

- **Goal 1**: Extend and sustain human activities across the solar system.
- **Goal 2**: Expand scientific understanding of Earth and the universe in which we live.
- **Goal 3**: Create innovative new space technologies for our exploration, science, and economic future.
- **Goal 4**: Advance aeronautics research for societal benefit.
- **Goal 5**: Enable program and institutional capabilities to conduct NASA’s aeronautics and space activities.
- **Goal 6**: Share NASA with the public, educators, and students to provide opportunities to participate in our mission, foster innovation, and contribute to a strong national economy.

In the decades since Congress enacted the National Aeronautics and Space Act of 1958, NASA has challenged its scientific and engineering capabilities in pursuing its mission, generating tremendous results and benefits for humankind. NASA will continue to push scientific and technical boundaries in pursuing these goals.

The Federal Acquisition Regulation (FAR), 48 CFR chapter 1, contains procurement regulations that apply to NASA and other Federal agencies. NASA implements and supplements FAR requirements through the NASA FAR Supplement (NFS), 48 CFR chapter 18. NASA will review and update the entire NFS. During the second half of FY 2012 with projected completion of January 2013, NASA will report
these regulatory actions in the spring 2012 Unified Agenda. Concurrently, we will continue to make routine changes to the NFS to implement NASA initiatives and Federal procurement policy.

**Retrospective Review of Existing Regulations**

Pursuant to section 6 of Executive Order 13579 “Regulation and Independent Regulatory Agencies” (Jul. 11, 2011), the following Regulation Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in NASA’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for NASA. These rulemakings can also be found on Regulations.gov. NASA’s final plans can be found at http://www.nasa.gov/open.

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<td>NASA Grant and Cooperative Agreement Handbook, Delete Requirement for U.S. Citizenship</td>
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<td>NASA Grant and Cooperative Agreement: Change Procedures for Letter of Credit Advance Payments</td>
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<td>2700–AD96</td>
<td>Update, Streamline and Reorganize</td>
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<td>Use of NASA Airfield Facilities by Aircraft Not Operated for the Benefit of the Federal Government</td>
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<td>Delegation of authority to license the use of Centennial of Flight Commission name, Delegation of authority of certain civil rights functions to Department of Health, Education, and Welfare, and Care and use of animals in the conduct of NASA activities - REPEALS</td>
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<td>Collection of Civil Claims of the United States Arising Out of the Activities of NASA.</td>
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Abstracts for regulations to be amended or repealed between October 2011 and October 2012 are reported in the fall 2011 edition of Unified Agenda of Federal Regulatory and Deregulation actions.

**BILLING CODE 7510–13–S**

**NATIONAL ARCHIVES AND RECORDS ADMINISTRATION (NARA)**

**Statement of Regulatory Priorities**

**Overview**

The National Archives and Records Administration (NARA) issues regulations directed to other Federal agencies and to the public. Records management regulations directed to Federal agencies concern the proper management and disposition of Federal records. Through the Information Security Oversight Office (ISOO), NARA also issues Governmentwide regulations concerning information security
classification and declassification programs. NARA regulations directed to the public address access to and use of our historically valuable holdings, including archives, donated historical materials, Nixon Presidential materials, and Presidential records. NARA also issues regulations relating to the National Historical Publications and Records Commission (NHPRC) grant programs.

NARA has three regulatory priorities for fiscal year 2012, which are included in The Regulatory Plan.

The first is a continuation of the previous fiscal year’s update to NARA’s regulations related to declassification of classified national security information in records transferred to NARA’s legal custody. The rule incorporates changes resulting from promulgation of Executive Order 13526, Classified National Security Information. These changes include establishing procedures for the automatic declassification of records in NARA’s legal custody and revising requirements for reclassification of information to meet the provisions of E.O. 13526. Executive Order 13526 also created the National Declassification Center (NDC) with a mission to align people, processes, and technologies to advance the declassification and public release of historically valuable permanent records while maintaining national security. The Notice of Proposed Rulemaking was published on July 8, 2011.

The second priority is NARA’s revisions to the Federal records management regulations found at 36 CFR chapter XII, subchapter B, to include the Electronic Records Archives (ERA). ERA is NARA’s system that Federal agencies use to draft new records retention schedules for records, officially submit those schedules for approval by NARA, request the transfer of records to NARA for accessioning or pre-accessioning, and submit electronic records for storage in the ERA electronic records repository. The revisions will cover provisions in 36 CFR parts 1220, 1225, 1226, and 1235.

The third priority is NARA’s revisions to its Freedom of Information Act (FOIA) regulations, clarifying the applicability of the FOIA to categories of records in NARA’s holdings.
147. • FEDERAL RECORDS MANAGEMENT; ELECTRONIC RECORDS ARCHIVES (ERA)

Priority:
Other Significant

Legal Authority:
44 USC 2107

CFR Citation:
36 CFR 1235

Legal Deadline:
None

Abstract:
The National Archives and Records proposes to revise the Federal records management regulations found at 36 CFR chapter XII, subchapter B, to include the Electronic Records Archives (ERA). ERA is NARA’s system that Federal agencies use to draft new records retention schedules for records, officially submit those schedules for approval by NARA, request the transfer of records to NARA for accessioning or pre-accessioning, and submit electronic records for storage in the ERA electronic records repository. The revisions will cover provisions in 36 CFR parts 1220, 1225, 1226, and 1235.

Statement of Need:
NARA will revise the Federal records management regulations found at 36 CFR chapter XII, subchapter B, to include the Electronic Records Archives (ERA). ERA is NARA’s system that Federal agencies use to draft new records retention schedules for records, officially submit those schedules for approval by NARA, request the transfer of records to NARA for accessioning or pre-accessioning, and submit electronic records for storage in the ERA electronic records repository. The revisions will cover provisions in 36 CFR parts 1220, 1225, 1226, and 1235.

Summary of Legal Basis:
44 U.S.C. 2107(2)

Alternatives:
None
Anticipated Cost and Benefits:
None

Risks:
None

Timetable:

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Regulatory Flexibility Analysis Required:
No

Government Levels Affected:
Federal

URL For Public Comments:
regulations.gov

Agency Contact:
Laura McCarthy
National Archives and Records Administration
8601 Adelphi Road
College Park, MD 20740
Phone: 301 837–3023
Email: laura.mccarthy@nara.gov

RIN: 3095–AB74

BILLING CODE:  7515-01-S
OFFICE OF PERSONNEL MANAGEMENT (OPM)

Statement of Regulatory Priorities
The Office of Personnel Management’s mission is to ensure the Federal Government has an effective civilian workforce. OPM fulfills that mission by, among other things, providing human capital advice and leadership for the President and Federal agencies; delivering human resources policies, products, and services; and holding agencies accountable for their human capital practices. OPM’s 2011 regulatory priorities are designed to support these activities.

**Pay System for Senior Professionals (SL/ST)**

OPM proposes to amend rules for setting and adjusting pay of senior-level (SL) and scientific and professional (ST) employees. The Senior Professional Performance Act of 2008 changed pay for these employees by eliminating their previous entitlement to locality pay and providing instead for rates of basic pay up to the rate payable for level III of the Executive Schedule (EX-III), or if the employee is under a certified performance appraisal system, the rate payable for level II of the Executive Schedule (EX-II). Consistent with this statutory emphasis on performance-based pay, these regulations will provide more flexible rules for agencies to set and adjust pay for SL and ST employees based primarily upon individual performance, contribution to the agency’s performance, or both, as determined under a rigorous performance appraisal system.

**Managing Senior Executive Performance**

OPM proposes to revise the regulations addressing the performance management of Senior Executives to provide for a Governmentwide appraisal system built around the Executive Core Qualifications and agency mission results. During fiscal year 2011, the President’s Management Council (PMC) sponsored several workgroups to address various SES-related issues. One of the recommendations from the work group on SES appraisal system certification, and supported by the PMC, the Chief Human Capital Officers Council, OPM, and OMB, was the creation of a Governmentwide appraisal system for the SES to support and facilitate interagency consistency and mobility of this
Governmentwide corps. The new regulations will provide a common structure and basic requirements, while allowing flexibility to address agency-specific needs.

**Recruitment, Relocation, and Retention Incentives**

In OPM’s continuing effort to improve the administration and oversight of recruitment, relocation, and retention incentives, OPM anticipates issuing final regulations to improve oversight of group recruitment incentive determinations and all retention incentives, add succession planning to the list of factors that an agency may consider before approving a retention incentive, and provide that OPM may require data on recruitment, relocation, and retention incentives from agencies on an annual basis. These regulations will help support OPM’s efforts to ensure agencies actively manage their incentive programs so that they continue to be cost-effective compensation tools.

**Benefits for Reservists and their Family Members**

OPM anticipates issuing final regulations to implement section 565(b)(1) of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2010 (Public Law 111-84, Oct. 28, 2009) that amends the Family and Medical Leave Act (FMLA) provisions at 5 U.S.C. 6381 to 6383 to add qualifying exigencies to the circumstances or events that entitle Federal employees to up to 12 administrative workweeks of FMLA unpaid leave during any 12-month period. The final regulations would amend OPM’s current regulations at part 630, subpart L, to cover qualifying exigencies when the spouse, son, daughter, or parent of the employee is on covered active duty in the Armed Forces or has been notified of an impending call or order to covered active duty. OPM proposes eight categories of qualifying exigencies: Short-notice deployments, military events and related activities, childcare and school activities, financial and legal arrangements, counseling, rest and recuperation, post-deployment activities, and additional
activities not encompassed in the other categories when the agency and employee agree they qualify as exigencies, including the timing and duration of the leave.

Suitability Reinvestigations

OPM anticipates issuing final regulations modifying suitability regulations to assist agencies in carrying out new requirements to reinvestigate individuals in public trust positions under Executive Order 13488, *Granting Reciprocity on Excepted Service and Federal Contractor Employee Fitness and Reinvestigating Individuals in Positions of Public Trust*, to ensure their continued employment is appropriate. The proposed rule was originally published on November 3, 2009, at 74 FR 56747, with the comment period ending on January 4, 2010. A new notice was provided on November 5, 2010, at 75 FR 68222 to provide additional information relative to the scope of reinvestigations for public trust positions in order to allow for further comment as to reinvestigation frequency.

Designation of National Security Position

OPM anticipates issuing final regulations regarding designation of national security positions. The proposed rule was published on December 14, 2010, at 75 FR 77783, as one of a number of initiatives OPM has undertaken to simplify and streamline the system of Federal Government investigative and adjudicative processes to make them more efficient and as equitable as possible. The purpose of the revised rule is to clarify the requirements and procedures agencies should observe when designating national security positions as required under Executive Order 10450, *Security Requirements for Government Employment*. The regulations will clarify the categories of positions, which by virtue of the nature of their duties have the potential to bring about a material adverse impact on the national security, whether or not the positions require access to classified information. The regulations also will
acknowledge, for greater clarity, complementary requirements set forth in part 731, Suitability, so that every position is properly designated with regard to both public trust risk and national security sensitivity considerations. Finally, the rule will clarify when reinvestigation of individuals in national security positions is required.

Pathways

OPM proposes to issue regulations based on the Executive Order (E.O.) 13562 "Recruiting and Hiring Students and Recent Graduates" issued December 27, 2010. This E.O. established the concept of Pathways Programs to promote employment opportunities for students and recent graduates in the Federal workforce, as well as provides an exception to the competitive hiring rules. The Pathways Programs consist of three discrete excepted service internships programs for students and recent graduates: The Internship Program; the Recent Graduates Program; and the Presidential Management Fellows Program. The E.O. also established a new excepted service Schedule D in the Code of Federal Regulation (5 CFR).

Hiring Reform—Recruitment, Selection, and Placement (General) Job Announcement and Applicant Notification

OPM proposes to amend the regulations concerning the content of a job announcement. We are also proposing to add regulations to require Federal agencies to notify applicants at key stages in the hiring process; to require agencies to use alternative valid assessment tools, excluding lengthy written essays or narratives of knowledge, skills, and abilities/competencies, and to require agencies to accept cover
letters and résumés as the initial application for a Federal job. With these changes, OPM plans to streamline the Federal hiring process and improve an applicant’s experience.

**Schedule A—Elimination of Job Readiness Certification for People With Disabilities**

OPM proposes to amend its regulations on the appointment of persons with mental retardation, severe physical disabilities, or psychiatric disabilities. The proposed changes will eliminate the certification of job readiness requirement for people with mental retardation, severe physical disabilities, or psychiatric disabilities using the Schedule A appointment authority.

**Noncompetitive Appointment of Certain Former Overseas Employees**

OPM is issuing a proposed regulation to clarify that an employee’s same-sex domestic partner qualifies and should be treated as a family member for purposes of eligibility for noncompetitive appointments based on overseas employment, as provided in section 315.608 of title 5, Code of Federal Regulations. These regulations implemented, in part, a June 2, 2010, Presidential Memorandum by providing same-sex domestic partners with the same employment opportunities that opposite-sex spouses of Federal employees receive under 5 CFR 315.608.

**Multi-State Exchanges; Implementations for Affordable Care Act Provisions**
The U.S. Office of Personnel Management (OPM) is proposing to implement regulations for the provisions of the Affordable Care Act of 2010 in order for OPM to contract with at least two multi-State plans for the Affordable Insurance Exchanges to be offered in 2014.

Retrospective Review of Existing Regulations

Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in The Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final agency plans can be found at: http://www.opm.gov/open/.

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<td>3206-AM18</td>
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<td>3206-AM20</td>
<td>Presumption of Insurable Interest for Same-Sex Domestic Partners</td>
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<td>3206-AM24</td>
<td>Regulatory Requirements for Alcoholism and Drug Abuse Programs and Services for Federal Civilian Employees</td>
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<td>3206-AM27</td>
<td>Designation of National Security Positions</td>
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<td>3206-AM31</td>
<td>Change in Definitions; Evacuation Pay and the Separate Maintenance Allowance at Johnston Island</td>
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<td>3206-AM34</td>
<td>Excepted Service, Career and Career-Conditional Employment; and Pathways Programs</td>
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<td>3206-AM35</td>
<td>Noncompetitive Appointment of Certain Former Overseas Employees</td>
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<td>Agency Use of Appropriated Funds for Child Care Costs for Lower Income Employees</td>
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<td>Federal Employees Health Benefits Program; Community-</td>
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<td>Rated Health Plans</td>
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<td>3206-AM45</td>
<td>Retirement Systems Modernization N/A</td>
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**BILLING CODE: 6325-44-S**

**PENSION BENEFIT GUARANTY CORPORATION (PBGC)**

**Statement of Regulatory and Deregulatory Priorities**

The Pension Benefit Guaranty Corporation (PBGC) protects the pensions of about 44 million people in about 27,500 private-sector defined benefit plans. PBGC receives no funds from general tax revenues. Operations are financed by insurance premiums, investment income, assets from pension plans trusteed by PBGC, and recoveries from the companies formerly responsible for the trusteed plans.

To carry out these functions, PBGC issues regulations on such matters as termination, payment of premiums, reporting and disclosure, and assessment and collection of employer liability. The Corporation is committed to issuing simple, understandable, flexible, and timely regulations to help affected parties.
PBGC intends that its regulations (new and existing) implement the law in ways that do not impede the maintenance of existing defined benefit plans or the establishment of new plans. Thus, in developing new regulations and reviewing existing regulations, the focus, to the extent possible, is to avoid placing burdens on plans, employers, and participants, and to ease and simplify employer compliance. In particular, PBGC strives to meet the needs of small businesses that sponsor defined benefit plans.

PBGC develops its regulations in accordance with the principles set forth in Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011) and PBGC’s Plan for Regulatory Review (Regulatory Review Plan), which can be found at www.pbgc.gov/documents/plan-for-regulatory-review.pdf. This Statement of Regulatory and Deregulatory Priorities reflects the initial results of the Regulatory Review Plan.

PBGC Insurance Programs

PBGC administers two insurance programs for privately defined benefit plans under title IV of the Employee Retirement Income Security Act of 1974 (ERISA): A single-employer plan termination insurance program and a multiemployer plan insolvency insurance program.

- **Single-Employer Program.** Under the single-employer program, when a plan terminates with insufficient assets to cover all plan benefits (distress and involuntary terminations), PBGC pays plan benefits that are guaranteed under title IV. PBGC also pays nonguaranteed plan benefits to the extent funded by plan assets or recoveries from employers.

- **Multiemployer Program.** The smaller multiemployer program covers about 1,500 collectively bargained plans involving more than one unrelated employer. PBGC provides financial assistance (in the form of a loan) to the plan if the plan is unable to pay benefits at the guaranteed level. Guaranteed benefits are less than single-employer guaranteed benefits.
At the end of fiscal year 2010, PBGC had a $23 billion deficit in its insurance programs.

**Regulatory Objectives and Priorities**

PBGC’s regulatory objectives and priorities are developed in the context of the Corporation’s statutory purposes:

- To encourage voluntary private pension plans;

- To provide for the timely and uninterrupted payment of pension benefits; and

- To keep premiums at the lowest possible levels.

Pensions and the statutory framework in which they are maintained and terminated are inherently complex. Despite this inherent complexity, PBGC is committed to issuing simple, understandable, flexible, and timely regulations and other guidance that do not impose undue burdens that could impede maintenance or establishment of defined benefit plans.

Through its regulations and other guidance, PBGC strives to minimize burdens on plans, plan sponsors, and plan participants; simplify filing; provide relief for small businesses and plans; and assist plans in complying with applicable requirements. To enhance policymaking through collaboration, PBGC also plans to expand opportunities for public participation in rulemaking (see Open Government and Public Participation below).

PBGC’s current regulatory objectives and priorities are to reconsider two proposed regulations, continue to provide targeted relief in certain premium situations, and complete implementation of the
Pension Protection Act of 2006 (PPA 2006). PBGC will streamline requirements and reduce unjustified burdens as much as possible in its planned rulemakings.

**Retrospective Review of Existing Regulations**

Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review" (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Department’s final retrospective review of regulations plan. The proposals are described below.

<table>
<thead>
<tr>
<th>Title</th>
<th>RIN</th>
<th>Effect on Small Business</th>
</tr>
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<tbody>
<tr>
<td>Reportable Events; Pension Protection Act of 2006</td>
<td>1212-AB06</td>
<td>Expected to reduce burden on small business</td>
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<tr>
<td>Liability for Termination of Single-Employer Plans; Treatment of Substantial Cessation of Operations; ERISA section 4062(e)</td>
<td>1212-AB20</td>
<td>Expected to reduce burden on small business</td>
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<tr>
<td>Assessment of and Relief From Information Penalties</td>
<td>1212-AB04</td>
<td>No significant effect on burden</td>
</tr>
<tr>
<td>Allocation of Assets in Single-Employer Plans; Valuation of Benefits and Assets</td>
<td>1212-AA55</td>
<td>Undetermined</td>
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</tbody>
</table>

*Reportable events.* PPA 2006 affected certain provisions in the PBGC’s reportable events regulation (part 4043), which requires employers to notify PBGC of certain plan or corporate events. In November 2009, PBGC published a proposed rule to conform the regulation to the PPA 2006 changes and make
In response to Executive Order 13563 and comments on the non-PPA provisions of the proposed rule, PBGC decided to re-propose the rule. PBGC is trying to take advantage of other existing reporting requirements and methods to avoid burdening companies and plans. PBGC is also considering how to implement stakeholder suggestions that different reporting requirements should apply in circumstances where the risk to PBGC is low or compliance is especially burdensome. PBGC expects that the new proposal will more effectively target troubled plans while reducing burden for healthy plans and sponsors. The target date for publication of a new proposed rule is March 2012.

ERISA section 4062(e). The statutory provision requires reporting of, and liability for, certain substantial cessations of operations by employers that maintain single-employer plans. In August 2010, PBGC issued a proposed rule to provide guidance on the applicability and enforcement of section 4062(e). In light of comments, PBGC is reconsidering its 2010 proposed rule. In particular, PBGC is considering reducing the reporting burden and tying 4062(e) to actual risk through the same approaches being considered for reportable events. The target date for publication of a new proposed rule is June 2012.

Information penalty policy. PBGC plans to amend its regulation on Rules for Administrative Review of Agency Decisions (part 4003) to cover information penalties under ERISA section 4071. This amendment, which was part of an earlier proposed rule, would make the process for assessing and reviewing information penalties more transparent and consistent with other agency determinations. The target date for publication of a final rule is January 2012.

Changes in other regulations to improve plan and PBGC administration. PBGC will review selected aspects its regulations on Benefits Payable in Terminated Single-Employer Plans (part 4022), Allocation of Assets in Single-Employer Plans (part 4044) and Withdrawal Liability for Multiemployer Plans

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(Subchapter I) and Insolvency, Reorganization, Termination, and Other Rules Applicable to Multiemployer Plans (Subchapter J) to eliminate obsolete provisions, simplify language, and fill in gaps where guidance would be helpful to the public and the relevant operating departments. See the Regulatory Review Plan for details.

**Premium Payment Relief**

PBGC is granting relief in three types of situations under its premium regulations.\(^3\) PBGC decided to grant this relief as a result of its regulatory review under Executive Order 13563 and in response to comments from premium payers and pension professionals. In that same spirit, PBGC is considering revising its premium penalty policy--appendix to PBGC’s regulation on Payment of Premiums (part 4007)--to be more flexible in the case of clerical or administrative errors generally and is already taking steps in this direction. Such changes could remove undue penalty burdens on plan sponsors where there is minimal risk to the pension insurance system or intent to evade regulatory requirements. See Small Businesses for a possible regulatory initiative affecting small businesses and plans.

**PPA 2006 Implementation**

*Cash balance plans.* PPA 2006 changed the rules for determining benefits in cash balance plans and other statutory hybrid plans. In October 2011, PBGC published a proposed rule implementing the changes in both PBGC-trusteered plans and in plans that close out in the private sector. PBGC expects to finalize the proposal in 2012.

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\(^3\) 76 Fed. Reg. 57082 (Sep. 15, 2011), www.pbgc.gov/Documents/2011-23692.pdf. For 2011 and later plan years, PBGC is waiving premium penalties assessed solely because payments are late by not more than 7 calendar days. For 2010 and later plan years, PBGC is providing relief similar to, but more expansive than, the relief provided in 2010 under Technical Update 10-2: Variable Rate Premiums; Alternative Premium Funding Target Elections; Box 5 Relief. For 2008 and 2009 plan years, PBGC is waiving premium penalties for late premiums in connection with certain errors in connection with alternative premium funding target elections.
Missing participants. Currently, PBGC’s Missing Participants Program applies only to terminating single-employer defined benefit plans insured by PBGC. PPA 2006 expanded the program to cover single-employer plans sponsored by professional service employers with fewer than 25 employees, multiemployer defined benefit plans, and 401(k) and other defined contribution plans. PBGC is developing a proposed rule to implement the expansion and streamline the existing program. The target date for publication of the proposed rule is June 2012.

Shutdown benefits. Under PPA 2006, the phase-in period for the guarantee of a benefit payable solely by reason of an “unpredictable contingent event,” such as a plant shutdown, starts no earlier than the date of the shutdown or other unpredictable contingent event. PBGC published a proposed rule implementing this statutory change in March 2011\(^4\) and received one comment. The target date for publication of a final rule is May 2012.

Commercial airline plans. Under PPA 2006, there are special rules for commercial airline plans that elected the PPA 2006 17-year funding relief and terminate within 10 years of the election. The amount of benefits guaranteed in such plans is fixed as of the first plan year to which funding relief applies, with plan assets first allocated to the amount of guaranteed benefits lost due to the new rules. The target date for a proposed rule implementing these rules is June 2012.

Owner-participant benefits. ERISA contains special guarantee and asset allocation rules that apply to owner-participants in terminating underfunded plans. PPA 2006 simplified these rules and applied them only to majority (50% or more) owners, as opposed to substantial (10% or more) owners, as was the case previously. The target date for publication of a proposed rule implementing these changes is June 2012.

Other Regulations

DC to DB plan rollovers. PBGC is developing a proposed rule to address title IV treatment of rollovers from defined contribution plans to defined benefit plans, including asset allocation and guarantee limits. The target date for publication of this proposed rule is May 2012.

ERISA section 4010. In response to comments, PBGC has begun reviewing its regulation on Annual Financial and Actuarial Information Reporting (part 4010) and the related e-filing application to consider ways of reducing reporting burden, without forgoing receipt of critical information. PBGC is considering waiving reporting for plans that must file 4010 information solely based on (1) the conditions for a statutory lien resulting from missed required contributions totaling over one million dollars being met or (2) outstanding funding waivers totaling over one million dollars. Waiving such reporting would reduce the compliance and cost burden on plan sponsors; PBGC can obtain some information similar to that reported under section 4010 from other sources, such as reportable events filings. PBGC is also considering other changes to section 4010 reporting that would further reduce burden for financially sound companies, by taking into account company financial health and targeting reporting more closely to the risk of plan termination; such changes might require legislative action.

Small Businesses

PBGC takes into account the special needs and concerns of small businesses in making policy. A large percentage of the plans insured by PBGC are small or maintained by small employers. PBGC is considering several proposed rules that will focus on small businesses:

Small plan premium due date. The premium due date for plans with fewer than 100 participants is 4 months after year-end (April 30 for calendar year plans). PBGC has heard that some small plans with year-end valuation dates have difficulty meeting the filing deadline because such plans traditionally do not complete their actuarial valuation for funding purposes until after the premium due date. In light of this concern, PBGC will review part 4007 to determine whether changes could be made that would enable small plans to streamline their premium valuation procedures and thereby reduce
actuarial fees. PBGC will consider several options (e.g., extending the due date or permitting the use of prior-year data).

*Missing participants.* See Missing participants under PPA 2006 Implementation above. Expansion of the program will benefit small businesses closing out terminating plans.

*Owner-participant benefits.* See Owner-participant benefits under PPA 2006 Implementation above. These rules primarily affect small businesses.

**Open Government and Public Participation**

PBGC views public participation as very important to regulatory development and review. For example, PBGC’s current efforts to reduce regulatory burden are in substantial part a response to public comments. Regulatory projects discussed above, such as reportable events, ERISA section 4062(e), and ERISA section 4010, highlight PBGC’s customer-focused efforts to reduce regulatory burden.

PBGC’s Regulatory Review Plan sets forth ways to expand opportunities for public participation in the regulatory process. For example, PBGC plans to hold public hearings as it develops major regulations, so that the agency has a better understanding of the needs and concerns of plan administrators and plan sponsors.

Further, PBGC plans to provide additional means for public involvement, including online town hall meetings, social media, and continuing opportunity for public comment on PBGC’s Web site. PBGC also invites comments on the Regulatory Review Plan on an ongoing basis as we engage in the review process. Comments should be sent to regs.comments@pbgc.gov.

PBGC will continue to look for ways to further improve its regulations.
Statement of Regulatory Priorities

Overview

The mission of the U.S. Small Business Administration (SBA) is to maintain and strengthen the Nation’s economy by enabling the establishment and viability of small businesses and by assisting in economic recovery of communities after disasters. In carrying out this mission, SBA strives to improve the economic and regulatory environment for small businesses, including those in areas that have significantly higher unemployment and lower income levels than the Nation’s averages and those in traditionally underserved markets. The Agency serves as a guarantor of small business loans and provides management and technical assistance to existing or potential small business owners to help them grow, sustain, or start their businesses. The Agency also provides direct financial assistance to communities that have experienced catastrophes. This assistance is a critical factor in rebuilding the communities and their devastated economies. SBA’s regulatory policy encompasses these objectives and is implemented primarily through several core program offices: Office of Capital Access, Office of Government Contracting and Business, Office of Entrepreneurial Development, and Office of Disaster Assistance. Other offices, such as the Office of Veterans Business Development and Office of Native American Affairs, also play a role in developing and shaping Agency regulatory policy that affects veterans, American Indians, Alaska Natives, Native Hawaiians, and the indigenous people of Guam and American Samoa.

Reducing Burden on Small Businesses

SBA strives to develop regulations that, to the extent possible, reduce or eliminate the burden on the public, especially its core constituents—small businesses. The Agency’s regulatory process generally includes an assessment of the relative costs and benefits of the regulations, as required by Executive Order 12866 “Regulatory Planning and Review” and Executive Order 13563, as well as an analysis under the Regulatory Flexibility Act of whether regulations will have a significant economic impact on small
businesses or small entities. Where practicable or feasible, SBA also analyzes whether there are alternative approaches to a proposed regulation that would be more beneficial to the public. SBA’s program offices are particularly invested in finding ways to reduce the burden imposed by the Agency’s loan, innovation, and procurement programs. As a result, SBA is exploring various electronic options for doing business with the Agency, including: E-applications for financial assistance, participation in Government contracting and surety bond assistance programs, as well as submission of loan data. Along those lines, SBA is analyzing the following initiatives that would streamline and simplify the process for participating in the various SBA programs:

- **Single Electronic Lender Application for 7(a) Loan Programs**

  There is potential for process improvement by adopting a single e-application for all SBA 7(a) guaranteed loans. This would reduce the paperwork burden on lenders (which in turn impacts small business borrowers) and will result in greater lender participation, particularly small community banks, credit unions, and rural lenders. These lenders usually support small businesses that seek relatively small amounts of capital to grow and succeed; hence, additional small, community lender-partners will potentially lead to increasing the amount of small-dollar loans flowing to small businesses. This e-application could add value by reducing the screen out rate currently experienced during the loan application process and could improve the timeliness of delivering loan approvals and hence delivery of loan proceeds to small businesses.

- **Uniform SBIR Portal for Information and Solicitations**

  For the Small Business Innovation Research program, there is no one form or database for applying for the program and submitting proposals. Often, there are multiple systems for a single submission—e.g., eRA Commons (Electronic Research Administration NIH website) and Grants.gov—in addition to the lack of uniformity across the participating 11 agencies in the program. The goal of the project would be to create a common, simple application form that ports over application data into the agencies’ application systems on an as-needed basis. This would not replace other application systems, but it would be a common form that ports data over more simply to multiple application systems. In addition to the
technology solution, the business process of narrowing and simplifying into a common base of information can be open-sourced to multiple agencies, as they may navigate the same challenges of common applicants for different programs.

- **Single Uniform Certification for SBA Contracting Programs**
  
  SBA will analyze the regulatory changes required and implications of developing and implementing a single certification process for common information collected across its small business contracting programs, such as the 8(a) Business Development, HUBZone, Women-Owned Small Business, Service-Disabled Veteran-Owned Small Business, and other Small Business Programs.

- **Automated Credit Decision Model for 7(a) Loan Program**
  
  For loans of less than $250,000, SBA could develop an optional credit scoring methodology to be used by SBA lender partners in their underwriting process, which could result in lowering the lenders’ cost of delivering capital to borrowers and would likely expand their interest in making low-dollar loans. This initiative may also attract additional lenders (e.g., small community banks, credit unions, and rural lenders) to become SBA partners and increase credit availability for small businesses.

- **Government Contracting Program Eligibility Website**
  
  SBA will analyze the feasibility of building a one-stop website for small businesses to input basic information about their business (e.g., number of employees, revenues, ownership (e.g., women-owned, service-disabled veteran-owned, minority owned)) to determine contracting and loan programs they may be eligible for, as well as help identify local district offices and resource partners in their area. This would make it easier for the public to access and participate in Federal small business programs.

- **Integrated Certification and Program Management System**
  
  SBA will review development of a system that will allow the certification and program management (e.g., reviews, protests) processes to be done electronically for the 8(a) and HUBZone programs. The system is also planned to be developed to allow for future additions for other programs such as the Women-Owned Small Business Federal Contract Program and the Service-Disabled Veteran-Owned Small Business program. This system would enable easier access to the small business programs and reduce the amount of paperwork submitted to SBA by applicants.
• Auto-Approve Disaster Loans Based on Credit Scores

Private industry approves a substantial number of loans through credit scoring to reduce the cost of underwriting. The portfolio analysis that is being currently completed indicates that the performance of loans to borrowers with a FICO score that is greater than 725 have limited risk. Changing this process would allow SBA more flexibility to design a loan approval that is in line with current private-sector practices and reduce the processing cost for lower-dollar disaster loans.

• Automated Process of Receiving Insurance Recovery Information

Under the disaster loan program, loan eligibility is based on the uncompensated disaster loss. Being able to automate the insurance recovery information would enhance our ability to ensure that insurance proceeds are addressed and no duplication of benefits occurs as a result of insurance recovery after loan approval. This would reduce the possibility that disaster victims will be asked to repay erroneously disbursed Federal disaster benefits.

Openness and Transparency

SBA is committed to developing regulations that are clear, simple, and easily understood. In addition, consistent with the President’s mandate, SBA continues to promote transparency, collaboration, and public participation in its rulemakings. To that end, SBA routinely solicits comments on its regulations, even those that are not subject to the public notice and comment requirement under the Administrative Procedure Act, and where appropriate, the Agency consults with other Federal agencies or other entities that the regulation might affect. In addition, in compliance with Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011), SBA invited the public to take an active role in helping SBA to develop a plan for conducting a retrospective review of the Agency’s regulations, including identification of rules that are obsolete, unnecessary, or excessively burdensome to the public. The final plan is available on SBA’s Open Government website at http://www.sba.gov/content/sba-final-plan-retrospective-analysis-existing-rules-0. SBA also conducted several public meetings throughout diverse areas of the country to solicit feedback on the Agency’s development and implementation of various rules required by the Small Business Jobs Act of 2010. The Agency will determine how the comments can inform the rules identified in this plan and the agenda overall, particularly those rules that concern
Government contracting programs and activities. Information on the completed SBJA Tour can be found at www.sba.gov/jobsacttour.

Finally, as part of the White House’s Startup America initiative, SBA and representatives from other agencies met with small business entrepreneurs in eight different cities across the country to solicit ideas and suggestions for reducing barriers and for regulations that foster a more supportive environment for entrepreneurship and innovation. As SBA develops its regulations, the relevant ideas and suggestions will be incorporated into the rules or used to inform the process generally. Information on the Startup America meetings can be found at www.sba.gov/content/startup-america-reducing-barriers-roundtables.

Regulatory Framework

The SBA FY 2011 to FY 2016 strategic plan serves as the foundation for the regulations that the Agency will develop during the next 12 months. This strategic plan proposes three primary strategic goals: (1) Growing businesses and creating jobs; (2) building an SBA that meets needs of today’s and tomorrow’s small businesses; and (3) serving as the voice for small business. In order to achieve these goals SBA will, among other objectives, focus on:

• Expanding access to capital through SBA’s extensive lending network;
• Ensuring Federal contracting goals are met or exceeded by collaborating across the Federal Government to expand opportunities for small businesses and strengthen the integrity of the Federal contracting data and certification process;
• Ensuring that SBA’s disaster assistance resources for businesses, nonprofit organizations, homeowners, and renters can be deployed quickly, effectively, and efficiently;
• Strengthening SBA’s relevance to high-growth entrepreneurs and small businesses to more effectively drive innovation and job creation; and
• Mitigating risk to taxpayers and improving program oversight.

Regulatory Priority

As reported in the SBA’s fall 2011 regulatory agenda, the Agency plans to publish several regulations during the coming year that are designed to achieve these goals. During this time, SBA’s highest regulatory priority will focus on implementing changes to the regulations or policy directives regarding (1)
Multiple award contracts and small business set-asides; (2) Small Business Innovation and Research (SBIR) Program; (3) Small Business Technology Transfer (STTR) Program; and (4) Mentor-Protégé Opportunities for the HUBZone, Women-Owned Small Business (WOSB) Contracting, and Service-Disabled Veteran-Owned Small Business (SDVOSB) Programs.

(1) Multiple Award Contracts and Small Business Set-Asides:

SBA intends to implement authorities provided by section 1331 of the Small Business Jobs Act that would allow Federal agencies to set aside a part or parts of multiple awards contracts for small business concerns; set aside orders placed against multiple award contracts for small business concerns; and reserve one or more contract awards for small business concerns under full and open competition in certain circumstances. Allowing small businesses to gain access to multiple award contracts through prime contract awards or through set-asides off the orders of the prime contracts should increase Federal contracting opportunities for such businesses.

(2) Small Business Innovation and Research (SBIR) Program:

The SBIR Policy Directive has been identified as one of the initial candidates for review under SBA’s Retrospective Review Plan under E.O. 13563. This review is also in step with a White House initiative, Innovation and Entrepreneurial Working Group (IEWG), to share best practices and improve the SBIR and STTR Programs. One of the issues highlighted during these discussions is the need to clarify the SBIR data rights afforded to SBIR awardees and the Federal Government. SBA has also worked with small businesses that have had difficulty protecting their SBIR Data Rights as a result of misunderstandings by the procuring agencies of the Government’s rights to such data. This confusion has resulted in disagreements between parties and, in some cases, the confusion about data rights may have resulted in small businesses shying away from the SBIR Program. As a result, SBA believes that there is critical need to update the SBIR Policy Directive to set clear guidelines for determining the right of the parties to the SBIR data. Accordingly, SBA plans to update the SBIR Policy Directive to, among other things, revise the definitions relating to SBIR data and clarify the rights of the SBIR awardees and the Federal Government to such data. SBA believes that clarifications to the directive regarding SBIR data rights will benefit both small businesses and the agencies and further could lead to an increase in responses to SBIR solicitations and savings of administrative costs.
(3) Small Business Technology Transfer (STTR) Program:

As identified in the Retrospective Review Plan required by E.O. 13563, SBA also plans to conduct a comprehensive review of the existing STTR Program Policy Directive, which has not been updated since 2005. Many elements of the STTR program are designed and intended to be identical to those of the SBIR program. The SBA is therefore planning to update the STTR Policy Directive to maintain the appropriate consistency with the SBIR program. As with the SBIR program, SBA also expects to make several amendments to the STTR Policy Directive that will reduce confusion for both small businesses and the Federal agencies that make awards under the program, especially on the issue of data rights. Possible benefits include a potential increase in responses to STTR solicitations and savings of administrative costs as a result of fewer informational inquiries and disputes.

(4) Small Business Mentor-Protégé Programs:

SBA currently has a mentor-protégé program for the 8(a) Business Development Program that is intended to enhance the capabilities of the protégé and to improve its ability to successfully compete for Federal contracts. The Small Business Jobs Act authorized SBA to use this model to establish similar mentor-protégé programs for the Service Disabled Veteran-Owned, HUBZone and Women-Owned Small Business Programs. This authority is consistent with recommendations issued by an interagency task force created by President Obama on Federal Contracting Opportunities for Small Businesses. Among other things, the task force recommended that mentor-protégé programs should be promoted through a new Governmentwide framework to give small businesses the opportunity to develop under the wing of experienced large businesses in an expanded Federal procurement arena. During the next 12 months, SBA will make it a priority to issue regulations establishing the three newly authorized mentor-protégé programs and set out the standards for participating as a mentor or protégé in each. As is the case with the current mentor-protégé program, the various forms of assistance that a mentor will be expected to provide to a protégé include technical and/or management assistance; financial assistance in the form of equity investment and/or loans; subcontracts and/or assistance in performing prime contracts with the Government in the form of joint venture arrangements.
Retrospective Review of Existing Regulations

Pursuant to section 6 of Executive Order 13563 “Improving Regulation and Regulatory Review” (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the Agency’s final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in the Regulatory Plan. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Regingo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final agency retrospective review plan can be found at:

http://www.sba.gov/about-sba-services/open-government

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<td>Small Business Technology Transfer (STTR) Policy Directive</td>
<td>YES</td>
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<tr>
<td>3245-AF84</td>
<td>Small Business Innovation Research (SBIR) Program Policy Directive</td>
<td>YES</td>
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<tr>
<td>3245-AG04</td>
<td>504 Regulatory Enhancements</td>
<td>YES</td>
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<td>3245-AG07</td>
<td>Small Business Size Standards: Professional, Scientific, and Technical Services</td>
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<td>Small Business Size Standards: Information</td>
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<td>Small Business Size Standards; Administrative and Support, Waste Management and Remediation Services Industries</td>
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<td>Small Business Size Standards: Real Estate, Rental and Leasing Industries</td>
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<td>Small Business Size Standards: Health Care and Social Assistance Services Industries</td>
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<td>Small Business Size Standards: Arts, Entertainment, and Recreation</td>
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<td>Small Business Size Standards: Construction</td>
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<tr>
<td>3245-AG38</td>
<td>Small Business HUBZone Program</td>
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SBA

PROPOSED RULE STAGE

148. SMALL BUSINESS TECHNOLOGY TRANSFER (STTR) POLICY DIRECTIVE

Priority:
Other Significant

Legal Authority:
15 USC 638 (p)

CFR Citation:
None

Legal Deadline:
None

Abstract:
SBA plans to propose amendments to the 2005 STTR Program Policy Directive. These proposed amendments bring the text up to date on issues, including the changes to program eligibility made by the SBA in 2005 and an adjustment to award guideline amounts consistent with the adjustments to the SBIR award amounts made in 2008, and they seek to add clarity to areas such as STTR data rights and incorporate several miscellaneous corrections to the text.

Statement of Need:
SBA is proposing to clarify SBIR data rights and make several necessary updates to the SBIR Policy Directive. Many elements of the STTR program are designed and intended to be identical to those of the SBIR program. SBA is therefore planning to update the STTR Policy Directive to maintain the appropriate consistency with the SBIR program.

Summary of Legal Basis:

Alternatives:
Not applicable.

Anticipated Cost and Benefits:
SBA believes that bringing the STTR Policy Directive up to date to conform with the SBIR Program Policy Directive will reduce confusion and benefit both small businesses and the agencies. The possible benefits include a potential increase in responses to STTR solicitations and savings of administrative costs as a result of fewer informational inquiries and disputes. Ultimately, SBA believes there will be negligible costs to the Federal Government with respect to the award and monitoring of STTR funding agreements as a result of this rule.

**Risks:**

Not applicable.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

Federal

**Additional Information:**

Includes Retrospective Review under Executive Order 13563 with small business burden reduction.

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Edsel M. Brown Jr.

Assistant Director, Office of Innovation

Small Business Administration

409 Third Street SW

Washington, DC 20416

Phone: 202 205–6450
SBA plans to update the SBIR Policy Directive to revise the definitions relating to SBIR data, add several new definitions, and clarify the rights in such SBIR data afforded to SBIR awardees and the Federal Government. In addition, the SBA proposes to clarify other parts of the Directive relating to Phase I, II, and III awards and the definition of Small Business Concern.

Statement of Need:
The White House's Innovation and Entrepreneurial Working Group (IEWG) is supporting an initiative to share best practices and improve the SBIR and Small Business Technology Transfer (STTR) Programs. During sessions concerning this initiative, SBA have discussed the issue of SBIR data rights and the need for clarification. In addition, SBA has worked with small businesses that have had difficulty protecting their SBIR data rights as a result of misunderstandings by the procuring agencies of the Government's rights to such data. As a result, SBA believes that the directive must be clarified.
SBA is also proposing to amend the definition of Small Business Concern. SBA amended this definition in 13 CFR section 121.702 of its regulations, at 69 FR 70185 (Dec. 3, 2004). SBA is updating language in the Policy Directive to reflect the current definition as set forth in the regulations.

**Summary of Legal Basis:**


**Alternatives:**

In clarifying SBIR data rights in the Directive, SBA considered using terms as defined in the sections of the FAR and DFARS that address SBIR data rights. However, SBA determined that some of the terms were not consistent with SBIR policy and other terms could be used with modification. For other proposed updates to the Directive, alternatives were not applicable.

**Anticipated Cost and Benefits:**

SBA believes that clarifications to the directive regarding SBIR data rights will benefit both small businesses and the agencies. It is our understanding that there is a misunderstanding of or confusion surrounding the rights in data of each party to an SBIR Funding Agreement. This confusion has resulted in disagreements between parties. In some cases, the confusion about data rights may have resulted in small businesses shying away from the SBIR Program. Therefore, the potential benefits include a potential increase in responses to SBIR solicitations and savings of administrative costs as a result of fewer disputes. Ultimately, SBA believes there will be negligible costs to the Federal Government with respect to the award and monitoring of SBIR funding agreements as a result of this rule.

**Risks:**

Not applicable.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**
Government Levels Affected:
Federal

Additional Information:
Includes Retrospective Review under Executive Order 13563 with small business burden reduction.

Agency Contact:
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RIN: 3245–AF84

SBA
150. ACQUISITION PROCESS: TASK AND DELIVERY ORDER CONTRACTS, BUNDLING, CONSOLIDATION

Priority:
Other Significant

Legal Authority:
PL 111–240, sec 1311, 1312, 1313, 1331

CFR Citation:
13 CFR 121, 124 to 127, 134

Legal Deadline:
Abstract:
The U.S. Small Business Administration (SBA) is proposing regulations that will establish guidance under which Federal agencies may set aside part of a multiple award contract for small business concerns, set aside orders placed against multiple award contracts for small business concerns, and reserve one or more awards for small business concerns under full and open competition for a multiple award contract. These regulations will apply to small businesses, including those small businesses eligible for SBA’s socioeconomic programs. The U.S. Small Business Administration is proposing regulations that will set forth a Governmentwide policy on bundling, which will address teams and joint ventures of small businesses and the requirement that each Federal agency must publish on its website the rationale for any bundled contract. In addition, the proposed regulations will address contract consolidation and the limitations on the use of such consolidation in Federal procurement to include ensuring that the head of a Federal agency may not carry out a consolidated contract over $2 million unless the Senior Procurement Executive or Chief Acquisition Officer ensures that market research has been conducted and determines that the consolidation is necessary and justified.

Statement of Need:
The law recognizes that many small businesses were losing Federal contract opportunities when agencies issue multiple award contracts. This will improve small business participation in the acquisition process and provide clear direction to contracting officers by authorizing small business set-asides in multiple-award contracts.

Summary of Legal Basis:
The Small Business Jobs Act of 2010, Public Law No. 111-240, section 1331, requires the SBA to issue regulations implementing this provision within one year from the date of enactment.

Alternatives:
SBA has not yet determined the costs resulting from this regulation.

Anticipated Cost and Benefits:
This provision will allow small businesses to gain access to multiple award contracts through prime contract awards or through set-asides of the orders of the prime contracts. This should increase opportunities for small businesses.
Risks:
Not applicable.

Timetable:

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Regulatory Flexibility Analysis Required:
Yes

Small Entities Affected:
Businesses

Government Levels Affected:
Federal

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RIN: 3245–AG20

151. SMALL BUSINESS JOBS ACT: SMALL BUSINESS MENTOR–PROTÉGÉ PROGRAMS

Priority:
Other Significant

Legal Authority:
SBA currently has a mentor-protégé program for the 8(a) Business Development Program that is intended to enhance the capabilities of the protégé and to improve its ability to successfully compete for Federal contracts. The Small Business Jobs Act authorized SBA to use this model to establish similar mentor-protégé programs for the Service Disabled Veteran-Owned, HUBZone, and Women-Owned Small Federal Contract Business Programs. This authority is consistent with recommendations issued by an interagency task force created by President Obama on Federal Contracting Opportunities for Small Businesses. During the next 12 months, SBA will make it a priority to issue regulations establishing the three newly authorized mentor-protégé programs and set out the standards for participating as a mentor or protégé in each. As is the case with the current mentor-protégé program, the various forms of assistance that a mentor will be expected to provide to a protégé include technical and/or management assistance; financial assistance in the form of equity investment and/or loans; subcontracts; and/or assistance in performing prime contracts with the Government in the form of joint venture arrangements.

Congress determined that the SBA-administered mentor-protégé program currently available to 8(a) BD participants is a valuable tool for all small business concerns and authorized SBA to establish mentor protégé programs for the HUBZone SBC, Service Disabled Veteran-Owned SBCs, and Women-Owned Small Business programs SBCs. This authority is consistent with recommendations issued by an interagency task force created by President Obama on Federal Contracting Opportunities for Small Businesses. Among other things, the task force recommended that mentor-protégé programs should be promoted through a new Governmentwide framework to give small businesses the opportunity to develop under the wing of experienced large businesses in an expanded Federal procurement arena.

Summary of Legal Basis:

**Alternatives:**

At this point, SBA believes that the best option for implementing the authority is to create a regulatory scheme that is similar to the existing mentor-protégé program.

**Anticipated Cost and Benefits:**

SBA has not yet quantified the costs associated with this rule. However, program participants, particularly the protégés, would be able to leverage the mentoring opportunities as a form of business development assistance that could enhance their capabilities to successfully compete for contracts in and out of the Federal contracting arena. This assistance may include technical and/or management assistance; financial assistance in the form of equity investments and/or loans; subcontracts; and/or assistance in performing prime contracts with the Government in the form of joint venture arrangements.

**Risks:**

None identified.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

Yes

**Small Entities Affected:**

Businesses

**Government Levels Affected:**

None

**Agency Contact:**

Dean R. Koppel
Assistant Director, Office of Policy and Research
Small Business Administration
SOCIAL SECURITY ADMINISTRATION (SSA)

Statement of Regulatory Priorities

We administer the Retirement, Survivors, and Disability Insurance programs under title II of the Social Security Act (Act), the Supplemental Security Income (SSI) program under title XVI of the Act, and the Special Veterans Benefits program under title VIII of the Act. As directed by Congress, we also assist in administering portions of the Medicare program under title XVIII of the Act. Our regulations codify the requirements for eligibility and entitlement to benefits and our procedures for administering these programs. Generally, our regulations do not impose burdens on the private sector or on State or local governments, except for the States' disability determination services. We fully fund the disability determination services in advance or by way of reimbursement for necessary costs in making disability determinations.

The six entries in our regulatory plan (plan) represent issues of major importance to the Agency. We describe the individual initiatives more fully in the attached plan.
Improving the Disability Process

Since the continued improvement of the disability program is of vital concern to us, we have five initiatives in the plan addressing disability-related issues. They include:

- A proposed rule that will modify the requirement to recontact medical source(s) first when we need to resolve an inconsistency or insufficiency in the evidence;

- A proposed rule that will allow adjudicators the discretion to proceed to the fifth step of the sequential process for assessing disability when we have insufficient information regarding a claimant’s past relevant work history;

- Three proposed rules updating the medical listings used to determine disability—evaluating respiratory system disorders, mental disorders, and hematological disorders. The revisions reflect our adjudicative experience and advances in medical knowledge, diagnosis, and treatment.

Enhance Public Service

We will revise our rules to establish a 12-month time limit for the withdrawal of an old-age benefits application. The final rules will permit only one withdrawal per lifetime.

Retrospective Review of Existing Regulations

Pursuant to section 6 of Executive Order 13563 "Improving Regulation and Regulatory Review" (Jan. 18, 2011), the following Regulatory Identifier Numbers (RINs) have been
identified as associated with retrospective review and analysis in our final retrospective review of regulations plan. Some of these entries on this list may be completed actions, which do not appear in *The Regulatory Plan*. However, more information can be found about these completed rulemakings in past publications of the Unified Agenda on Reginfo.gov in the Completed Actions section for that agency. These rulemakings can also be found on Regulations.gov. The final agency plans can be found at: http://www.socialsecurity.gov/open/regsreview/EO-13563-Final-Plan.html.

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<td>0960-AF35</td>
<td>Revised Medical Criteria for Evaluating Neurological Impairments</td>
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<tr>
<td>0960-AF58</td>
<td>Revised Medical Criteria for Evaluating Respiratory System Disorders</td>
<td>No</td>
</tr>
<tr>
<td>0960-AF69</td>
<td>Revised Medical Criteria for Evaluating Mental Disorders</td>
<td>No</td>
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<tr>
<td>0960-AF88</td>
<td>Revised Medical Criteria for Evaluating Hematological Disorders</td>
<td>No</td>
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<td>0960-AG21</td>
<td>New Medical Criteria for Evaluating Language and</td>
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<td>0960-AG28</td>
<td>Revised Medical Criteria for Evaluating Growth Impairments</td>
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<td>Revised Medical Criteria for Evaluating Musculoskeletal Disorders</td>
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<td>Revised Medical Criteria for Evaluating Immune (HIV) System Disorders</td>
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<td>0960-AH04</td>
<td>Revised Medical Criteria for Evaluating Congenital Disorders That Affect Multiple Body Systems</td>
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152. REVISED MEDICAL CRITERIA FOR EVALUATING RESPIRATORY SYSTEM DISORDERS
(859P)

Priority:
Other Significant. Major under 5 USC 801.

Legal Authority:
42 USC 402; 42 USC 405(a); 42 USC 405(b); 42 USC 405(d) to 405(h); 42 USC 416(i); 42 USC 421(a); 42 USC 421(i); 42 USC 423; 42 USC 902(a)(5); 42 USC 1381a; 42 USC 1382c; 42 USC 1383; 42 USC 1383b

CFR Citation:
20 CFR 404.1500, app 1

Legal Deadline:
None

Abstract:
Sections 3.00 and 103.00, Respiratory System, of appendix 1 to subpart P of part 404 of our regulations describe respiratory system disorders that we consider severe enough to prevent an individual from doing any gainful activity or that cause marked and severe functional limitations for a child claiming SSI payments under title XVI. We are proposing to revise these sections to ensure that the medical evaluation criteria are up to date and consistent with the latest advances in medical knowledge and treatment.

Statement of Need:
These proposed regulations are necessary to update the Respiratory System listings to reflect advances in medical knowledge, treatment, and methods of evaluating respiratory disorders. The changes would
ensure that determinations of disability have a sound medical basis, that claimants receive equal
treatment through the use of specific criteria, and that people who are disabled can be readily identified
and awarded benefits if all other factors of entitlement or eligibility are met.

Summary of Legal Basis:
Administrative—not required by statute or court order.

Alternatives:
We considered not revising the listings and continuing to use our current criteria. However, we believe
that proposing these revisions is preferable because of the medical advances that have been made in
treating and evaluating respiratory diseases and because of our adjudicative experience.

Anticipated Cost and Benefits:
Estimated costs—low.

Risks:
None.

Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Additional Information:
Includes Retrospective Review under E.O. 13563.

URL For Public Comments:
153. REVISED MEDICAL CRITERIA FOR EVALUATING HEMATOLOGICAL DISORDERS (974P)

Priority:

Other Significant

Legal Authority:

42 USC 402; 42 USC 405(a); 42 USC 405(b); 42 USC 405(d) to 405(h); 42 USC 416(i); 42 USC 421(a);
42 USC 421(i); 42 USC 423; 42 USC 902(a)5); 42 USC 1381a; 42 USC 1382c; 42 USC 1383; 42 USC
1383b

CFR Citation:
Legal Deadline:
None

Abstract:
Sections 7.00 and 107.00, Hematological Disorders, of appendix 1 to subpart P of part 404 of our regulations, describe hematological disorders that we consider severe enough to prevent a person from performing any gainful activity or that cause marked and severe functional limitation for a child claiming Supplemental Security Income payments under title XVI. We are proposing to revise the criteria in these sections to ensure that the medical evaluation criteria are up to date and consistent with the latest advances in medical knowledge and treatment.

Statement of Need:
These proposed regulations are necessary to update the hematological listings to reflect advances in medical knowledge, treatment, and methods of evaluating hematological disorders. The changes ensure that determinations of disability have a sound medical basis, that claimants receive equal treatment through the use of specific criteria, and that people who are disabled can be readily identified and awarded benefits if all other factors of entitlement or eligibility are met.

Summary of Legal Basis:
Administrative—not required by statute or court order.

Alternatives:
We considered not revising the listings or making only minor technical changes and continuing to use our current criteria. However, we believe that proposing these revisions is preferable because of the medical advances that have been made in treating and evaluating these types of impairments.

Anticipated Cost and Benefits:
Estimated savings—low.

Risks:
None.

Timetable:

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NPRM 03/00/12

Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Additional Information:
Includes Retrospective Review under E.O. 13563.

URL For Public Comments:
www.regulations.gov

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Phone: 410 965–1483

RIN: 0960–AF88
154. REVISED MEDICAL CRITERIA FOR EVALUATING MENTAL DISORDERS (886F)

Priority:
Other Significant

Legal Authority:
42 USC 402; 42 USC 405(a); 42 USC 405(b); 42 USC 405(d) to 42 USC 405(h); 42 USC 416(i); 42 USC 421(a); 42 USC 421(h); 42 USC 421(i); 42 USC 423; 42 USC 902(a)(5); 42 USC 1381a; 42 USC 1382c; 42 USC 1383; 42 USC 1383b

CFR Citation:
20 CFR 404.1500, app 1; 20 CFR 404.1520a; 20 CFR 416.920a; 20 CFR 416.934

Legal Deadline:
None

Abstract:
Sections 12.00 and 112.00, Mental Disorders, of appendix 1 to subpart P of part 404 of our regulations describe those mental impairments that we consider severe enough to prevent a person from doing any gainful activity, or that cause marked and severe functional limitations for a child claiming Supplemental Security Income payments under title XVI. We will revise the criteria in these sections to ensure that the medical evaluation criteria are up to date and consistent with the latest advances in medical knowledge and treatment.

Statement of Need:
These regulations are necessary to update the listings for evaluating mental disorders to reflect advances in medical knowledge, treatment, and methods of evaluating these disorders. The changes will ensure that determinations of disability have a sound medical basis, that claimants receive equal treatment through the use of specific criteria, and that people who are disabled can be readily identified and awarded benefits if all other factors of entitlement or eligibility are met.

Summary of Legal Basis:
Administrative—not required by statute or court order.
**Alternatives:**

We considered not revising the listings or making only minor technical changes. However, we believe that these revisions are preferable because of the medical advances that have been made in treating and evaluating these types of disorders. We have not comprehensively revised the current listings in over 15 years. Medical advances in disability evaluation and treatment and our program experience make clear that the current listings do not reflect state-of-the-art medical knowledge and technology.

**Anticipated Cost and Benefits:**

Savings estimates for fiscal years 2010 to 2018: (in millions of dollars) OASDI-315, SSI-370.

**Risks:**

None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Additional Information:**

Includes Retrospective Review under E.O. 13563.
URL For Public Comments: www.regulations.gov

Agency Contact:
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Phone: 410 966–9822

RIN: 0960–AF69

SSA

155. HOW WE COLLECT AND CONSIDER EVIDENCE OF DISABILITY (3487P)

Priority:
Other Significant

Legal Authority:
42 USC 402; 42 USC 405(a); 42 USC 405(d)(h); 42 USC 416(i); 42 USC 421(a); 42 USC 421(i); 42 USC 421(m); 42 USC 421 note; 42 USC 422(c); 42 USC 423; 42 USC 423 note; 42 USC 425; 42 USC
We propose to modify the requirement to recontact your medical source(s) first when we need to resolve an inconsistency or insufficiency in the evidence he or she provided. Depending on the nature of the inconsistency or insufficiency, there may be other, more appropriate sources from whom we could obtain the information we need. By giving adjudicators more flexibility in determining how best to obtain this information, we will be able to make a determination or decision on disability claims more quickly and efficiently in certain situations. Eventually, our need to recontact your medical source(s) in many situations will be significantly reduced as a result of our efforts to improve the evidence collection process through the increased utilization of Health Information Technology (HIT).

**Statement of Need:**

The final rule would modify the requirement to recontact a claimant's medical source(s) first when we need to resolve an inconsistency or insufficiency in the evidence he or she provided. Depending on the nature of the inconsistency or insufficiency, there may be other, more appropriate sources from whom we could obtain the information we need. By giving adjudicators more flexibility in determining how best to obtain this information, we will be able to make a determination or decision on disability claims more quickly and efficiently in certain situations.

**Summary of Legal Basis:**

Administrative—not required by statute or court order.

**Alternatives:**

We could have chosen not to make these changes at all. However, the Integrated Disability Process workgroup recommended these changes, and we know from the intercomponent review process that our
adjudicators support them. The changes affect the process of collecting and considering evidence, and we believe that this final rule represents our best course of action.

**Anticipated Cost and Benefits:**

These changes will have only a negligible net effect on the projected level of OASDI and Federal SSI benefit outlays.

**Risks:**

None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**URL For Public Comments:**

www.regulations.gov

**Agency Contact:**

Janet Truhe

Social Insurance Specialist

Social Security Administration

Office of Disability Programs

6401 Security Boulevard

Baltimore, MD 21235–6401

Phone: 410 966–7203
SSA

156. AMENDMENTS TO REGULATIONS REGARDING WITHDRAWALS OF APPLICATIONS AND VOLUNTARY SUSPENSION OF BENEFITS (3573F)

Priority:
Other Significant

Legal Authority:
42 USC 402; 42 USC 402(i); 42 USC 402(j); 42 USC 402(o); 42 USC 402(p); 42 USC 402(r); 42 USC 403(a); 42 USC 403(b); 42 USC 405(a); 42 USC 416; 42 USC 416(i)(2); 42 USC 423; 42 USC 423(b); 42 USC 425; 42 USC 428(a) to 428(e); 42 USC 902(a)(5)

CFR Citation:
20 CFR 404.313; 20 CFR 404.640

Legal Deadline:
None

Abstract:
We will modify our regulations to establish a 12-month time limit for the withdrawal of an old age benefits application. We will also permit only one withdrawal per lifetime. These changes will limit the voluntary suspension of benefits only to those benefits disbursed in future months.

Statement of Need:
We are under a clear congressional mandate to protect the Trust Funds. It is crucial that we change our current policies that have the effect of allowing beneficiaries to withdraw applications or suspend benefits and use benefits from the Trust Funds as something akin to an interest-free loan.

**Summary of Legal Basis:**

Discretionary

**Alternatives:**

None.

**Anticipated Cost and Benefits:**

Not yet determined.

**Risks:**

None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

Undetermined

**Agency Contact:**

Deidre Bemister

Social Insurance Specialist

Social Security Administration
157. EXPEDITED VOCATIONAL ASSESSMENT UNDER THE SEQUENTIAL EVALUATION PROCESS

(3684P)

Priority:
Other Significant

Legal Authority:
42 USC 402; 42 USC 405(a) to 405(b); 42 USC 405(d) to 405(h); 42 USC 416(i); 42 USC 421(a); 42 USC 421(i); 42 USC 421(j); 42 USC 421(m); 42 USC 421 note; 42 USC 422(c); 42 USC 423; 42 USC 423 note; 42 USC 425; 42 USC 902(a)(5); 42 USC 902 note; 42 USC 1382; 42 USC 1382c; 42 USC 1382h; 42 USC 1382h note; 42 USC 1383(a); 42 USC 1383(c); 42 USC 1383(d)(i); 42 USC 1383(p); 42 USC 1383b

CFR Citation:
404.1505; 404.1520; 404.1545; 404.1560; 404.1565; 404.1569; 404.1594; 416.905; 416.920; 416.945; 416.960; 416.965; 416.969; 416.987; 416.994

Legal Deadline:
None

**Abstract:**

We propose to give adjudicators the discretion to proceed to the fifth step of the sequential evaluation process for assessing disability when we have insufficient information about a claimant's past relevant work history to make the findings required for step 4. If an adjudicator finds at step 5 that a claimant may be unable to adjust to other work existing in the national economy, the adjudicator would return to the fourth step to develop the claimant's work history and make a finding about whether the claimant can perform his or her past relevant work. This proposed new process would not disadvantage any claimant or change the ultimate conclusion about whether a claimant is disabled, but it would promote administrative efficiency and help us make more timely disability determinations and decisions.

**Statement of Need:**

This expedited process will shorten case processing time, give our adjudicators more flexibility to assess disability claims, and assist in reducing the disability backlog.

**Summary of Legal Basis:**

Administrative—not required by statute or court order.

**Alternatives:**

Undetermined at this time.

**Anticipated Cost and Benefits:**

Undetermined at this time.

**Risks:**

None.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No
Small Entities Affected:
No

Government Levels Affected:
None

URL For Public Comments:
www.regulations.gov

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RIN: 0960–AH26

BILLING CODE: 4191-02-S
A. CFPB Purposes and Functions

The Bureau of Consumer Financial Protection (CFPB) was established as an independent bureau of the Federal Reserve System by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111-203, 124 Stat. 1376) (Dodd-Frank Act). Pursuant to the Act, the CFPB has rulemaking, supervisory, enforcement, and other authorities relating to consumer financial products and services. Among these are the consumer financial protection authorities that transferred to the CFPB from seven Federal agencies on the designated transfer date, July 21, 2011. These authorities include the ability to issue regulations under more than a dozen Federal consumer financial laws.

As provided in section 1021 of the Dodd-Frank Act, the purpose of the CFPB is to implement and enforce Federal consumer financial laws consistently for the purpose of ensuring that all consumers have access to markets for consumer financial products and services and that such markets are fair, transparent, and competitive. The CFPB is authorized to exercise its authorities for the purpose of ensuring that:

1. Consumers are provided with timely and understandable information to make responsible decisions about transactions involving consumer financial products and services;
2. Consumers are protected from unfair, deceptive, or abusive acts and practices and from discrimination;
3. Outdated, unnecessary, or unduly burdensome regulations concerning consumer financial products and services are regularly identified and addressed in order to reduce unwarranted regulatory burdens;

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1 This Statement of Regulatory Priorities (Statement) supplements the semiannual regulatory agenda that is being published contemporaneously. The CFPB is submitting this Statement on a voluntary basis.
Federal consumer financial law is enforced consistently, without regard to status as a depository institution, in order to promote fair competition; and

Markets for consumer financial products and services operate transparently and efficiently to facilitate access and innovation.

B. Immediate Regulatory Priorities

The CFPB is working on a wide range of initiatives to address issues in markets for consumer financial products and services that are not reflected in this notice because the Unified Agenda is limited to rulemaking activities. With regard to the exercise of its rulemaking authorities, as reflected in the CFPB’s semiannual regulatory agenda, the CFPB’s immediate focus is on completing various rulemakings that are mandated by the Dodd-Frank Act and resolving a handful of proposals that had been issued by the transferor agencies prior to July 21, 2011. In addition, the CFPB must issue a number of procedural rules relating to the stand-up of the CFPB as an independent regulatory agency.

The semiannual regulatory agenda provides more detailed descriptions of individual rulemaking projects. The CFPB is particularly focused on meeting the rulemaking deadlines set forth in the Dodd-Frank Act, in order to provide certainty to consumers, financial services providers, and the broader economy. These rules include:

- Regulations governing international money transfers (remittances) under the Electronic Fund Transfer Act. These regulations concern disclosures, error resolution procedures, and other topics. The Board of Governors of the Federal Reserve System issued a Notice of Proposed Rulemaking concerning these rules in May 2011, and the CFPB now has responsibility for finalizing this rulemaking, as appropriate. Final rules on certain topics are required by January 21, 2012.

- An initial rule determining which nondepository covered persons are subject to the CFPB’s supervision authority as “larger participant[s]” of “other markets” for consumer financial products and services. The Dodd-Frank Act vests the CFPB with authority to examine all sizes of nondepository financial services providers engaged in mortgage lending and certain related services, payday lending, and private student lending. It also authorizes examinations of a “larger participant of a
market for other consumer financial products or services,” as defined by the rule. An initial rule defining who is a larger participant in these other markets is required by July 21, 2012.

- Consolidated mortgage loan disclosures and related rules under the Truth in Lending Act and Real Estate Settlement Procedures Act. The Dodd-Frank Act requires the CFPB to develop consolidated mortgage loan disclosures to satisfy the requirements of both the Truth in Lending Act and Real Estate Settlement Procedures Act. The Dodd-Frank Act also imposes certain new disclosure requirements, and the CFPB inherits proposals to amend Truth in Lending Act regulations relating to mortgage loan disclosures that were issued by the Board of Governors of the Federal Reserve System in August 2009 and September 2010. The consolidated disclosures proposal is required by July 21, 2012.

- Regulations defining lenders’ obligations to assess borrowers’ ability to repay mortgage loans, including certain protections from liability for “qualified mortgages.” The Dodd-Frank Act requires lenders to make a reasonable, good faith determination of applicants’ ability to repay closed-end mortgage loans. “Qualified mortgages” as defined under the Act and by regulation receive certain protections from liability. The Board of Governors of the Federal Reserve System issued a Notice of Proposed Rulemaking concerning these rules in May 2011, and the CFPB now has responsibility for finalizing this rulemaking, as appropriate. Although the statutory deadline for final rules is January 2013, this rulemaking is a particular priority for the CFPB because it impacts basic underwriting practices and serves as a building block for other Dodd-Frank Act rulemakings.

- Regulations to implement other requirements concerning mortgage origination and servicing under title XIV of the Dodd-Frank Act. As described in more detail in the individual agenda entries, these regulations will address a variety of origination and servicing practices, including loan originator compensation and anti-steering rules, restrictions on high-cost loans, maintenance of escrow accounts and other servicing practices, and (on an interagency basis) various regulations concerning appraisals. Final rules are required by January 21, 2013.

In carrying out these mandates, the CFPB is focused on developing clear, simple disclosures that will give consumers the information they need to determine which consumer financial products and services best meet their needs while avoiding unwarranted regulatory burdens on industry. The CFPB has made
the consolidation of mortgage disclosure forms a priority because streamlining the existing, overlapping forms could significantly benefit both consumers and industry members alike.

Because the CFPB is at an early stage of its operations, it is still in the process of assessing the need and resources available for additional substantive rulemakings beyond those listed in its fall 2011 agenda. The CFPB expects to include any such projects that it realistically anticipates considering before October 2012 in its spring 2012 agenda.

BILLING CODE 4810–AM–S
CONSUMER PRODUCT SAFETY COMMISSION (CPSC)

Statement of Regulatory Priorities

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of death and injury associated with consumer products. To achieve this goal, the Commission:

- Develops mandatory product safety standards or banning rules when other, less restrictive efforts are inadequate to address a safety hazard, or where required by statute;

- Obtains repair, replacement, or refund of the purchase price for defective products that present a substantial product hazard;

- Develops information and education campaigns about the safety of consumer products;

- Directs staff to participate in the development or revision of voluntary product safety standards; and

- Follows congressional mandates to enact specific regulations.
Unless directed otherwise by congressional mandate, when deciding which of these approaches to take in any specific case, the Commission gathers and analyzes the best available data about the nature and extent of the risk presented by the product. The Commission’s rules require the Commission to consider, among other factors, the following criteria when deciding the level of priority for any particular project:

- Frequency and severity of injury;
- Causality of injury;
- Chronic illness and future injuries;
- Costs and benefits of Commission action;
- Unforeseen nature of the risk;
- Vulnerability of the population at risk; and
- Probability of exposure to the hazard.

**Significant Regulatory Actions:**

Currently, the Commission is considering two rules that would constitute “significant regulatory actions” under the definition of that term in Executive Order 12866:

1.  **Flammability Standard for Upholstered Furniture**

   Under section 4 of the Flammable Fabrics Act (FFA), the Commission may issue a flammability standard or other regulation for a product of interior furnishing if the Commission determines that such a standard is needed to adequately protect the public against unreasonable risk of the occurrence of fire leading to death or personal injury, or significant property damage. The Commission’s regulatory proceeding could result in several actions, one of which could be the development of a mandatory standard requiring that upholstered furniture meet mandatory labeling requirements, resist ignition, or meet other performance criteria under test conditions specified in the standard.
2. Testing and Certification Rule

Section 102(d)(2) of the CPSIA, as amended by H.R. 2715, requires the Commission to: (1) Initiate by regulation a program by which a manufacturer or private labeler may label a consumer product as complying with the certification requirements of section 102(a) of the CPSIA and (2) establish protocols and standards (i) for ensuring that a children’s product tested for compliance with an applicable children’s product safety rule is subject to testing periodically and when there has been a material change in the product’s design or manufacturing process, including the sourcing of component parts; (ii) for the testing of representative samples to ensure continued compliance; (iii) for verifying that a children’s product tested by a conformity assessment body complies with applicable children’s product safety rules; and (iv) for safeguarding against the exercise of undue influence on a third party conformity assessment body by a manufacturer or private labeler.

FEDERAL TRADE COMMISSION (FTC)

Statement of Regulatory Priorities

I. Regulatory Priorities

Background

The Federal Trade Commission (“FTC” or “Commission”) is an independent agency charged by its enabling statute, the Federal Trade Commission Act, with protecting American consumers from “unfair methods of competition” and “unfair or deceptive acts or practices” in the marketplace. The Commission strives to ensure that consumers benefit from a vigorously competitive marketplace. The Commission’s work is rooted in a belief that competition, based on truthful and non-misleading information about products and services, brings the best choice of products and services at the lowest prices for consumers.

The Commission pursues its goal of promoting competition in the marketplace through two different,
but complementary, approaches. Unfair or deceptive acts or practices injure both consumers and honest
competitors alike and undermine competitive markets. Through its consumer protection activities, the
Commission seeks to ensure that consumers receive accurate, truthful, and non-misleading information in
the marketplace. At the same time, for consumers to have a choice of products and services at
competitive prices and quality, the marketplace must be free from anticompetitive business practices.
Thus, the second part of the Commission’s basic mission—antitrust enforcement—is to prohibit
anticompetitive mergers or other anticompetitive business practices without unduly interfering with the
legitimate activities of businesses. These two complementary missions make the Commission unique
insofar as it is the Nation’s only Federal agency to be given this combination of statutory authority to
protect consumers.

The Commission is, first and foremost, a law enforcement agency. It pursues its mandate primarily
through case-by-case enforcement of the Federal Trade Commission Act and other statutes. In addition,
the Commission is also charged with the responsibility of issuing and enforcing regulations under a
number of statutes. Most notably, pursuant to the FTC Act, the Commission currently has in place 16
trade regulation rules. Other examples include the regulations enforced pursuant to credit and financial
statutes\(^1\) and to energy laws.\(^2\) The Commission also has adopted a number of voluntary industry guides.
Most of the regulations and guides pertain to consumer protection matters and are intended to ensure
that consumers receive the information necessary to evaluate competing products and make informed
purchasing decisions.

Commission Initiatives

The Commission protects consumers through a variety of tools, including both regulatory and non-
regulatory approaches. To that end, it has encouraged industry self-regulation, developed a corporate
leniency policy for certain rule violations, and established compliance partnerships where appropriate.

\(^1\)For example, the Fair Credit Reporting Act (15 U.S.C. sections 1681 to 1681(u), as amended) and the
6801 to 6809 and sections 6821 to 6827, as amended).

\(^2\)For example, the Energy Policy Act of 1992 (106 Stat. 2776, codified in scattered sections of the U.S.
(EISA)).
As detailed below, help for consumers in financial distress, health care, consumer privacy and data security, and evolving technology and innovation continue to be at the forefront of the Commission’s consumer protection and competition programs. By subject area, the FTC discusses the major workshops, reports,\(^3\) and initiatives pursued since the 2010 Regulatory Plan was published.

(a) Help for Consumers in Financial Distress. Historic levels of consumer debt, increased unemployment, and an unprecedented downturn in the housing and mortgage markets have contributed to high rates of consumer bankruptcies and mortgage loan delinquency and foreclosure. Debt relief services have proliferated in recent years as the economy has declined and greater numbers of consumers hold debts they cannot pay. On August 10, 2010, the Commission published a final rule amending the Telemarketing Sales Rule to protect consumers from deceptive or abusive practices in the telemarketing of debt relief services. 75 FR 48458. On October 27, 2010, the Commission issued a policy statement staying enforcement of the debt relief provisions of the TSR against companies offering tax relief services; i.e., services offered to renegotiate, settle, or alter the terms of obligation between a consumer and a taxing entity.

The recent national mortgage crisis has launched an industry of companies purporting, for a fee, to obtain mortgage loan modifications or other relief for consumers facing foreclosure. The Commission and other law enforcement have also taken action against mortgage companies that harm consumers through their advertising and servicing practices. The Commission initiated and completed rulemakings to protect distressed homeowners, one relating to Mortgage Assistance Relief Services ("MARS") and another relating to Mortgage Acts and Practices ("MAP")-Advertising, through the life cycle of the mortgage loan.\(^4\) The Commission ceased work on a pending NPRM for MAP-Servicing on July 21, 2011, and other MAP rules, when the legal authority to promulgate rulemaking transferred to the new Consumer Financial Protection Bureau pursuant to the Dodd-Frank Wall Street Reform Act of 2010.

In December 2009, the Commission issued compulsory information requests to nine of the Nation’s largest debt buying companies, requiring them to produce information about their practices in buying and

\(^3\) The FTC also prepares a number of annual and periodic reports on the statutes it administers. These are not discussed in this plan.

\(^4\) See Mortgage Loans Rule under Rulemakings and Studies Required by Statute, infra.
selling consumer debt. These nine companies collectively purchased about 75 percent of the debt sold in the United States in 2008. The Commission is using the information for a study of the debt buying industry. In recent years, debt buyers have become a significant part of the debt collection system. In February 2009, the Commission issued a report, based on an agency debt collection workshop, in which it found major problems in the flow of information among creditors, debt buyers, and collection agencies. The Commission issued the compulsory information requests to determine whether the practice of debt buying is contributing to these problems and, more generally, to obtain a better understanding of the role of debt buyers in the debt collection system. The Agency plans to report its findings in early 2012.

In 2011, Commission staff initiated an outreach project to inform various advocacy and educational/research organizations about the litigation research and recommendations in the Commission’s July 2010 roundtable report entitled “Repairing a Broken System: Protecting Consumers in Debt Collection Litigation and Arbitration.” Some State reform efforts have been motivated by the Commission’s recommendations, and the project has created opportunities for FTC staff to discuss the Commission’s findings and recommendations with groups and individuals who work on these issues. The underlying 2010 report concluded that the system for resolving consumer debt collection disputes is broken and recommended significant litigation and arbitration reforms to improve efficiency and fairness to consumers.

On April 28, 2011, the Commission held a workshop, “Debt Collection 2.0: Protecting Consumers as Technologies Change.” The workshop addressed the impact of technological advances on the debt collection system, the resulting consumer protection concerns, and the need for responsive policy changes. Technologies discussed included the tools collectors use to locate consumers and their assets; changing modes of collector-consumer communications, such as mobile phones, auto-dialers, and electronic mail; the software that collectors use to manage information about consumers and debts; and collector use of social media applications. The workshop featured a diverse group of speakers, including consumer advocates, academics, technologists, law enforcers, and industry representatives. Staff officials are drafting a document highlighting the workshop’s key findings and their policy implications.

On July 20, 2011, in response to concerns about possible unfair, deceptive, or abusive practices by certain debt collectors, the Commission finalized a policy statement clarifying that the Agency will not take enforcement action under the Fair Debt Collection Practices Act (FDCPA) or the FTC Act against companies that are attempting to collect the debts of deceased consumers, if the companies communicate with someone who is authorized to pay debts from the estate of the deceased. 76 FR 44915 (Jul. 27, 2011). The policy statement also emphasizes that debt collectors may not mislead relatives to believe that they are personally liable for a deceased consumer’s debts or use other deceptive or abusive tactics.

(b) Health Care. The FTC continues to work to end anticompetitive settlement deals featuring payments by branded drug firms to a generic competitor to keep generic drugs off the market (so called, “pay for delay” agreements). The Commission has a two-pronged approach to ending these anticompetitive pay-for-delay agreements: Active support for legislation to ban harmful pay-for-delay agreements—one example being the proposed legislation that Senate Judiciary Committee recently approved6—and Federal court challenges to invalidate individual agreements. The FTC currently has three cases in active litigation.7 An FTC Staff Report issued during FY 2010 found a record number (31) of potential pay for delay agreements.8

The Commission also studied the competitive impact of authorized generics, which are generic versions of drugs sold by the branded company. On August 31, 2011, the Commission issued a final report on authorized generic drugs, finding that when branded pharmaceutical companies introduce an authorized generic version of their brand-name drug, it can reduce both retail and wholesale drug prices during the first 6 months of competition. The report also found that authorized generics have a

6 S.27, “Preserve Access to Affordable Generics Act.”
substantial effect on the revenues of competing generic firms. Over the longer term, by lowering expected profits for generic competitors, the introduction of an authorized generic could affect a generic drug company’s decision to challenge patents on branded drug products with low sales. However, the report concludes that in spite of this, patent challenges by generic competitors remain robust even on drugs with low sales.

Additionally, the FTC is playing an active role in health care reform. The FTC and the Department of Justice’s Antitrust Division (the Antitrust Agencies) are working with the Centers for Medicare & Medicaid Services (CMS) and the Office of the Inspector General of the Department of Health and Human Services (HHS OIG) to implement provisions of the Patient Protection and Affordable Care Act (the Act), Pub. L. No. 111-48 (2010), that provide for the formation of Accountable Care Organizations (ACOs) under a new Shared Savings Program. That program encourages health care providers to create integrated, efficient health care delivery systems that can improve the quality of health care services and lower health care costs. The purpose of this interagency project is to develop well coordinated rules and policy guidance that avoid conflicting or duplicative requirements and encourage the formation of pro-competitive, legally compliant Shared Savings Program ACOs.

In April 2011, the Antitrust Agencies jointly proposed an enforcement policy statement to provide the antitrust guidance providers need to form pro-competitive ACOs that will participate in both the Shared Savings Program and commercial markets. At the same time, CMS issued its proposed rules for Shared Savings ACOs, and HHS OIG issued its proposed policy guidance. After working with CMS and HHS OIG to revise these documents in light of public comments, the Agencies issued on October 20, 2011, the final version of a joint policy statement detailing how the agencies will enforce U.S. antitrust laws with respect to new ACOs.

(c) Privacy Challenges to Consumers Posed by Technology and Business Practices. During 2009 to 2010, the Commission hosted a series of roundtables to explore the privacy issues and challenges associated with 21st century technology and business practices to determine how best to protect
consumer privacy while supporting beneficial uses of information and technological innovation. In December 2010, the FTC staff issued a preliminary privacy report proposing a framework that promotes privacy by design, transparency, consumer choice, and business innovation. The report is intended to inform policymakers, including Congress, as they develop solutions, policies, and potential laws governing privacy, and to guide and motivate industry as it develops more robust and effective best practices and self-regulatory guidelines. The report suggests implementation of a “Do Not Track” mechanism, so consumers can control the collection of data about their online searching and browsing activities. Since the release of the report, self-regulatory efforts have progressed and several companies have come forward with ideas and innovations to enhance consumer choice and online privacy. FTC Staff are closely watching these initiatives.

(d) Children’s Identity Theft. The FTC and the Office for Victims of Crime (OVC), Office of Justice Programs, U.S. Department of Justice, held a forum on July 12, 2011, which explored the nature of child identity theft, including foster care identity theft and identity theft within families, with the goal of advising parents and victims on how to prevent the crime and how to resolve child identity theft problems. The Agencies have released educational materials for public distribution.

(e) Food Marketing to Children. In an effort to combat childhood obesity—the most serious health crisis facing today’s youth—a working group of four Federal agencies on April 28, 2011, released for public comment a set of proposed voluntary non-regulatory principles that can be used by industry as a guide for marketing food to children. The Interagency Working Group on Food Marketed to Children, comprised of the FTC, the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Department of Agriculture, was established by a provision in the FY 2009 Omnibus Appropriations Act (H.R. 1105) and is charged with conducting a study and developing recommendations for nutritional standards for foods marketed to children ages 17 and under. The working group also held a half-day forum on May 24, 2011, to provide stakeholders with a chance to comment in person. The

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The comment period closed July 14, 2011, with approximately 29,000 comments submitted. Members of the Interagency Working Group are sharing responsibility for reviewing the comments on the proposed principles. Comments pertaining to the proposed nutrition principles, including those about the food categories identified in the principles, are being reviewed primarily by the CDC, FDA, and USDA. Comments relating to the marketing aspects of the recommended principles, as well as general comments, are being reviewed primarily by the FTC. The Working Group will make final recommendations in a pending report to Congress.

Following OMB approval on July 8, 2010, on August 12, 2010, the Commission issued information requests to 48 major food, beverage manufacturers, and quick-service restaurant companies about spending and marketing activities targeting children and adolescents, as well as nutritional information for food and beverage products that the companies market to these young consumers. The study will advance the Commission’s understanding of how food industry promotional dollars targeted to children and adolescents are allocated, the types of activities and marketing techniques the food industry uses to market its products to children and adolescents, and the extent to which self-regulatory efforts are succeeding in improving the nutritional quality of foods advertised to children and adolescents. The Bureau of Consumer Protection is analyzing the data and preparing a report, which is expected to be released sometime in late 2011 or early 2012.

(f) Alcohol Advertising. Regarding advertising for beverage alcohol products, the Commission issued on September 8, 2010, compulsory information requests requiring three mid-sized suppliers to provide information about advertising and marketing practices and compliance with self-regulatory guidelines. The Commission has reviewed the three companies’ responses and communicated with them about the results. This procedure is consistent with a 2008 commitment by the Commission to conduct small studies of industry self-regulation in years when no major study was underway. Further, in early 2011, the Commission began the process of seeking Office of Management and Budget approval, under the Paperwork Reduction Act, to conduct another major study of alcohol marketing and self-regulation; that study will evaluate the advertising practices of the major alcohol suppliers. The Commission will also
continue to promote the “We Don’t Serve Teens” consumer education program, supporting the legal
drinking age.10

(g) Gasoline Prices. On September 1, 2011, the Commission issued a Bureau of Economics staff
report examining trends in the petroleum industry and how they have affected gasoline prices between
2005 and early 2011.11 It concludes that while a broad range of factors influence the price of gasoline,
worldwide crude oil prices continue to be the main driver of what Americans pay at the pump. The report
spells out the factors that determine what consumers pay for gas, and why prices seem to “rocket up” but
“feather down” (in other words, why prices increase faster in response to cost increases than they fall in
response to cost decreases). In addition to the price of crude oil, by far and away the largest factor in
gasoline prices, the report looks at factors such as refinery profit margins; and the possible impact of
futures speculation on oil and gas prices.

(h) Financing of Motor Vehicles. The Commission is holding a series of roundtable events to gather
information on possible consumer protection issues that may arise in the sale, lease, or financing of motor
vehicles. For many consumers, buying or leasing a car is their most expensive financial transaction aside
from owning a home. With prices averaging more than $28,000 for a new vehicle and $14,000 for a used
vehicle from a dealer, most consumers seek to lease or finance the purchase of a new or used car.
Financing obtained at a dealership may provide benefits for many consumers, such as convenience,
special manufacturer-sponsored programs, access to a variety of banks and financial entities, or access
to credit otherwise unavailable to a buyer. Dealer-arranged financing, however, can be a complicated,
opaque process and could potentially involve unfair or deceptive practices.

The first event took place in Detroit, Michigan, on April 12, 2011. The FTC’s second motor vehicle
roundtable took place in San Antonio, Texas on August 2-3, 2011. Dates for future additional roundtables
will be posted on the FTC Web site at http://www.ftc.gov.

10 More information can be found at http://www.dontserveteens.gov/.
(i) Fraud Forum Surveys. The FTC’s Bureau of Economics continues to conduct fraud surveys and related research on consumer susceptibility to fraud. For example, the FTC is conducting an exploratory study during 2011 on consumer susceptibility to fraudulent and deceptive marketing. This research is intended to further the FTC’s mission of protecting consumers from unfair and deceptive marketing. The FTC also submitted a clearance request for a second study with the OMB, proposing to survey consumer experiences with consumer fraud. Neither study is intended to lead to enforcement actions; rather, study results may aid the FTC’s efforts to better target its enforcement actions and consumer education initiatives, and improve future fraud surveys.

(j) Protecting Consumers from Cross-Border Harm. The FTC continues to protect American consumers from fraud by making greater use of the tools provided by the U.S. SAFE WEB Act. The FTC has used the Act to cooperate with its foreign law enforcement counterparts in investigations and enforcement actions involving Internet fraud and other technological abuses and deceptive schemes that victimize U.S. consumers. During the past year, the FTC added to its U.S. SAFE WEB scorecard by sharing information in response to nine requests from five foreign law enforcement agencies. It also issued twelve civil investigative demands on behalf of two foreign agencies in three investigations. In many of these cases, the foreign agencies investigated conduct that directly harms U.S. consumers. In others, the FTC’s assistance has led to reciprocal assistance in other FTC investigations. Given the success of the U.S. SAFE WEB Act, the Commission continues to recommend that Congress repeal the Act’s seven-year sunset provision before it expires in 2013.

Significant consumer protection developments this year include the launch of the Asia-Pacific Economic Cooperation Cross-Border Privacy Enforcement Arrangement, and a new asset recovery initiative with Federal and provincial Canadian law enforcers. This year the Agency also worked with its counterparts in the Global Privacy Enforcement Network, a group of privacy enforcement agencies around the globe, to launch the organization’s website, which provides a platform for the participants to interact. The Commission was also instrumental in the development of the Organization for Economic Cooperation and Development’s new Consumer Policy Toolkit, which was released at an event hosted by the FTC featuring Karen Kornbluh, U.S. Ambassador to the OECD.
The FTC also stepped up its efforts to reduce Internet-related fraud by convening, with the FBI, a roundtable discussion for law enforcement agencies, domain name registrars, and Internet registries to discuss measures to curb malicious Internet conduct. Law enforcement officials from the United States, Brazil, Canada, Switzerland, and the United Kingdom met with U.S.-based and foreign domain name registrars and four Internet registries to discuss measures to curtail domain name abuse.

(k) Journalism and the Internet. In 2009 to 2010, the FTC began a project to examine how the Internet has transformed the competitive dynamics of the news media landscape. The Agency first held a series of exploratory workshops, seeking expert views and public comments on varied aspects of the challenges and new opportunities facing the news industry. The Agency continues to analyze the issues discussed at those workshops and elsewhere, including the economics of journalism in a digital world, new business and non-profit models for journalism, and potential changes to a variety of Government policies, including antitrust, copyright, and tax policy, relevant to journalism. The Agency plans to release a report in late fall 2011.

(l) Intellectual Property. After a series of eight hearings on the Evolving Intellectual Property (IP) Marketplace since the issuance of the FTC’s October 2003 report “To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,” the Commission released a report in March 2011, “The Evolving IP Marketplace Aligning Patent Notice and Remedies with Competition,” that recommends improvements to policies affecting patent notice and remedies for patent infringement. Specifically, the report recommends improving policies relevant to the patent notice function through actions by the courts and the Patent and Trademark Office. Clear notice of what a patent covers promotes innovation by encouraging collaboration, technology transfer, and design-around. The report suggests notice mechanisms to improve the public’s ability to identify relevant patents, to understand the scope of patent claims, and to predict the breadth of claims that are likely to emerge from patent applications. The report also explains that patent remedies that align compensation of patent holders with the economic value of their patented inventions are important for both innovation and competition. Patent damages that undercompensate patentees for infringement can deter innovation, but overcompensation can lead to higher prices and encourage speculation in patent rights, which also deters innovation. Finally, the report makes
recommendations to courts that would ground damages calculations and injunction analysis in economic principles that recognize competition among patented technologies.

(m) Self-Regulatory and Compliance Initiatives with Industry. The Commission continues to engage industry in compliance partnerships in at least two areas involving the funeral and franchise industries. Specifically, the Commission’s Funeral Rule Offender Program, conducted in partnership with the National Funeral Directors Association, is designed to educate funeral home operators found in violation of the requirements of the Funeral Rule, 16 CFR 453, so that they can meet the rule’s disclosure requirements. More than 350 funeral homes have participated in the program since its inception in 1996.

In addition, the Commission established the Franchise Rule Alternative Law Enforcement Program in partnership with the International Franchise Association (IFA), a nonprofit organization that represents both franchisors and franchisees. This program is designed to assist franchisors found to have a minor or technical violation of the Franchise Rule, 16 CFR 436, in complying with the rule. Violations involving fraud or other section 5 violations are not candidates for referral to the program. The IFA teaches the franchisor how to comply with the rule and monitors its business for a period of years. Where appropriate, the program offers franchisees the opportunity to mediate claims arising from the law violations. Since December 1998, 21 companies have agreed to participate in the program.

Effect of the Consumer Financial Protection Act of 2010

On July 21, 2010, President Obama signed into law the “Dodd-Frank Wall Street Reform and Consumer Protection Act,” Public Law No. 111-203. Title X of the statute, known as the Consumer Financial Protection Act of 2010 (or the Consumer Financial Protection Act), created a new Bureau of Consumer Financial Protection (“CFPB”) within the Board of Governors of the Federal Reserve System (“Federal Reserve Board”). Most of the FTC’s rulemaking authority under certain “enumerated consumer laws” was transferred to the CFPB on July 21, 2011. These laws include all or most of the rulemaking authority under the Truth in Lending Act, the Fair Credit Reporting Act (including the Fair and Accurate Credit Transactions Act of 2003 (“FACTA”)), the Gramm-Leach-Bliley Act, the Equal Credit Opportunity Act, the Electronic Funds Transfer Act, the Federal Deposit Insurance Corporation Improvement Act of 1991, and the Omnibus Appropriations Act of 2009. Therefore, the Commission removed the following nine matters from its regulatory review schedule because authority to modify or repeal them were
transferred to the CFPB: Disclosure Requirements for Depository Institutions Lacking Federal Deposit Insurance, 16 CFR part 320; Mortgage Assistance Relief Services Rule, 16 CFR part 322; Statements of General Policy or Interpretations [of the Fair Credit Reporting Act Rules], 16 CFR part 600; [Identity Theft] Definitions, 16 CFR part 603; Free Annual File Disclosures Rule, 16 CFR part 610 Prohibition Against Circumventing Treatment as a Nationwide Consumer Reporting Agency, 16 CFR part 611; Duration of Active Duty Alerts, 16 CFR part 613; Appropriate Proof of Identity, 16 CFR part 614; and Procedures for State Application for Exemption From the Provisions of the [Federal Debt Collection Practices] Act, 16 CFR part 901.2. Further information on the impact of the Consumer Financial Protection Act on the Commission’s rulemakings, studies, and guidelines is discussed below.

Rulemakings and Studies Required by Statute

Congress has enacted laws requiring the Commission to undertake rulemakings and studies. This section discusses required rules and studies. The final actions section below describes actions taken on the required rulemakings and studies since the 2010 Regulatory Plan was published.

FACTA Rules. The Commission has already issued nearly all of the rules required by FACTA. These rules are codified in several parts of 16 CFR 600 et seq., amending or supplementing regulations relating to the Fair Credit Reporting Act. The enforcement of the Red Flags Rule (or Identity Theft Rule), 16 CFR 681, was delayed by the Commission from its initial effective date of November 1, 2008, until January 1, 2011, pending clarification by Congress. The “Red Flag Program Clarification Act of 2010” (or the Act), Public Law No. 111-319, was signed into law on December 18, 2010. The Commission and the banking agencies expect to revise the Red Flags Rule to implement the Act by the spring of 2012.

FACTA Studies. On March 27, 2009, the Commission issued compulsory information requests to the nine largest private providers of homeowner’s insurance in the Nation. The purpose was to help the FTC collect data for its study on the effects of credit-based scores in the homeowners’ insurance market, a study mandated by section 215 of the FACTA. During the summer of 2009 these nine insurers submitted responses to the Commission’s requests. FTC staff has reviewed the large policy-level data files included in these submissions and has identified a sample set of data to be used for the study. Staff expects to prepare and submit the report to Congress before the end of 2012. The data collection phase of the
The FTC is also conducting a national study of the accuracy of consumer reports in connection with section 319 of the FACTA. This study is a follow-up to the Commission’s two previous pilot studies that were undertaken to evaluate a potential design for a national study. Section 319 requires the FTC to study the accuracy and completeness of information in consumers’ credit reports and to consider methods for improving the accuracy and completeness of such information. Section 319 of the Act also requires the Commission to issue a series of biennial reports to Congress over a period of 11 years. A major report on the study, which is presently in the field, is due by December 2012. This study is also not affected by the Consumer Financial Protection Act.

Mortgage Loans Rules, 16 CFR 321, 322: Section 626 of the Omnibus Appropriations Act of 2009 directed the Commission to initiate a rulemaking proceeding with respect to mortgage loans and prescribed that any violation of the Rule shall be treated as a violation of a rule under section 18 of the FTC Act regarding unfair or deceptive acts or practices. On June 1, 2009, the Commission published an ANPRM in two parts: (1) Mortgage Assistance Relief Services (practices of entities providing assistance to consumers in modifying mortgage loans or avoiding foreclosure) (or MARS), 74 FR 26,130, and (2) Mortgage Acts and Practices through the life cycle of the mortgage loan (i.e., loan advertising, marketing, origination, appraisals, and servicing) (or MAP), 74 FR 26,118.

- MARS – After issuing an NPRM on March 10, 2010, the Commission published a MARS final rule. 75 FR 75092 (Dec. 1, 2011). The final MARS rule prohibits providers of these services from making false or misleading claims, mandates that providers disclose certain information about these services, bars the collection of advance fees for these services, prohibits persons from providing substantial assistance or support to an entity they know or consciously avoid knowing is engaged in a violation of these rules, and imposes recordkeeping and compliance requirements. All provisions of the rule

except the advance-fee ban became effective December 29, 2010. The advance-fee ban provisions became effective January 31, 2011. Additionally, on July 15, 2011, the FTC issued a stay of enforcement stating that the Agency would forbear from enforcing the MARS Rule, with the exception of the prohibition on misrepresentations, against real estate professionals who assist consumers in negotiating or obtaining short sales.

- **MAP-Advertising** – After issuing an NPRM on September 30, 2010, the Commission announced a final rule for MAP-Advertising on July 19, 2011. 76 FR 43826. The final rule prohibits misrepresentation in commercial communications regarding any term of a mortgage credit product and imposes certain recordkeeping requirements. The rule became effective on August 19, 2011.

- **MAP-Servicing** – The Commission ceased work on a pending NPRM for MAP-Servicing on July 21, 2011. On that date, the Commission's rulemaking authority for all of the MAP rules under the Omnibus Appropriations Act of 2009 was transferred to the CFPB.

Rule Concerning Disclosures Regarding Energy Consumption and Water Use of Certain Home Appliances and Other Products Required Under the Energy Policy and Conservation Act (Appliance Labeling Rule), 16 CFR 305: Under direction from Congress to examine the effectiveness of light bulb labels, the FTC introduced a new “Lighting Facts” label in July 2010 for medium screw-base light bulbs. 75 FR 41696. On July 22, 2011, the Commission announced an NPRM seeking comment on expanding the “Lighting Facts” label coverage to additional bulb types and a specific test procedure for light-emitting diode (LED) bulbs. During November 2011, the Commission will issue an ANPRM seeking comment on disclosures to help consumers, distributors, contractors, and installers easily determine whether a specific furnace, central air conditioner, or heat pump meets the applicable new Department of Energy efficiency standard for the regions where it will be installed. The Commission will seek comment on the content, location, and format of such disclosures. As part of this effort, the Commission staff will hold a public meeting with the Department of Energy (DOE) to discuss possible disclosures. The statutory deadline for the Commission to issue regional efficiency standards is 15 months after DOE issued their final efficiency standards on October 25, 2011. 76 FR at 37408.

Section 325 of the Energy Independence and Security Act of 2007 provides the Commission with the authority to promulgate energy labeling rules for consumer electronics. On October 27, 2010, the
Commission announced it was issuing a final rule that will require televisions manufactured after May 10, 2011, to display EnergyGuide labels that include information on estimated yearly energy and the cost range compared to similar models. Staff anticipates sending a recommendation to the Commission by December 2011 regarding a proposed notice of rulemaking for other consumer electronics.

Retrospective Review of Existing Regulations

In 1992, the Commission implemented a program to review its rules and guides regularly. The Commission’s review program is patterned after provisions in the Regulatory Flexibility Act, 5 U.S.C. 601 to 612. Under the Commission’s program, rules have been reviewed on a ten-year schedule. For many rules, this has resulted in more frequent reviews than is generally required by section 610 of the Regulatory Flexibility Act. This program is also broader than the review contemplated under the Regulatory Flexibility Act, because it provides the Commission with an ongoing systematic approach for seeking information about the costs and benefits of its rules and guides and whether there are changes that could minimize any adverse economic effects, not just a “significant economic impact upon a substantial number of small entities.” 5 U.S.C. 610.

As part of its continuing ten-year review plan, the Commission examines the effect of rules and guides on small businesses and on the marketplace in general. These reviews may lead to the revision or rescission of rules and guides to ensure that the Commission’s consumer protection and competition goals are achieved efficiently and at the least cost to business. In a number of instances, the Commission has determined that existing rules and guides were no longer necessary nor in the public interest. Most of the matters currently under review pertain to consumer protection and are intended to ensure that consumers receive the information necessary to evaluate competing products and make informed purchasing decisions. Pursuant to this program, the Commission has rescinded 37 rules and guides promulgated under the FTC’s general authority and updated dozens of other since the early 1990s.

In light of Executive Orders 13563 and 13579, the FTC has taken a fresh look at its longstanding regulatory review process. The Commission is taking a number of steps to ease burdens on business and promote transparency in its regulatory review program:
• The Commission recently issued a revised 10-year review schedule (see next paragraph below) and is accelerating the review of a number of rules and guides in response to recent changes in technology and the marketplace. More than a third of the Commission’s 66 rules and guides will be under review, or will have just been reviewed, by the end of 2011.

• The Commission is requesting public comment on the effectiveness of its regulatory review program and suggestions for its improvement.

• The FTC has launched a web page at http://www.ftc.gov/regreview that will serve as a one-stop shop for the public to obtain information and provide comments on individual rules and guides under review as well as the Commission’s regulatory review program generally.

Pursuant to section 2 of Executive Order 13579 "Regulation and Independent Regulatory Agencies" (Jul. 11, 2011), the following Regulatory Identifier Numbers (RINs) have been identified as associated with retrospective review and analysis in the FTC’s regulatory review plan. The table includes rulemakings that the Agency expects to issue in proposed or final form during the upcoming year. Each entry includes the title of the rulemaking subject to the Agency’s retrospective analysis, the RIN and whether it is expected to reduce burdens on small businesses. The regulatory review plan can be found at: www.ftc.gov.

<table>
<thead>
<tr>
<th>Rule</th>
<th>Regulatory Identifier Numbers (RIN)</th>
<th>Expected to Reduce Burdens on Small Business (Yes/No)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Business Opportunity Rule, 16 CFR 437</td>
<td>3084-AB04</td>
<td>Yes</td>
</tr>
<tr>
<td>Trade Regulation Rule Concerning Cooling Off Period for Sales Made at Homes or at Certain Other Locations, 16 CFR 429</td>
<td>3084-AB10</td>
<td>Yes</td>
</tr>
<tr>
<td>Children's Online Privacy Protection Rule, 16 CFR 312</td>
<td>3084-AB20</td>
<td>No</td>
</tr>
</tbody>
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In addition, the Commission’s ten-year periodic review for 2011 includes the following rules and guides (76 FR 41151, July 13, 2011):

(1) Guides for Advertising of Warranties and Guaranties, 16 CFR 239;

(2) Rules and Regulations under the Wool Products Labeling Act of 1939, 16 CFR part 300;
Due to resource constraints, the Commission is postponing review of the following matters previously scheduled for 2011 review: Administrative Interpretations, General Policy Statements, and Enforcement Policy Statements, 16 CFR part 14; the Guides for the Jewelry, Precious Metals, and Pewter Industries, 16 CFR part 23; the Preservation of Consumers’ Claims and Defenses Rule [Holder in Due Course Rule], 16 CFR part 433; and the Credit Practices Rule, 16 CFR part 444.

Furthermore, consistent with the goal of reducing unnecessary burdens, within and outside the Government, Commission staff officials are in the process of identifying reports required by statute as well as statutes themselves that appear to be of limited value, but that divert business or Commission resources from more pressing work. Thus far, staff preliminarily has identified two reports that do not appear to be useful. The first is a report, required annually, on concentration in the ethanol market. The Commission has found each year that the market is extremely unconcentrated, and that entry is easy and ongoing. Therefore, this report seems to provide little useful information. The second report is prepared by the Commission together with the Department of Justice and the Department of Education, and simply describes actions taken to address scholarship scams. Though stopping scholarship scams is an important priority, the report appears to provide little valuable information. The Commission will make appropriate recommendations to Congress at the conclusion of its review.

Ongoing Rule and Guide Reviews
The Commission is continuing review of a number of rules and guides, which are discussed first under (a) Rules and then (b) Guides.

(a) Rules

Labeling Requirements for Alternative Fuels and Alternative Fueled Vehicles Rule ("Alternative Fuel Rule"), 16 CFR 309. The Alternative Fuel Rule, which became effective on November 20, 1995, and was last reviewed in 2004, requires disclosure of appropriate cost and benefit information to enable consumers to make reasonable purchasing choices and comparisons between non-liquid alternative fuels, as well as alternative-fueled vehicles. On June 1, 2011, the Commission requested comments on the rule, as part of the Commission's systematic review of all current Commission rules and guides. The Commission also sought comment on whether to merge its alternative fueled vehicle (AFV) labels with fuel economy labels proposed by the Environmental Protection Agency (EPA) and the National Highway Traffic Safety Administration (NHTSA), add new definitions for AFVs contained in recent legislation, and change labeling requirements for used AFVs. The comment period closed on July 25, 2011, and staff is reviewing the comments. On June 1, 2011, the Commission also postponed any amendments to its Guide Concerning Fuel Economy Advertising for New Automobiles upon completion of ongoing review by the Environmental Protection Agency and the National Highway Traffic Safety Administration of current fuel economy labeling requirements and the Commission's accelerated regulatory review of its own Alternative Fuel Rule. 76 FR 31467.
Telemarketing Sales Rule (TSR). Caller ID—The Commission issued an advance notice of proposed rulemaking on December 15, 2010, requesting public comment on provisions of the Telemarketing Sales Rule concerning caller identification services and disclosure of the identity of the seller or telemarketer responsible for telemarketing calls. 75 FR 78,179. The comment period closed on January 28, 2011. The Commission solicited comments on whether changes should be made to the TSR to reflect the current use and capabilities of Caller ID technologies. In particular, the Commission is interested in whether the TSR should be amended to better achieve the objectives of the Caller ID provisions—including enabling consumers and law enforcement to use Caller ID information to identify entities responsible for illegal telemarketing practices. Staff is reviewing the comments and anticipates making a recommendation to the Commission by April 2012.

Business Opportunity Rule. Regarding the Business Opportunity Rule, the Commission issued an NPRM (71 FR 19,054, Apr. 12, 2006) and a revised NPRM (73 FR 16,110, Mar. 26, 2008), then later held a workshop on June 1, 2009, to explore changes to the proposed rule, including the effectiveness of a proposed disclosure form. On October 28, 2010, the Commission released a staff report recommending that coverage of the FTC’s Business Opportunity Rule be expanded to include work-at-home opportunities such as envelope stuffing, medical billing, and product assembly, many of which have not been covered before. 75 FR 68,559 (Nov. 8, 2010). FTC staff also recommended streamlining the disclosures required by the Business Opportunity Rule so that companies or individuals selling business opportunities make important disclosures to consumers on a simple, easy-to-read document. If adopted, the changes will make it less burdensome for legitimate sellers to comply with the Rule, while still protecting consumers from “widespread and persistent” business opportunity fraud. Public comments on the staff report were accepted until January 18, 2011. Staff anticipates Commission action relating to a proposed final rule by the end of 2011.

Children’s Online Privacy Protection Rule ("COPPA Rule"), 16 CFR 312. The COPPA Rule requires operators of websites, and online service providers directed at children under 13 (operators), with certain exceptions, to obtain verifiable parental consent before collecting, using, or disclosing personal
information from or about children under the age of 13. An operator must make reasonable efforts, in
light of available technology, to ensure that the person providing consent is the child's parent. The
Commission issued an ANPRM requesting comments on the Rule as part of the systematic regulatory
review process. 75 FR 17089 (Apr. 5, 2010). The Commission held a public roundtable on the Rule on
June 2, 2010, and the comment period, as extended, ended on July 12, 2010. On September 15, 2011,
the Commission announced it was proposing modifications to the Rule in five areas to respond to
changes in online technology, including in the mobile marketplace, and, where appropriate, to streamline
the Rule: Definitions, including the definitions of "personal information" and "collection," parental notice,
parental consent mechanisms, confidentiality and security of children's personal information, and the role
of self-regulatory "safe harbor" programs. 76 FR 59804. In addition, the Commission also proposed
adding a new provision addressing data retention and deletion. The comment period will close on
November 28, 2011.

Mail or Telephone Order Merchandise Rule. The Mail Order Rule, 16 CFR 435, requires that, when
sellers advertise merchandise, they must have a reasonable basis for stating or implying that they can
ship within a certain time. On September 30, 2011, 13 the Commission published a NPRM proposing to:
clarify that the Rule covers all orders placed over the Internet; revise the Rule to allow sellers to provide
refunds and refund notices by any means at least as fast and reliable as first class mail; clarify sellers’
obligations when buyers use payment systems not enumerated in the Rule; and require that refunds be
made with seven working days for purchases made using third-party credit cards. 76 FR 60765. The
comment period closes on December 14, 2011.

Used Car Rule. The Used Motor Vehicle Trade Regulation Rule ("Used Car Rule"), 16 CFR 455, sets
out the general duties of a used vehicle dealer; requires that a completed Buyers Guide be posted at all
times on the side window of each used car a dealer offers for sale; and mandates disclosure of whether
the vehicle is covered by a warranty and, if so, the type and duration of the warranty coverage, or whether
the vehicle is being sold "as is—no warranty." The Commission published a notice seeking public

13 Please see Final Action section for information about a separate FR Notice that announces that the
Commission is retaining MOTR with minor technical corrections.
comments on the effectiveness and impact of the rule. 73 FR 42285 (Jul. 21, 2008). The notice seeks comments on a range of issues including, among others, whether a bilingual Buyers Guide would be useful or practicable, as well as what form such a Buyers Guide should take. Second, the notice seeks comments on possible changes to the Buyers Guide that reflect new warranty products, such as certified used car warranties, that have become increasingly popular since the rule was last reviewed. Finally, the notice seeks comments on other issues including the continuing need for the rule and its economic impact, the effect of the rule on deception in the used car market, and the rule’s interaction with other regulations. The comment period, as extended and then reopened, ended on June 15, 2009. Staff anticipates sending a recommendation to the Commission by the end of 2011.

Cooling-Off Rule. The Cooling-Off Rule requires that a consumer be given a 3-day right to cancel certain sales greater than $25.00 that occur at a place other than a seller’s place of business. The rule also requires a seller to notify buyers orally of the right to cancel, to provide buyers with a dated receipt or copy of the contract containing the name and address of the seller and notice of cancellation rights, and to provide buyers with forms which buyers may use to cancel the contract. An ANPRM seeking comment was published on April 21, 2009. 74 FR 18170. The comment period, as extended, ended on September 25, 2009. 74 FR 36972 (Jul. 27, 2009). Staff prepared a recommendation for the Commission and anticipates publication of an NPRM by the end of 2011.

Negative Option Rule. The Negative Option Rule governs the operation of prenotification subscription plans. Under these plans, sellers ship merchandise automatically to their subscribers and bill them for the merchandise within a prescribed time. The rule protects consumers by requiring the disclosure of the terms of membership clearly and conspicuously and establishes procedures for administering the subscription plans. An ANPRM was published on May 14, 2009, 74 FR 22720, and the comment period closed on July 27, 2009. On August 7, 2009, the Commission reopened and extended the comment period until October 13, 2009. 74 FR 40121. Staff anticipates sending a recommendation to the Commission by the end of 2011.
Pay-Per-Call Rule. The Commission’s review of the Pay-Per-Call Rule, 16 CFR 308, is continuing. The Commission has held workshops to discuss proposed amendments to this rule, including provisions to combat telephone bill "cramming"—inserting unauthorized charges on consumers’ phone bills—and other abuses in the sale of products and services that are billed to the telephone including voicemail, 900-number services, and other telephone based information and entertainment services. The most recent workshop focused on the use of 800 and other toll-free numbers to offer pay-per-call services, the scope of the rule, the dispute resolution process, the requirements for a pre-subscription agreement, and the need for obtaining express authorization from consumers before placing charges on their telephone bills. The review record has remained open to encourage additional comments on expansion of the rule’s coverage. Staff expects to prepare a recommendation for the Commission by December 2012.

(b) Guides

Guides for the Use of Environmental Marketing Claims (Green Guides), 16 CFR 260: After holding three public workshops, analyzing public comments, and studying consumer perceptions of certain environmental claims, the Commission announced on October 6, 2010, proposed revisions to the Green Guides to help marketers avoid making misleading environmental claims. The proposed changes are designed to update the Guides and make them easier for companies to understand and use. The changes to the Green Guides include new guidance on marketers' use of product certifications and seals of approval, “renewable energy” claims, “renewable materials” claims, and “carbon offset” claims. The comment period closed on December 10, 2010. The staff is currently reviewing 338 non-duplicate comments and anticipates sending a recommendation to the Commission by the end of 2011.

Vocational Schools Guides. The Commission sought public comments on its Private Vocational and Distance Education Schools Guides, commonly known as the Vocational Schools Guides. 74 FR 37973 (Jul. 30, 2009). Issued in 1972 and most recently amended in 1998 to add a provision addressing misrepresentations related to post-graduation employment, the guides advise businesses offering vocational training courses—either on the school’s premises or through distance education, such as
correspondence courses or the Internet—how to avoid unfair and deceptive practices in the advertising, marketing, or sale of their courses. The comment period closed on October 16, 2009. Staff is reviewing comments and anticipates sending a recommendation to the Commission by the end of 2011.

Final Actions

Since the publication of the 2010 Regulatory Plan, the Commission has issued the following final rules or taken other actions to terminate rulemaking proceedings.

FACTA Risk-Based Pricing Rule. After the Commission issued a risk-based pricing rule jointly with the Federal Reserve, 75 FR 2724 (Jan. 15, 2010), the Dodd-Frank Act subsequently amended the Fair Credit Reporting Act to require that this risk-based pricing notice include a credit score if one was used. After issuing an NPRM, the Agencies published final rules requiring creditors to disclose credit score information to consumers when a credit score is used in setting or adjusting the terms of credit. 76 FR 41602 (Jul. 15, 2011).

Hart-Scott-Rodino Rules. For the Hart-Scott-Rodino Premerger Notification Rules (HSR Rules), 16 CFR 801 to 803), the Commission in conjunction with the Antitrust Division, Department of Justice, published a final rule on July 19, 2011, streamlining the HSR Form and capturing new information that will help the Agencies conduct their initial review of a proposed transaction’s competitive impact. 76 FR 42471. These final rules were effective August 18, 2011.

Fuel Ratings Rule. The Fuel Ratings Rule sets out a uniform method for determining the octane rating of gasoline from the refiner through the chain of distribution to the point of retail sale. The rule enables consumers to buy gasoline with an appropriate octane rating for their vehicle and establishes standard procedures for determining, certifying, and posting octane ratings. After notice and comment, 75 FR 12,470 (Mar. 16, 2010), on April 8, 2011, the Commission issued amendments to the rule that allow an

14 Other final actions can be found under Rulemakings and Studies Required by Statute, supra.
alternative octane rating method and made other minor changes. 76 FR 19684. The effective date for the amendments was May 31, 2011. The Commission declined to issue final ethanol labeling amendments at that time, but is currently considering this for possible further action.

Mail or Telephone Order Merchandise Rule. The Mail Order Rule, 16 CFR 435, requires that, when sellers advertise merchandise, they must have a reasonable basis for stating or implying that they can ship within a certain time. During 2007, the Commission sought comments about non-substantive changes to the rule to bring it into conformity with changing conditions; including consumers’ usage of means other than the telephone to access the Internet when ordering, consumers paying for merchandise by demand draft or debit card, and merchants using alternative methods to make prompt rule-required refunds. 72 FR 51728 (Sep. 11, 2007). On September 30, 2011, the Commission announced it was retaining MTOR. 76 FR 60715. Based on previous Rule proceedings and after reviewing public comments received regarding the Rule’s overall costs, benefits, and regulatory and economic impact, the Commission concluded that the Rule continues to benefit consumers and the Rule’s benefits outweigh its costs. For clarity, the Commission reorganized the Rule by alphabetizing the definitions at the beginning of the Rule.

Summary

In both content and process, the FTC’s ongoing and proposed regulatory actions are consistent with the President’s priorities. The actions under consideration inform and protect consumers, while minimizing the regulatory burdens on businesses. The Commission will continue working toward these goals. The Commission’s 10-year review program is patterned after provisions in the Regulatory Flexibility Act and complies with the Small Business Regulatory Enforcement Fairness Act of 1996. The Commission’s 10-year program also is consistent with section 5(a) of Executive Order 12866, which directs executive branch agencies to develop a plan to reevaluate periodically all of their significant

15 Please see Ongoing Rule and Guide Reviews section above for information on a separate FR Notice proposing amendments to MOTR.
existing regulations. 58 FR 51735 (Sep. 30, 1993). In addition, the final rules issued by the Commission continue to be consistent with the President’s Statement of Regulatory Philosophy and Principles, Executive Order 12866, section 1(a), which directs agencies to promulgate only such regulations as are, inter alia, required by law or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public.

The Commission continues to identify and weigh the costs and benefits of proposed actions and possible alternative actions, and to receive the broadest practicable array of comment from affected consumers, businesses, and the public at large. In sum, the Commission’s regulatory actions are aimed at efficiently and fairly promoting the ability of “private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.” Executive Order 12866, section 1.

II. Regulatory Actions

The Commission has no proposed rules that would be a “significant regulatory action” under the definition in Executive Order 12866.16

BILLING CODE: 6750-01-S

NATIONAL INDIAN GAMING COMMISSION (NIGC)

16 Section 3(f) of the Executive order defines a regulatory action to be “significant” if it 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 governments 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; or
(4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive order.
Statement of Regulatory Priorities

In 1988, Congress adopted the Indian Gaming Regulatory Act (IGRA) (P.L. 100-497, 102 Stat. 2475) with a primary purpose of providing “a statutory basis for the operation of gaming by Indian tribes as a means of promoting tribal economic development, self-sufficiency, and strong tribal governments.” IGRA established the National Indian Gaming Commission (NIGC or the Commission) to protect such gaming, amongst other things, as a means of generating tribal revenue.

At its core, Indian gaming is a function of sovereignty exercised by tribal governments. In addition, the Federal Government maintains a government-to-government relationship with the tribes—a responsibility of the NIGC. Thus, while the Agency is committed to strong regulation of Indian gaming, the Commission is equally committed to strengthening government-to-government relations by engaging in meaningful consultation with tribes to fulfill IGRA’s intent. The NIGC’s vision is to adhere to principles of good government, including transparency to promote Agency accountability and fiscal responsibility, to operate consistently to ensure fairness and clarity in the administration of IGRA, and to respect the responsibilities of each sovereign in order to fully promote tribal economic development, self-sufficiency, and strong tribal governments. The NIGC is fully committed to working with tribes to ensure the integrity of the industry by exercising its regulatory responsibilities through technical assistance, compliance, and enforcement activities.

Retrospective Review of Existing Regulations
As an independent regulatory agency, the NIGC has been performing a retrospective review of its existing regulations well before Executive Order 13579 was issued on July 11, 2011. The NIGC, however, recognizes the importance of E.O. 13579 and its regulatory review is being conducted in the spirit of E.O. 13579, to identify those regulations that may be outmoded, ineffective, insufficient, or excessively burdensome and to modify, streamline, expand, or repeal them in accordance with input from the public. In addition, as required by Executive Order 13175, the Commission has been conducting government-to-government consultations with tribes regarding each regulation’s relevancy, consistency in application, and limitations or barriers to implementation, based on the tribes’ experiences. The consultation process is also intended to result in the identification of areas for improvement and needed amendments, if any, new regulations, and the possible repeal of outdated regulations.

The following Regulatory Identifier Numbers (RINs) have been identified as associated with the review:

<table>
<thead>
<tr>
<th>RIN</th>
<th>TITLE</th>
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<tr>
<td>3141-AA15</td>
<td>Tribal Background Investigations and Licensing</td>
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<tr>
<td>3141-AA27</td>
<td>Class II and Class III Minimum Internal Control Standards and Class II Minimum Technical Standards</td>
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<td>3141-AA40</td>
<td>Fees</td>
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<td>3141-AA43</td>
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<td>3141-AA44</td>
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<tr>
<td>3141-AA45</td>
<td>Review and Approval of Pre-Existing Ordinances or Resolutions</td>
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More specifically, the NIGC is reviewing and considering revising its existing regulations in the following areas: (i) Tribal background investigations and licensing, in order to streamline the process for submitting information to the NIGC; (ii) minimum internal control standards (MICS) and minimum technical standards for gaming equipment used in the play of Class II games, in order to respond to changing technologies in the industry and to ensure that the MICS and technical standards remain relevant and appropriate; (iii) requirements for obtaining a self-regulation certification for Class II gaming; (iv) appeals of the Chair's actions on ordinances, management contracts, notices of violations (NOV), civil fine assessments, and closure orders, in order to clarify the appeals process for the regulated community; (v) facility licensing notifications, renewals, and submissions; (vi) monitoring and investigations; (vii) fees, in order to allow for the calculation of fees based on each tribe's fiscal year (instead of calendar year) and to require quarterly fee payments instead of semiannual payments, to ensure fingerprint fees reflect the true cost of fingerprint processing by providing for the annual review and adjustment of fees, and to implement a late payment system in lieu of NOVs for late submissions of fees and utilizing the NOV system only in rare instances; and (viii) enforcement, in order to provide for pre-enforcement procedures.

The NIGC is also currently considering promulgating new regulations: (i) Concerning a definition of the term “sole proprietary interest” with regard to the conduct of gaming on Indian lands, in order to reduce uncertainty surrounding the types of development, consulting, financing, and lease agreements tribes may enter into with regard to their gaming activities; and (ii) that would give preference to qualified Indian-
owned business when purchasing goods or services needed to carry out the Commission’s duties. Lastly, the NIGC has issued a Notice of Proposed Rulemaking repealing the regulation on the review and approval of gaming ordinances enacted by tribes prior to the existence of the Commission, as such ordinances may no longer exist and thus there is no further need for this regulation. The NIGC anticipates that the ongoing consultations with regulated tribes will continue to play an important role in the development of the NIGC’s rulemaking efforts.

BILLING CODE: 7565-01-S

U.S. NUCLEAR REGULATORY COMMISSION

Fiscal Year 2011 Regulatory Plan Statement of Regulatory Priorities

Under the authority of the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, the U.S. Nuclear Regulatory Commission (NRC) regulates the possession and use of source, byproduct, and special nuclear material. The NRC’s regulatory mission is to ensure that civilian uses of nuclear materials and facilities are carried out in a manner that will protect public health and safety and the environment and that will not be inimical to the common defense and security of the United States. The NRC regulates the operation of nuclear power plants and fuel cycle plants; the safeguarding of nuclear materials from theft and sabotage; the safe transport, storage, and disposal of radioactive materials and wastes; the decommissioning and safe release for other uses of licensed facilities that are no longer in operation; and the medical, industrial, and research applications of nuclear material. In addition, the NRC licenses the import and export of radioactive materials.

As part of its regulatory process, the NRC routinely conducts comprehensive regulatory analyses that examine the costs and benefits of contemplated regulations. The NRC has developed internal procedures and programs to ensure that it imposes only necessary
requirements on its licensees and to review existing regulations to determine whether the requirements imposed are still necessary.

The NRC’s fiscal year (FY) 2011 regulatory plan is not indicative of all rulemakings ongoing in FY 2011. The NRC anticipates publication of one major rule in FY 2011.

The NRC will update its requirement to recover approximately 90 percent of its budget authority in FY 2011, not including amounts appropriated from the Nuclear Waste Fund, amounts appropriated for Waste Incidental to Reprocessing, and amounts appropriated for generic homeland security activities (nonfee items), through fees to NRC licensees and applicants. The NRC receives 10 percent of its budget authority (not including nonfee items) from the general fund each year to pay for the cost of Agency activities that do not provide a direct benefit to NRC licensees, such as international assistance and Agreement State activities (as defined under section 274 of the Atomic Energy Act of 1954, as amended).

The NRC's other significant regulatory priorities for FY 2012 and beyond includes the following:

- Revise the environmental protection requirements for renewing nuclear power plant operating licenses.

- Develop performance-based acceptance criteria for fuel cladding performance during loss-of-coolant accidents at nuclear power plants.

- Certify new designs for nuclear power plants and amend existing approved designs.
• Specify the requirements for a site-specific analysis to demonstrate compliance with low-level waste disposal performance objectives, and the technical requirements needed for this analysis.

• Amend the regulations that govern the medical use of byproduct material related to reporting and notifications of medical events to clarify requirements for permanent implant branchytherapy.

• Expand the options for independent storage of spent nuclear fuel by amending and approving new spent fuel storage cask designs.

• Revise the fitness-for-duty requirements specific to drug and alcohol testing of employees working at nuclear power plants and other licensed facilities, and amend the fatigue management requirements pertaining to personnel who perform quality control and quality verification functions.

• Put in place security requirements for Category 1 and Category 2 quantities of radioactive material.

In addition to the previously stated priorities, additional regulatory priorities may be required due to: (1) Recommendations from a task force established to examine the NRC’s regulatory requirements, programs, processes, and implementation in light of information from the Fukushima Daiichi site in Japan, following the March 11, 2011, earthquake and tsunami; and (2) other emerging events.
The proposed rule would amend the Commission’s regulations that govern medical use of byproduct material related to reporting and notifications of medical events to clarify requirements for permanent implant brachytherapy.

Statement of Need:
The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to change the criteria for defining a medical event (ME) for permanent implant brachytherapy from dose-based to activity-based.

Several medical use events involving therapeutic use of byproduct material in 2003, as well as advice from the Advisory Committee on the Medical Use of Isotopes (ACMUI), prompted the reconsideration of the appropriateness and adequacy of the regulations regarding MEs and written directives (WDs).

A proposed rule was published in the Federal Register on August 6, 2008 (73 FR 45635), for public comment. Most of the 57 comment letters received primarily opposed parts of the rulemaking. During fall
of 2008, a substantial number of MEs involving permanent implant brachytherapy were reported to the NRC. Based on its evaluation of this information, including an independent analysis by an NRC medical consultant, the staff developed a re-proposed rule in SECY-10-0062, “Re-proposed Rule: Medical Use of Byproduct Material — Amendments/Medical Event Definitions,” dated May 18, 2010, for Commission approval.

In SRM-SECY-10-0062, dated August 10, 2010, the Commission disapproved the staff's recommendation to publish the re-proposed rule. Instead, the Commission directed the staff to work closely with the ACMUI and the broader medical and stakeholder community to develop event definitions that will protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users. Additionally, the staff was directed to hold a series of stakeholder workshops to discuss issues associated with the ME definition. The staff plans to expand this part 35 rulemaking to: Modify preceptor attestation requirements, consider extending grandfathering to certain certified individuals (Ritenour petition PRM-35-20), and to consider other issues that have developed in implementation of the current regulations. The NRC intends to merge this proposed rule with RIN 3150-AI63, Preceptor Attestation Requirements (NRC-2009-0175).

**Summary of Legal Basis:**


**Alternatives:**

As an alternative to the rulemaking, the NRC staff considered the “no-action” alternative. Under this option the NRC would not modify part 35, and the medical events would continue to be considered under dose-based criteria than the activity-based criteria for the permanent brachytherapy implants.

**Anticipated Cost and Benefits:**

The NRC is in the process of preparing a regulatory analysis to support this rulemaking. The analysis examines the costs and benefits of the alternatives considered by the NRC. The analysis will be available as part of the rulemaking package.

**Timetable:**
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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Federalism:**

Undetermined

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**Related RIN:** Merged with 3150–AI63

**RIN:** 3150–AI26
Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
42 USC 2201; 41 USC 5841

CFR Citation:
10 CFR 26

Legal Deadline:
None

Abstract:
The proposed rule would amend the Commission's regulations to ensure that personnel who actually perform independent quality control/verification (QC/QV) checks under the licensee's NRC-approved quality assurance program are subject to the same part 26, subpart I, provisions as operating personnel identified in section 26.4(a)(1). The proposed rule would also consider requests the Commission received in Petitions for Rulemaking 26-3, 26-5, and 26-6. Part 26, subpart I, currently does not include QC/QV personnel as covered workers for fatigue management. Also, petitions for rulemaking have raised additional concerns from affected stakeholders. A detailed regulatory analysis will be performed per NRC processes which detail the costs and benefits associated with the proposed rule. This regulatory analysis will be published with the proposed rule.

Statement of Need:
Part 26, subpart I, currently does not include QC/QV personnel as covered workers for fatigue management. Also, petitions for rulemaking have raised additional concerns from affected stakeholders.

Anticipated Cost and Benefits:
A detailed regulatory analysis will be performed per NRC processes which detail the costs and benefits associated with the proposed rule. This regulatory analysis will be published with the proposed rule.

Timetable:
160. U.S. EVOLUTIONARY POWER REACTOR (EPR) DESIGN CERTIFICATION AMENDMENT

[NRC–2010–0132]

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
**Legal Deadline:**

None

**Abstract:**

The proposed rule would amend the Commission's regulations to part 52 by issuing a new appendix for the initial certification of the U.S. Evolutionary Power Reactor standard plant design. Applicants or licensees intending to construct and operate a nuclear power plant using the EPR design may do so by referencing this design certification rule.

**Statement of Need:**

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to certify an amendment to the U.S. Evolutionary Power Reactor (U.S. EPR) standard plant design. This action is necessary so that applicants or licensees intending to construct and operate a U.S. EPR design may do so by referencing this design certification rule. The applicant for certification of the amendment to the U.S. EPR design is AREVA Nuclear Power.

A design certification amendment does not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for combined licenses. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. As a result, there is no monetary impact for this final rule.

**Alternatives:**

The NRC has not prepared alternatives for this rule. The NRC evaluates alternatives for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs.
Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of alternatives in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC.

**Anticipated Cost and Benefits:**

The NRC has not prepared a regulatory analysis for this rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of a regulatory analysis in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Federalism:**

Undetermined

**Agency Contact:**

Fred Schofer
161. DISPOSAL OF UNIQUE WASTE STREAMS [NRC–2011–0012]

Priority:
Other Significant. Major status under 5 USC 801 is undetermined.

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
10 CFR 61

Legal Deadline:
None

Abstract:
The proposed rule would amend the Commission's regulations to require operating and future low-level radioactive waste disposal facilities to conduct a performance assessment and an intruder assessment, to demonstrate compliance with performance objectives in 10 CFR part 61 to enhance safe disposal of low-level radioactive waste. These analyses will identify any additional measures that would enhance adequate protection of public health and safety. The NRC is also proposing additional changes to the current regulations to reduce ambiguity, facilitate implementation, and to better align the requirements with current health and safety standards. This rule would affect existing and future low-level radioactive waste disposal facilities that are regulated by the NRC and the Agreement States.

Statement of Need:
The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations to require low-level radioactive waste (LLRW) disposal facilities to conduct site-specific analyses to demonstrate compliance with the performance objectives. Although the NRC believes that part 61 is adequate to protect public health and safety, requiring a site-specific analysis to demonstrate compliance with the performance objectives would enhance the safe disposal of LLRW and would provide added assurance that waste streams not considered in the part 61 technical basis comply with the part 61 performance objectives. Further, these analyses would identify any additional measures that would be prudent to implement, and these amendments would improve the efficiency of the regulations by making changes to reduce ambiguity, facilitate implementation, and better align the requirements with the current and more modern health and safety regulations. This rulemaking would correct ambiguities and provide added assurance that LLRW disposal continues to meet the performance objectives in part 61.

**Summary of Legal Basis:**


**Alternatives:**

As an alternative to the rulemaking, the NRC staff considered the “no-action” alternative. Under this option the NRC would not modify part 61, no long-term analyses would be required, no period of performance would be specified, and no intruder assessment would be required.

**Anticipated Cost and Benefits:**

The NRC is in the process of preparing a regulatory analysis to support this rulemaking. The analysis examines the costs and benefits of the alternatives considered by the NRC. The analysis will be available as part of the rulemaking package.

**Risks:**

Not conducting this rulemaking would allow the ambiguities in the part 61 regulations to continue and would not provide the added assurance that disposal of the waste streams not considered in the part 61 technical basis comply with the part 61 performance objectives.

**Timetable:**

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<td>05/03/11</td>
<td>76 FR 24831</td>
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Comment Period End 06/18/11
NPRM 04/00/12

Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Federalism:
Undetermined

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RIN: 3150–AI92

162. • REVISION OF FEE SCHEDULES: FEE RECOVERY FOR FY 2012 [NRC–2011–0207]

Priority:
Economically Significant. Major under 5 USC 801.

Unfunded Mandates:
Undetermined

Legal Authority:
The Omnibus Budget Reconciliation Act of 1990 (OBRA-90), as amended, requires that the NRC recover approximately 90 percent of its budget authority in fiscal year (FY) 2012, less the amounts appropriated from the Nuclear Waste Fund, amounts appropriated for Waste Incidental to Reprocessing, and amounts appropriated for generic homeland security activities (non-fee items). The OBRA-90 requires that the fees for FY 2010 must be collected by September 30, 2012.

Abstract:
This proposed rule would amend the Commission's licensing, inspection, and annual fees charged to its applicants and licensees. The amendments would implement the Omnibus Budget Reconciliation Act of 1990 (OBRA-90), as amended, which requires that the NRC recover approximately 90 percent of its budget authority in fiscal year (FY) 2012, less the amounts appropriated from the Nuclear Waste Fund, and for Waste Incidental to Reprocessing, and generic homeland security activities.

Based on the FY 2012 NRC budget sent to Congress, the NRC's required fee recovery amount for the FY 2012 budget is approximately $909.5 million. After accounting for carryover and billing adjustments, the total amount to be recovered through fees is approximately $908.5 million.

Statement of Need:
This rulemaking would amend the licensing, inspection, and annual fees charged to NRC licensees and applicants for an NRC license. The amendments are necessary to recover approximately 90 percent of the NRC budget authority for FY 2012, less the amounts appropriated for non-fee items. The OBRA-90, as amended, requires that the NRC accomplish the 90 percent recovery through the assessment of fees. The NRC assesses two types of fees to recover its budget authority. License and inspection fees are assessed under the authority of the Independent Offices Appropriation Act of 1952 (IOAA) to recover the costs of providing individually identifiable services to specific applicants and licensees (10 CFR part 170).
IOAA requires that the NRC recover the full cost to the NRC of all identifiable regulatory services that each applicant or licensee receives. The NRC recovers generic and other regulatory costs not recovered from fees imposed under 10 CFR part 170 through the assessment of annual fees under the authority of OBRA-90 (10 CFR part 171). Annual fee charges are consistent with the guidance in the Conference Committee Report on OBRA-90 that the NRC assess the annual charge under the principle that licensees who require the greatest expenditure of the Agency's resources should pay the greatest annual fee.

**Summary of Legal Basis:**
The OBRA-90 requires that the fees for FY 2012 must be collected by September 30, 2012.

**Alternatives:**
Because this action is mandated by statute and the fees must be assessed through rulemaking, the NRC did not consider alternatives to this action.

**Anticipated Cost and Benefits:**
The cost to NRC licensees is approximately 90 percent of the NRC FY 2012 budget authority less the amounts appropriated for non-fee items. The dollar amount to be billed as fees to NRC applicants and licensees for FY 2012 is approximately $909.5 million.

**Risks:**
Not applicable.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**
Yes

**Small Entities Affected:**
Businesses, Governmental Jurisdictions, Organizations

**Government Levels Affected:**
Local, State

**Federalism:**
Undetermined
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RIN: 3150–AJ03

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<th>FINAL RULE STAGE</th>
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Priority:
Other Significant

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
10 CFR 50; 10 CFR 52

Legal Deadline:
None

Abstract:
The proposed rule would amend the Commission's regulations to allow for a risk-informed alternative to the present loss-of-coolant accident break size. This rulemaking would address a petition for rulemaking submitted by the Nuclear Energy Institute (NEI) (PRM-50-75). The final rule was provided to the Commission on December 10, 2010, in SECY-10-0161.
The NRC staff provided an initial draft final rule to the Advisory Committee on Reactor Safeguards (ACRS) on October 16, 2006. After reviewing the draft rule, the ACRS informed the Commission of numerous technical and policy concerns and recommended that the rule not be issued. The staff prepared a Commission paper (SECY-07-0082; May 16, 2007) to inform the Commission of the impact of the ACRS recommendations and to request guidance before proceeding with the rule. The Commission provided its guidance in a Staff Requirements Memorandum on August 10, 2007. On April 1, 2008, the staff provided an updated rule schedule to the Commission. In a meeting on August 6, 2008, selected NRC managers approved the staff's recommended resolution of the open issues related to the final rule. The staff prepared draft rule language incorporating the new positions into the rule and adding additional requirements for defense-in depth for pipe breaks larger than the transition break size. The OGC reviewed the revised rule language and recommended that portions of the rule be re-noticed to provide an opportunity for public comments on some of the new rule requirements. In a meeting on October 8, 2008, NRC managers decided to repropose the entire rule. On December 18, 2008, the EDO signed a memorandum informing the Commission that the staff will re-notice the section 50.46a rule for additional public comments in August 2009. The staff discussed the revised proposed rule with the ACRS on May 6-7, 2009, and then published the rule on August 10, 2009 (74 FR 40006). On September 24, 2009, in response to a request from NEI, the NRC extended the public comment period by 120 days to close on January 22, 2010 (74 FR 48667). The NRC evaluated the public comments and prepared draft final rule language, which was posted on Regulations.gov on May 12, 2010. A public meeting was held on June 4, 2010, to discuss resolution of public comments and the draft rule language. The staff discussed the rule with the ACRS in September and October of 2010. In its letter of October 20, 2010, the ACRS concluded that the rule was an acceptable alternative for operating reactors. The final rule was provided to the Commission on December 10, 2010 (SECY-10-0161).

Statement of Need:

This rulemaking would codify alternative requirements for ECCS at nuclear power reactors by using risk information to refine ECCS requirements based on the likelihood of pipe breaks of various sizes. The rule would divide all coolant piping breaks currently considered in emergency core cooling requirements into two size groups: Breaks up to and including a “transition” size, and breaks larger than the transition size
up to the largest pipe in the reactor coolant system. Selection of the transition size was based upon pipe break frequency estimates and associated uncertainties. Because pipe breaks in the smaller size group are considered more likely, they would be analyzed using existing criteria for ensuring that the reactor core stays cool during and after an accident. Larger breaks are considered less likely and would be analyzed with less conservative methods. Plants would still have to mitigate the effects of breaking the largest pipe and maintain core cooling. Under the draft final rule, power plant operators could make plant design changes that could enhance safety and/or provide operational benefits. The rule includes risk acceptance criteria to ensure that modified designs would continue to provide adequate protection of public health and safety.

**Alternatives:**

The alternative is for the NRC not to issue these requirements. The alternative would not allow operators of nuclear power plants to have the increased design and operational flexibility that would be allowed by these risk-informed requirements.

**Anticipated Cost and Benefits:**

There are no costs or benefits associated with this alternative rule for licensees who choose not to implement it. For the licensees who do choose to comply with the alternative requirements, if they request to increase power generation at their facilities and eliminate the need for fast-starting of emergency diesel generators, they would need to invest an estimated overall total of approximately $445 to $1,221 million (in 2008$ @ 3 percent discount rate) for plant modifications and staff support. Total estimated NRC cost associated with implementing the alternative requirements and reviewing licensees’ design change requests at these facilities would be approximately $22 to $24 million (in 2008$ @ 3 percent discount rate). Substantial net benefits would result after subtracting both licensee and NRC costs from the benefits that licensees would obtain from making these plant modifications. The total cumulative net benefits are estimated to range from $279 to $2,876 million (in 2008$ @ 3 percent discount rate).

**Risks:**

The rule would allow plant design and operational changes which could result in small but acceptable increases in risk. Specific acceptance criteria for risk increases are contained in the rule which limit overall risk increases to very small amounts. Allowable risk increases under this rule are consistent with

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Agency Contact:**

Richard F. Dudley

Nuclear Regulatory Commission
The proposed rule would amend the Commission's regulations to put in place security requirements for the use of Category 1 and Category 2 quantities of radioactive material. The objective is to ensure that effective security measures are in place to prevent the dispersion of radioactive material for malevolent purposes. The proposed amendment would also address background investigations and access controls, enhanced security for use, and transportation security for Category 1 and Category 2 quantities of radioactive material. This rulemaking subsumes RIN 3150-AI56, "Requirements for Fingerprinting and Criminal History Record Checks for Unescorted Access to Radioactive Material and Other Property (part 37)."
The objective of this rule is to provide reasonable assurance of preventing the theft or diversion of category 1 and category 2 quantities of radioactive material by establishing generally applicable security requirements similar to those previously imposed on certain licensees by the NRC orders. Although a security order is legally binding on the licensee receiving the order, a rule makes requirements generally applicable to all licensees. In addition, notice and comment rulemaking allows for public participation and is an open process. This rulemaking places the security requirements for use of category 1 and category 2 quantities of radioactive material into the regulations.

Summary of Legal Basis:
Atomic Energy Act of 1954, as amended.

Alternatives:
NRC could continue to regulate the security aspects for these facilities by Commission order. This alternative would not significantly reduce the burden as the majority of the cost is associated with the order requirements.

Anticipated Cost and Benefits:
This final rule will result in maximum annual impact to the economy of approximately $17.9 million (using a 7% discount rate, annualizing the one-time costs over 20 years, and adding these “annualized” one-time costs to the annual costs) or $24.4 million (using a 3% discount rate). The Office of Management and Budget has indicated that the annual cost of the orders should be included in the annual impact to the economy calculation. The estimated annual cost to the industry using the pre-order was $111.6 million. Therefore, this final rule is considered a major rule as defined by the Congressional Review Act.

The qualitative values of the rule are associated with safeguard and security considerations of the decreased risk of a security-related event, such as theft or diversion of radioactive material and subsequent use for unauthorized purposes. Increasing the security of high-risk radioactive material decreases this risk and increases the common defense and security of the Nation. Other qualitative values that are positively affected by the decreased risk of a security-related event include public and occupational health due to an accident or event and the risk of damage to on-site and off-site property. In addition, regulatory efficiency is enhanced by the rule.
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**Regulatory Flexibility Analysis Required:**
Yes

**Small Entities Affected:**
Businesses, Governmental Jurisdictions

**Government Levels Affected:**
Local, State

**Federalism:**
Undetermined

**Agency Contact:**
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**RIN:** 3150–AI12
Priority:
Other Significant

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
10 CFR 51

Legal Deadline:
None

Abstract:
The proposed rule would amend the Commission's regulations that provide the environmental protection requirements for renewing nuclear power plant operating licenses. The regulations require that licensees consider the impact that the licensing action could have on the human environment.

Statement of Need:
The Nuclear Regulatory Commission (NRC) is amending its environmental protection regulations by updating the Commission's 1996 findings on the environmental effect of renewing the operating license of a nuclear power plant. The rule redefines the number and scope of the environmental impact issues which must be addressed by the NRC during license renewal environmental reviews. The rule also incorporates lessons learned and knowledge gained from license renewal environmental reviews conducted by the NRC since 1996.

Summary of Legal Basis:
NRC's environmental protection regulations are in 10 CFR part 51, and implement section 102(2) of the National Environmental Policy Act of 1969 (NEPA).

Anticipated Cost and Benefits:
A detailed regulatory analysis was published with the proposed rule, and can be accessed in ADAMS at ML090260568.
Timetable:

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Federalism:
Undetermined

Agency Contact:
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RIN: 3150–AI42
166. AP1000 DESIGN CERTIFICATION AMENDMENT [NRC–2010–0131]

Priority:
Other Significant

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
10 CFR 52

Legal Deadline:
None

Abstract:
The proposed rule would amend the Commission's regulations for the AP1000 design certification to replace combined license information and design acceptance criteria with specific design information, address compliance with the aircraft impact assessment rule, and incorporate design improvements resulting from detailed design efforts. Applicants or licensees intending to construct and operate a nuclear power plant using the AP1000 design as amended may do so by referencing this design certification rule.

Statement of Need:
The U.S. Nuclear Regulatory Commission (NRC or Commission) is amending its regulations to certify an amendment to the AP1000 standard plant design. The purpose of the amendment is to replace the combined license (COL) information items and design acceptance criteria (DAC) with specific design information, address the effects of the impact of a large commercial aircraft, incorporate design improvements, and increase standardization of the design. This action is necessary so that applicants or licensees intending to construct and operate an AP1000 design may do so by referencing this design certification rule (DCR), and need not demonstrate in its application the safety of the certified design as amended.

The applicant for certification of the amendment to the AP1000 design is Westinghouse Electric Company, LLC (Westinghouse).
A design certification amendment does not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for combined licenses. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. As a result, there is no monetary impact for this final rule.

Alternatives:
The NRC has not prepared alternatives for this rule. The NRC evaluates alternatives for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of alternatives in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC.

Anticipated Cost and Benefits:
The NRC has not prepared a regulatory analysis for this rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of a regulatory analysis in this circumstance would not be useful because the design to be certified is
proposed by the applicant rather than the NRC. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Federalism:
Undetermined

Agency Contact:
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RIN: 3150–AI81

NRC
Priority:
Other Significant

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
10 CFR 52

Legal Deadline:
None

Abstract:
The proposed rule would amend the Commission's regulations in appendix A “Design Certification Rule for the U.S. Advanced Boiling Water Reactor” to 10 CFR part 52 “Licenses, Certifications, and Approvals for Nuclear Power Plants” to comply with 10 CFR 50.150 “Aircraft Impact Assessment.” Applicants or licensees intending to construct and operate a nuclear power plant using the ABWR design may comply with 10 CFR 50.150 by referencing the amended design certification rule.

Statement of Need:
The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to certify an amendment to the U.S. Advanced Boiling Water Reactor (U.S. ABWR) standard plant design to comply with the NRC's aircraft impact assessment (AIA) regulations. This action allows applicants or licensees intending to construct and operate a U.S. ABWR to comply with the NRC's AIA regulations by referencing the amended design certification rule (DCR). The applicant for certification of the amendment to the U.S. ABWR design is STP Nuclear Operating Company (STPNOC).

A design certification amendment does not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for combined licenses. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. As a result, there is no monetary impact for this final rule.
Alternatives:
The NRC has not prepared alternatives for this rule. The NRC evaluates alternatives for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of alternatives in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC.

Anticipated Cost and Benefits:
The NRC has not prepared a regulatory analysis for this rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of a regulatory analysis in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

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Small Entities Affected:
No

Government Levels Affected:
None

Federalism:
Undetermined

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RIN: 3150–AI84

NRC

168. ECONOMIC SIMPLIFIED BOILING–WATER REACTOR (ESBWR) DESIGN CERTIFICATION
[NRC–2010–0135]

Priority:
Other Significant

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
10 CFR 52

Legal Deadline:
None
Abstract:
The proposed rule would amend the Commission's regulations to part 52 by issuing a new appendix for the initial certification of the ESBWR standard plant design. Applicants or licensees intending to construct and operate a nuclear power plant using the ESBWR design may do so by referencing this design certification rule.

Statement of Need:
The U.S. Nuclear Regulatory Commission (NRC or the Commission) is amending its regulations to certify an amendment to the Economic Simplified Boiling-Water Reactor (ESBWR) standard plant design. This action is necessary so that applicants or licensees intending to construct and operate an ESBWR design may do so by referencing this design certification rule (DCR). The applicant for certification of the amendment to the ESBWR design is GE-Hitachi Nuclear Energy.

A design certification amendment does not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for combined licenses. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. As a result, there is no monetary impact for this final rule.

Alternatives:
The NRC has not prepared alternatives for this rule. The NRC evaluates alternatives for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of alternatives in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC.
Anticipated Cost and Benefits:
The NRC has not prepared a regulatory analysis for this rule. The NRC prepares regulatory analyses for rulemakings that establish generic regulatory requirements applicable to all licensees. Design certifications (and amendments thereto) are not generic rulemakings in the sense that design certifications (and amendments thereto) do not establish standards or requirements with which all licensees must comply. Rather, design certifications (and amendments thereto) are Commission approvals of specific nuclear power plant designs by rulemaking, which then may be voluntarily referenced by applicants for COLs. Furthermore, design certification rulemakings are initiated by an applicant for a design certification (or amendments thereto), rather than the NRC. Preparation of a regulatory analysis in this circumstance would not be useful because the design to be certified is proposed by the applicant rather than the NRC. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

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Regulatory Flexibility Analysis Required:
No

Small Entities Affected:
No

Government Levels Affected:
None

Federalism:
Undetermined

Agency Contact:
George M. Tartal
Nuclear Regulatory Commission
169. LIST OF APPROVED SPENT FUEL STORAGE CASKS—MAGNASTOR, REVISION 2 [NRC–2011–0008]

Priority:
Other Significant

Legal Authority:
42 USC 2201; 42 USC 5841

CFR Citation:
10 CFR 72

Legal Deadline:
None

Abstract:
The direct final rule amends the Commission’s regulations by revising the MAGNASTOR System to include Amendment No. 2 to the Certificate of Compliance. Amendment No. 2 will include changes to allow: The addition of various boron-10 areal densities for use with Pressurized Water Reactor and Boiling Water Reactor baskets; correction of the code reference in Table 2.1-2 of the Final Safety Analysis Report, table entitled “ASME Code Alternatives for MAGNASTOR® components;” change of transportable storage canister surface contamination limits for loose contamination; and other changes in appendices A and B of the technical specification to incorporate minor editorial corrections. This direct final rule allows the holders of power reactor operating licenses to store spent fuel in this approved cask system under a general license.
Statement of Need:

On March 22, 2010, and as supplemented on March 30, March 31, June 8, July 1, November 10, and November 19, 2010, and April 22 and May 17, 2011, NAC, the holder of CoC No. 1031, submitted an application to the NRC that requested an amendment to CoC No. 1031. Specifically, NAC requested changes to revise: TS 3.3.2 to reduce the transportable storage canister removable surface contamination limits; TS 4.1.1 to add various boron-10 areal densities for use with Pressurized Water Reactor and Boiling Water Reactor baskets and to replace the fuel tube orthogonal pitch with the minimum fuel tube outer diagonal dimension; Table 2.1-2, “ASME Code Alternatives for MAGNASTOR® components,” of the Final Safety Analysis Report to correct the code reference; and appendices A and B of the TSs to make editorial corrections.

As documented in the SER, the NRC staff performed a detailed safety evaluation of the proposed CoC amendment request and found that an acceptable safety margin is maintained. In addition, the NRC staff has determined that there continues to be reasonable assurance that public health and safety will be adequately protected.

This direct final rule revises the MAGNASTOR® System listing in 10 CFR 72.214 by adding Amendment No. 2 to CoC No. 1031. The amendment consists of the changes previously described, as set forth in the revised CoC and TSs. The revised TSs are identified in the SER. The amended MAGNASTOR® System cask design, when used under the conditions specified in the CoC, the TSs, and NRC regulations, will meet the requirements of 10 CFR part 72; thus, adequate protection of public health and safety will continue to be ensured. When this direct final rule becomes effective, persons who hold a general license under 10 CFR 72.210 may load spent nuclear fuel into MAGNASTOR® System casks that meet the criteria of Amendment No. 2 to CoC No. 1031 under 10 CFR 72.212.

Summary of Legal Basis:

This rule is limited to the changes contained in Amendment No. 2 to CoC No. 1031 and does not include other aspects of the MAGNASTOR® System. The NRC is using the “direct final rule procedure” to issue
this amendment because it represents a limited and routine change to an existing CoC that is expected to be noncontroversial. Adequate protection of public health and safety continues to be ensured.

**Alternatives:**

The alternative to this action is to withhold approval of Amendment No. 2 and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into MAGNASTOR® System casks under the changes described in Amendment No. 2 to request an exemption from the requirements of 10 CFR 72.212 and 72.214. Under this alternative, each interested 10 CFR part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

**Anticipated Cost and Benefits:**

Approval of the direct final rule is consistent with previous NRC actions. Further, as documented in the SER and the environmental assessment, the direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other Government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of the direct final rule are commensurate with the NRC’s responsibilities for public health and safety and the common defense and security. For these reasons, the Commission concludes that preparation of a regulatory analysis is neither required nor appropriate.

**Timetable:**

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**Regulatory Flexibility Analysis Required:**

No

**Small Entities Affected:**

No

**Government Levels Affected:**

None

**Agency Contact:**

Gregory Trussell